Outcome, work and activities of the Special Committee on Beating Cancer

September 2020 - December 2021

- An overview -
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1. European Parliament resolution of 16 February 2022 on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy

European Parliament
2019-2024

TEXTS ADOPTED

P9_TA(2022)0038
Strengthening Europe in the fight against cancer
Special Committee on Beating Cancer
PE693.752
European Parliament resolution of 16 February 2022 on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy (2020/2267(INI))

The European Parliament,

– having regard to its decision of 18 June 2020 on setting up a special committee on beating cancer, and defining its responsibilities, numerical strength and term of office,

– having regard to the working document of its Special Committee on Beating Cancer of 27 October 2020 entitled ‘Inputs of the Special Committee on Beating Cancer (BECA) to influence the future Europe’s Beating Cancer Plan’,

– having regard to the Commission communication of 3 February 2021 on Europe’s Beating Cancer Plan (COM(2021)0044),

– having regard to the EU’s Framework Programme for Research and Innovation 2021-2027 (Horizon Europe) and the dedicated Horizon Europe Mission on Cancer,

– having regard to the Commission communication of 11 December 2019 on the European Green Deal (COM(2019)0640),

– having regard to the Council conclusions of 15 June 2021 on access to medicines and medical devices for a stronger and resilient EU,

– having regard to the guides developed by the Joint Actions on cancer (EPAAC, CANCON, iPAAC) and the Rare Cancer Agenda 2030 established under the Joint Action on Rare Cancers (JARC),

– having regard to the Commission communication of 30 September 2020 on a new ERA for Research and Innovation (COM(2020)0628),

– having regard to Council Recommendation 2003/878/EC of 2 December 2003 on cancer screening,

– having regard to the report of the International Agency for Research on Cancer (IARC) of May 2017 on the implementation of the Council Recommendation on cancer screening,

– having regard to the European guidelines for quality assurance in breast, cervical and colorectal cancer screening and diagnosis,

– having regard to the Commission communication of 20 May 2020 entitled ‘A Farm to Fork Strategy for a fair, healthy and environmentally friendly food system’ (COM(2020)0381),

– having regard to the Commission communication of 28 June 2021 on the EU strategic framework on health and safety at work 2021-2027 (COM(2021)0323),


– having regard to Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work,

– having regard to the public consultation synopsis report of its Special Committee on Beating Cancer of 19 April 2021 entitled ‘The impact of the COVID-19 pandemic on cancer prevention, health services, cancer patients and research: lessons from a public health crisis’,

5 OJ C 269 I, 7.7.2021, p. 3.
8 OJ L 158, 30.4.2004, p. 50.

having regard to Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-202710,


having regard to Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use (the Clinical Trials Regulation)11 and to the Clinical Trials Information System set up in accordance with that regulation,

having regard to Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme12,

having regard to Report No 21/2019 of the European Environment Agency (EEA) entitled ‘Healthy environment, healthy lives: how the environment influences health and well-being in Europe’13,

having regard to the opinion of the European Economic and Social Committee of 9 June 2021 on Europe’s Beating Cancer Plan14,

having regard to the conclusions and recommendations of the study prepared for its Panel for the Future of Science and Technology (STOA) in July 2021 on ‘The health impact of 5G’15,

having regard to the UN Sustainable Development Goals (SDGs), in particular SDG 3 on good health and well-being,

having regard to the fourth edition of the European Code Against Cancer16,

having regard to the European Code of Cancer Practice17,

having regard to the Commission communication of 24 March 2021 entitled ‘EU strategy on the rights of the child’ (COM(2021)0142),

17 https://www.europeancancer.org/2-standard/66-european-code-of-cancer-practice
having regard to the Commission staff working document of 19 July 2018 on combatting HIV/AIDS, viral hepatitis and tuberculosis in the European Union and neighbouring countries – State of play, policy instruments and good practices (SWD(2018)0387),

having regard to the report of the World Health Organization (WHO) of 2020, entitled ‘Alcohol and cancer in the WHO European Region: An appeal for better prevention’18,

having regard to the activity and conclusions of the all-party interest group MEPs Against Cancer (MAC),

having regard to its resolution of 15 January 2020 on the European Green Deal19,

having regard to its resolution of 2 March 2017 on EU options for improving access to medicines20,

having regard to its resolution of 10 July 2020 on the Chemicals Strategy for Sustainability21,

having regard to its resolution of 12 February 2019 on the implementation of the Cross-Border Healthcare Directive22,

having regard to its resolution of 16 January 2019 on the Union’s authorisation procedure for pesticides23,

having regard to its resolution of 10 July 2020 on the EU’s public health strategy post-COVID-1924,

having regard to its resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem25,

having regard to its resolution of 15 December 2016 on the regulation on paediatric medicines26 and the Commission’s inception impact assessment concerning the revision of the EU legislation on medicines for children and rare diseases,

having regard to Rule 54 of its Rules of Procedure,

having regard to the report of its Special Committee on Beating Cancer (A9-0001/2022),

A. whereas Europe’s Beating Cancer Plan (‘the Plan’) should effectively respond to the call for progress by the families and health professionals of the 1.3 million people who die from cancer each year in Europe, including 6 000 children and young people, the crucial needs of patients who are currently in need of timely diagnosis and effective, innovative, accessible and affordable treatments and care for cancer and cancer-related complications and comorbidities, the rightful expectations of more than 12 million cancer survivors and their families facing the difficult return back to a ‘normal life’, the clear will of future generations

23 OJ C 411, 27.11.2020, p. 48.
to be protected against health threats and risk factors, and the concern of governments facing a growing economic and social burden from cancer and its related treatments; whereas Union actions in the fight against cancer should aim to increase the five-year survival rate of cancer patients;

B. whereas Europe represents less than 10 % of the world’s population, but accounts for a quarter of all cancer cases, and whereas cancer is the second leading cause of death in Europe after cardiovascular diseases and the first cause of death by disease in children older than one year; whereas the specific needs of children and adolescents with cancer require continued attention and support globally, and paediatric oncology should be differentiated from adult cancer management; whereas although there has been a slight decrease in mortality rates thanks to screening campaigns, improved diagnostics and therapeutic innovation, the number of cases diagnosed is nevertheless increasing, notably due to longer life expectancies, which result in ageing populations; whereas almost three quarters of all cancer diagnoses in the EU occur in people aged 60 or above;

C. whereas cancer illustrates social injustice and inequity in healthcare, as differences in cancer survival rates across the EU Member States exceed 25 %; whereas EU citizens are facing inequities in terms of prevention, and are unequally protected against risk factors, unequally educated in terms of healthy behaviours and unequally equipped against misinformation; whereas EU citizens are unequal in terms of timely access to affordable and quality treatment and care from Member State to Member State and from region to region in any given country; whereas access to fully multidisciplinary and multiprofessional medical teams varies widely across Europe; whereas after recovery or when in remission, EU citizens are unequal in their ability to return to work, to be financially independent and to return to a harmonious familial, social and emotional life; whereas class and gender are important measures and drivers of inequalities and inequities at all stages of the disease;

D. whereas specific national or regional cancer policies have been set up in most Member States, whose missions, capacities and budgets are heterogeneous; whereas some regions have become hubs in the fight against cancer, with an expertise that should be shared all over the Union;

E. whereas the goal of the Plan should not only be to fight against a crucial public health issue and to help patients live longer and better lives, but should also be to initiate a reduction in health inequalities and inequities and lower the social and economic burden of the disease; whereas the Commission should promote a patient-centred and citizens’ rights-based approach by integrating considerations of justice, sustainability, equity, solidarity, innovation and collaboration at the very core of the Plan, including its ‘Helping Children with Cancer Initiative’;

F. whereas the COVID-19 pandemic has caused, and is still causing, severe disruptions to cancer screening programmes, treatment, research, and survivorship and follow-up services, with the resulting impact on cancer patients, families and healthcare professionals; whereas the pandemic has created an urgent need to build back cancer services in all European countries and to address highly concerning backlogs in prevention actions, as well as in early detection and diagnosis; whereas an estimated 100 million screening tests were not performed in Europe during the pandemic and 1 million cancer cases are undiagnosed; whereas 1 in 5 cancer patients did not receive the surgical or chemotherapy treatment they needed on time27;

27 https://www.europeancancer.org/resources/201:time-to-act.html
https://www.europeancancer.org/timetoact/impact/data-intelligence
whereas healthcare professionals have taken on the burden of a pandemic and have had to cope in a very stressful working environment;

G. whereas health literacy includes the acquisition of knowledge and skills, awareness of rights and the confidence to take action to improve personal and community health; whereas actions to promote health literacy under the Plan should focus on empowering patients and citizens through state-of-the-art communication tools, and also by seeking the expertise of, and collaborating with, patient organisations and other NGOs which have been working on disseminating and spreading health literacy for years; whereas patient empowerment requires assisting patients in understanding their rights; whereas all efforts to increase health literacy, including digital literacy, should take into account people who are experiencing exclusion and the needs of people with learning disabilities; whereas inequalities in knowledge of, access to and use of IT technologies, as well as regional, national, social and economic differences, should be taken into account; whereas the necessary information should be available in common non-EU languages in order to reach migrants, new arrivals and other vulnerable groups and minority communities; whereas in efforts to improve health literacy, the onus should also be on assisting citizens in identifying misinformation, noting the harmful impacts this can have across all areas of cancer care, including prevention, vaccination and treatment;

H. whereas about 40% of cancer cases in the EU are preventable; whereas prevention is more effective than any cure, as well as the most cost-effective long-term cancer control strategy; whereas the Plan should address all key risk factors and social determinants of cancer; whereas the EU level is crucial in cancer prevention as it has significant competences that have an impact on most risk factors for cancer;

I. whereas according to Report No 21/2019 of the EEA, cancer is the top non-communicable disease attributable to the environment, with more than 250,000 cancer deaths attributed to the environment in 2016 in 32 high-income European countries; whereas the EEA identified ambient air pollution, chemicals, indoor fuel combustion and radiation as environmental risk factors for cancer;

J. whereas air pollution is a main driver of mortality, with pollutants from a wide range of sources, including energy, transport, agriculture and industry, contributing to 400,000 premature deaths per year, including from lung cancer, heart disease and strokes;

K. whereas the Commission communication on strengthened cooperation against vaccine-preventable diseases (COM(2018)0245) recommends developing EU guidance to establish comprehensive electronic immunisation information systems at national level for effective monitoring of immunisation programmes; whereas this should be done in full compliance with data protection rules; whereas human papillomavirus (HPV) is a sexually transmitted infection associated with almost 5% of all cancers in women and men worldwide, namely cervical and oropharyngeal, but also anal, penile, vaginal and vulval cancers; whereas both reaching HPV vaccination coverage targets for girls and setting up high-quality organised cervical cancer screening is necessary in order to reach the 2030 WHO goals regarding the elimination of cervical cancer as a public health problem; whereas HPV vaccination rates are worryingly low across the Member States; whereas, regretfully, there are major discrepancies in vaccination coverage between Member States, ranging from less than 30% to more than 70% (with the required level of population immunity being at 70%); whereas Helicobacter pylori is the principal infectious cause of cancer worldwide, mainly for non-cardia gastric adenocarcinoma;

L. whereas certain endocrine cancers (such as thyroid, breast and testicular cancer) are on the rise; whereas endocrine treatments for hormone-dependent cancers can have endocrine side
effects; whereas cancer treatments can have long-term effects such as endocrine comorbidities in cancer survivors; whereas obesity is a known risk factor for many cancers, including endocrine cancers; whereas exposure to endocrine-disrupting chemicals (EDCs) is known to have an effect on the development of obesity and cancer; whereas EDCs cost the Member States between EUR 157 and 270 billion annually (up to 2 % of EU GDP)\(^\text{28}\) in healthcare expenses and lost earning potential, largely due to neurodevelopmental and metabolic disorders and cancer;

M. whereas exposure to dangerous substances at work is responsible for about 120 000 work-related cancer cases each year, leading to approximately 80 000 fatalities annually, which represents 8 % of all cancer deaths (12 % of cancer deaths among men, and 7 % of cancer deaths among women); whereas it can be difficult to establish causal relationships, however, due to long latency periods; whereas the WHO’s IARC has identified 50 priority carcinogens and shown that workers are widely exposed to them in Europe; whereas the vast majority of cancers induced by occupational carcinogens at work appear to be preventable if the carcinogens are regulated accordingly but, under Directive 2004/37/EC, binding occupational exposure limit (OEL) values exist to date for only 27 of them; whereas further action is necessary to prevent, detect and better recognise occupational cancers related to night-shift work as well as UV radiation (for outdoor workers);

N. whereas a changing labour market with demographic developments, new technologies and new types of jobs has potential impacts on occupational health and safety; whereas more workers are moving into platform work, non-traditional work or atypical employment; whereas factors such as radiation, stress, work organisation and working conditions have all been linked to work-related cancer\(^\text{29}\); whereas there is currently a lack of reliable and comparable EU-level data on workplace exposure to cancer risk factors\(^\text{30}\);

O. whereas contrary to workplace accidents, where injuries can be more easily assessed and compensation awarded, it can take years or decades before work-related cancers are diagnosed and the cause is properly identified; whereas the Commission Recommendation on occupational diseases\(^\text{31}\) recommends that Member States introduce, as soon as possible, into their national laws, regulations or administrative provisions concerning occupational diseases liable for compensation the European schedule set out in Annex I to the aforementioned recommendation; whereas the existing disparities between Member States with regard to the recognition rate of occupational diseases mean that many workers never have their occupational disease recognised;

P. whereas radon is a radioactive gas that has no colour or odour, and as radon decays in the air, it releases radiation that can damage the DNA of cells inside the body; whereas radon levels vary widely in different regions or even residential areas and can be present in both outdoor and indoor air;

Q. whereas in 2011 the IARC classified radiofrequency electromagnetic fields as possibly carcinogenic to humans, based on an increased risk of glioma associated with mobile phone use; whereas there are studies, published in 2015 and 2018, showing a significant increase (more than doubling) in glioblastoma tumours over 20 years (1995-2015) in all age groups, and others showing the increased risk of glioblastoma associated with mobile and cordless


phone use in people aged 18-80; whereas more studies are needed to establish these associated risks;

R. whereas 24% of all new cancer diagnoses, including all paediatric cancers, across Europe each year are rare forms of cancer and represent a public health challenge in themselves; whereas patients with rare cancers face challenges linked to late or incorrect diagnosis, lack of access to appropriate therapies and expertise, lack of understanding of underlying science, lack of commercial feasibility in developing new therapies, few available tissue banks, difficulties in conducting well-powered clinical studies, and also feelings of isolation;

S. whereas the Plan should be implemented in close association with the recommendations and actions of the IARC, the UN SDGs for global health, including the objective of achieving universal health coverage, the recommendations and guidelines of the WHO, international health agreements including the WHO Framework Convention on Tobacco Control and the WHO Global Initiative for Childhood Cancer, the EU Joint Actions on Cancer, and recommendations and guidelines by experts and patients’ associations; whereas the Plan should acknowledge as a priority the EU’s solidarity and partnership with low- and middle-income countries, including those in the wider WHO Europe region;

T. whereas the Act concerning the conditions of accession of Austria, Finland and Sweden grants an exemption to Sweden from the EU-wide prohibition of the sale of certain types of tobacco for oral use;

U. whereas the Mediterranean diet is known as a healthy, balanced diet that plays a protective role in the primary and secondary prevention of the main chronic degenerative diseases;

V. whereas while the Plan gives remarkable attention to a range of policy needs in respect of cancer screening, less initiative is offered for early detection of cancers not covered by screening programmes; whereas targeted action is therefore necessary to foster better awareness of cancer warning signs among citizens and healthcare professionals;

W. whereas the increase in the prices of cancer medicines has exceeded the increase of total cancer spending, and new cancer medicines coming onto the market at a high price were identified as an important driver of the increase in cancer care expenditure; whereas the WHO Technical Report of 2018 on the pricing of cancer medicines and its impacts\(^\text{32}\) recognised that prices of cancer medicines were higher than for other indications and their costs were growing at a faster rate, resulting in lack of access to treatment for many patients worldwide and hampering the capacity of governments to provide affordable access for all;

X. whereas addressing cancer in a comprehensive strategy such as the Beating Cancer Plan presented by the Commission could be used as a model for other non-communicable diseases, and whereas patients with other chronic diseases should therefore also benefit from the achievements and principles of the Plan, and similar plans should be developed for other pathologies with high mortality rates;

Y. whereas coordination between European countries, a common policy driven at European level and cross-border knowledge-sharing are absolutely essential for progress in the area of cancer; whereas the primary responsibility for health protection and healthcare systems lies with the Member States;

Z. whereas a comprehensive, multidisciplinary and coordinated approach to addressing behaviour-related, biological, environmental, work-related, socio-economic and commercial health determinants is needed at regional, national and European level in order to support actions targeting all aspects of cancer (prevention, detection, treatment, palliative care, follow-up care for survivors and reintegration) through the effective mobilisation of key tools such as adequate resources and funding, legislation, research and knowledge-sharing; whereas patient-centred approaches to treatment have been shown to improve the quality of life and overall survivorship of patients; whereas new technologies and artificial intelligence have high potential for improvements in the field of cancer research, treatment processes and care;

AA. whereas research and innovation are our only hope of definitely beating cancer one day; whereas sustained and effective funding is needed to support ambitious projects and good and stable working conditions for researchers working in the cancer field; whereas pharmaceutical companies, including SMEs, are key stakeholders for innovation in the cancer field;

AB. whereas the ‘Health in All Policies’ and ‘One Health’ approaches should be promoted further, and efforts to fight cancer should be integrated into all EU policies;

AC. whereas the EU and its Member States should mobilise their forces and provide adequate incentives and sustainable budgets so as to achieve the ambitious objective of conquering the cancer burden and the fatality of cancer in Europe;

AD. whereas the Plan could therefore represent an important step towards a real European Health Union and a public demonstration to citizens of the success that EU health cooperation can achieve;

1. Welcomes the Plan and calls on the Commission to seek new synergies between the Plan and the EU4Health Programme, the Pharmaceutical Strategy for Europe, the Chemicals Strategy and the updated European Industrial Strategy; considers that such a comprehensive cancer framework would contribute to the prevention, early detection and curing cancer; calls on the Commission to work towards developing a common cancer policy which includes, where necessary, proposals for draft legislation;

A. Areas of action

I. Cancer prevention in all European policies

2. Strongly believes that comprehensive preventive actions against cancer, through measures supporting the elimination or reduction of harm caused by modifiable risk factors, should be implemented across all European policies and funding programmes; calls on the Commission and the Member States to integrate public awareness-raising campaigns about cancer prevention into all relevant policies; calls on the Commission to streamline the objectives of the Plan into all relevant sectoral policies; strongly believes that preventive actions should be evidence-based; therefore, calls on the Commission and Member States to increase the funding for scientific research into the causes of cancer and the efficiency and implementation of preventive measures;

3. Calls on the Commission and Member States to design and implement effective prevention measures at national and EU level which are based on independent scientific expertise, best practices and lessons learned, and clinical guidance; in this regard calls, in particular, for the implementation of the European Code Against Cancer (ECAC) to reduce cancer risks on the basis of the latest scientific evidence, and for regular updates to the ECAC through a cycle that is based on continuous monitoring and evaluation;
4. Acknowledges that more than 40% of all cancers are preventable through coordinated actions targeting behaviour-related, biological, environmental, work-related, socio-economic and commercial health determinants; calls for more attention to be dedicated to maintaining a healthy lifestyle in order to prevent cancer and reduce recurrence of certain cancers;

5. Supports Horizon Europe Mission on Cancer’s aim of averting more than 3 million additional premature deaths over the 2021-2030 period, by accelerating progress in cancer prevention and control programmes, which strive for equal opportunities in access to these programmes; calls on the Commission to allocate adequate funding to the Horizon Europe Mission on Cancer and other relevant programmes (such as ‘Science and Policy for a Healthy Future’ - HBM4EU) in order to achieve this objective;

6. Deplores the significant health inequalities and inequities in the EU in cancer prevention; insists on the need to identify, as well as to pay special attention to, vulnerable, marginalised, socially excluded populations and people living in remote areas (such as in rural, isolated or outermost regions far from medical centres), in order to ensure their access to cancer prevention services; considers in this regard that cancer prevention also needs to be framed in the context of social justice, entailing the need for systemic changes through population-wide public policies beyond changes in individual behaviour;

7. Acknowledges that tobacco use is by far the largest preventable cause of cancer in the EU, as the cause of 15-20% of European cancer cases and the main risk factor for cancer death in Europe (27% of cancer fatalities equalling 700,000 cancer deaths annually in the EU); recalls that major differences exist across the EU since the proportion of smokers varies more than fivefold from one country to another;

8. Strongly supports the goal of a ‘tobacco-free generation’, as set out in the Plan, whose aim is for less than 5% of the population to use tobacco by 2040, compared to around 25% today; urges the Commission to establish interim goals that are constantly monitored and promoted, including at national level, and are reported within the Cancer Inequalities Registry in order to best direct efforts to achieve the overall target; calls on the Commission to fund programmes that promote smoking cessation; calls on the Commission to back cooperation between Member States in exchanging the best and most effective practices for reducing smoking;

9. Welcomes the Commission’s intention to review the Tobacco Products Directive33, the Tobacco Products Tax Directive34 and the legal framework on cross-border purchases of tobacco by private individuals, and urges the Commission to take appropriate measures and to bring forward legislative proposals, in order to introduce the following:

(a) an increase and an upward convergence in minimum excise duties for all tobacco products and their final market price, which would improve prevention by reducing tobacco uptake and use, notably among current smokers, and prevent young people from starting smoking;

(b) a requirement for standardised plain packaging and the obligation to include health warnings on 80% of the front and back of tobacco product packaging, including pictorial warnings; and

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the strict enforcement of the ban on characterising flavours in tobacco products to reduce the appeal of these products to smokers, non-smokers, and young people;

10. Calls for the evaluation and review of currently used measurement methods for tar, nicotine and carbon monoxide in tobacco and related products, based on independent and recent scientific research;

11. Calls for the full implementation by Member States of the obligations under the Single Use Plastics Directive 2019/904 as regards filters in tobacco products containing plastics to address environmental and health concerns related to these filters;

12. Calls on the Commission to follow up on the scientific evaluations of the health risks related to electronic cigarettes, heated tobacco products and novel tobacco products, including the assessment of the risks of using these products compared to consuming other tobacco products, and the establishment at European level of a list of substances contained in, and emitted by, these products; considers that electronic cigarettes could allow some smokers to progressively quit smoking; considers at the same time that e-cigarettes should not be attractive to minors and non-smokers; calls on the Commission, therefore, to evaluate, in the framework of the Tobacco Products Directive, which flavours in e-cigarettes are in particular attractive to minors and non-smokers, and to propose a ban on these, and furthermore, to propose a ban on all characteristic flavours in heated tobacco products and novel tobacco products;

13. Calls for the rapid and complete implementation of the WHO Framework Convention on Tobacco Control (FCTC) and the WHO Protocol to Eliminate Illicit Trade in Tobacco Products, paying specific attention to the FCTC Article 5.3 and its guidelines on protection of public health policies from the vested interests of the tobacco industry; urges the Commission to implement specific rules of conduct for all of its officials and other servants when interacting with the tobacco industry, in line with the European Ombudsman’s decision in case 852/2014/LP;

14. Supports the Commission’s proposal to update the Council recommendation of 30 November 2009 on smoke-free environments to extend its coverage to emerging products, such as e-cigarettes and heated tobacco products, and to extend smoke-free environments to include outdoor spaces;

15. Recalls that ethanol and acetaldehyde from the metabolism of ethanol in alcoholic beverages are classified as carcinogenic to humans by the IARC, and that in Europe an estimated 10% of all cancer cases in men and 3% of all cancer cases in women are attributable to alcohol consumption; underlines that the lower the amount of alcohol consumed, the lower the risk of developing cancer is; underlines that harmful alcohol consumption is a risk factor for many different cancers, such as oral cavity, pharynx, larynx, oesophagus, liver, colorectal and female breast cancer; recalls the study referred to by WHO which recognises that the safest

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36 https://fctc.who.int/who-fctc/overview
37 https://fctc.who.int/protocol/overview
level of alcohol consumption is none when it comes to cancer prevention, and stresses the need to take this into account when devising and implementing cancer prevention policy;

16. Welcomes the Commission’s target of achieving a reduction of at least 10% in the harmful use of alcohol by 2025; encourages the Commission and the Member States to promote actions to reduce and prevent alcohol-related harm within the framework of a revised EU alcohol strategy, including a European zero alcohol consumption strategy for minors, accompanied, where appropriate, by legislative proposals, while respecting the principle of subsidiarity and current national legislation on age limits on alcohol consumption; supports the provision of better information to consumers by improving the labelling of alcohol beverages to include moderate and responsible drinking information and introducing the mandatory indication of the list of ingredients and nutritional information, and in addition, by introducing digital labelling; asks the Commission to take specific actions targeting heavy and risky drinking; considers it important to protect minors from commercial communication on alcohol consumption, as well as product placement and sponsorship of alcohol brands, including in the digital environment, as advertising must not be aimed specifically at minors and not encourage alcohol consumption; calls for the prohibition of alcohol advertising and sponsorship at sport events when those events are mainly attended by minors; calls for the close monitoring of the implementation of the revised Audiovisual Media Service Directive; calls for the proposed Digital Services Act to strengthen the ability of Member States to uphold and enforce legislation seeking to protect minors and other vulnerable populations from commercial communication for alcoholic beverages; encourages the allocation of public funds for national and European awareness campaigns; supports the planned review of EU legislation on the taxation of alcohol and on cross-border purchases of alcohol by private individuals and a review of alcohol pricing policies, including considering an increase of taxes on alcoholic beverages;

17. Underlines that food has a significant influence on the health of individuals, and that scientific evidence shows that the consumption of inappropriately-sized food portions has negative impacts on health and may increase the risk of developing cancer; calls for the development of comprehensive nutrition campaigns, aligned with the European Union’s Farm to Fork Strategy;

18. Encourages Member States to consider making nutrition counselling available in primary healthcare;

19. Emphasises the role of a healthy diet in preventing and limiting the incidence and the recurrence of cancer, and stresses that individual cancer risks can be reduced by an increased consumption of sustainably-produced plants and plant-based foods, such as fresh fruits and vegetables, whole grains and legumes; emphasises, furthermore, the need to address the overconsumption of meat and ultra-processed products, and products high in sugars, salt and fats; welcomes, therefore, the upcoming revision of the EU school fruit, vegetables and milk scheme and of the EU’s policy on the promotion of agricultural products; asks the Commission and the Member States to encourage and help consumers to make informed, healthy and sustainable choices about food products by means of the adoption of a mandatory

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42 https://www.thelancet.com/action/showPdf?pii=S0140-6736%2818%2931310-2
44 https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(21)00279-5/fulltext
and harmonised EU front-of-pack nutritional label that is developed based on robust and independent scientific evidence; welcomes the focus on healthy nutrition in the EU Child Guarantee and calls for a new EU Action Plan on Childhood Obesity; supports fiscal measures to make fresh foods (such as fruits and vegetables, pulses, legumes and wholegrains) more affordable and accessible at national level, especially for people on low incomes; encourages Member States to use pricing policies, such as value added tax differentiation, and marketing controls to influence demand for, access to, and the affordability of food and drink low in saturated fats, trans-fats, salt and sugar; supports Member States in revising the relevant provisions to restrict the advertising of sweetened beverages and processed food products high in fats, salt and sugar, including advertising on social media, and calls on the Commission to come forward with a proposal for a comprehensive EU-wide regulation to prohibit such advertising to minors;

20. Acknowledges that obesity is considered as a risk factor for many types of cancer, such as colorectal, kidney or breast cancers, among others; calls on the Member States to actively fight against obesity by making available healthy dietary choices and the practice of sports, not only by educating and encouraging citizens to make the right choices, but also by including integral programmes in primary healthcare that help patients suffering from obesity to lose weight in a healthy way; calls on the Commission and Member States to support research and innovation related to obesity aiming to describe the influence of genetic factors, the human microbiota or psychological status, among others, on body weight, and to explore the most effective interventions;

21. Welcomes the Commission’s intention to tackle the presence of carcinogenic contaminants in food; recalls to the Commission Parliament’s resolution of 8 October 2020 calling for setting strict legal limits for the presence of acrylamide in food to adequately protect consumers, especially the most vulnerable such as infants and children; urges the Commission to swiftly come forward with regulatory proposals;

22. Calls on the Commission to heed Parliament’s various calls in its resolution of 16 January 2019 to improve the Union’s authorisation procedure for pesticides;

23. Calls on Member States, regional and local governments, civil society representatives and employers to promote and facilitate the practice of physical activities and sports throughout life, as they are known to limit both the incidence and the recurrence of cancer, as well as to reduce mental health problems and to favour social inclusion; highlights the importance of making the practice of physical activity and sports accessible and inclusive from a young age, in particular for vulnerable groups, by financing public infrastructures, equipment and programmes; calls on the Member States to facilitate access to physical activity for hospitalised patients if clinically recommended;

24. Welcomes the launch of the EU’s ‘HealthLifestyle4all’ campaign involving the promotion of sports, physical activity and healthy diets, in addition to other key sectors; recommends that schools include health education in their curricula to ensure that minors and adolescents learn how to lead a healthy lifestyle and are made aware of the ECAC, and calls for health education to be an integral part of social assistance educational policies;

25. Points out that radiation from the sun contains invisible ultraviolet (UV) radiation which can lead to skin cancer; calls therefore on the Commission to revise Directive 2006/25/EC on the...

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exposure of workers to risks from physical agents (artificial optical radiation)\textsuperscript{48} and to include solar radiation in its scope; supports the strengthening of protection against exposure to UV radiation at EU level, especially through occupational health and safety legislation for outdoor workers; welcomes the Commission’s commitment to explore measures on exposure to UV radiation, including from artificial tanning devices (sunbeds)\textsuperscript{49}; points out the importance of information campaigns to make people aware of the risks associated to excessive sun exposure and to teach them how to recognise possible warning signs; calls for specific measures to reduce the exposure to UV radiation of minors and adolescents; calls for stricter legislation on the use of sunbeds for cosmetic purposes and a ban on the use of it by minors; calls on Member States to include the reporting of melanoma skin cancer in national cancer registries;

26. Acknowledges that around 2\% of the European cancer burden can be attributed to ionising radiation and that indoor exposure to radon and its decay products is the second leading cause of lung cancer in Europe; looks forward to the results of the Euratom Research and Training Programme\textsuperscript{50}, which will improve knowledge on exposure to radon, and the proposed countermeasures to reduce its accumulation in dwellings; recalls that ionising radiation could also be present in private households; encourages therefore the Commission and Member States to map current and potential critical areas in order to effectively react to this threat; calls on the Commission to allocate funds to the creation of such a forecast map and to promote information campaigns for the public in order to raise awareness on this matter; encourages Member States to regularly update their national plans to reduce exposure to radon, as requested in the Directive on Exposure to Radioactive Sources\textsuperscript{51} and to update guidelines on radon mitigation for new constructions; calls on the Commission to assess the implementation and effectiveness of current measures to protect workers exposed to ionising radiation such as airline crews, nuclear power plant workers, workers in relevant industrial settings and researchers, health professionals and veterinarians working in the radiology, radiotherapy or nuclear medicine sectors, and to review these measures where necessary and proportionate;

27. Calls on the Commission to promote multidisciplinary scientific research on the existence of links between electromagnetic fields (EMFs), including 5G, and cancer in order to gather scientific evidence on the long-term effects of EMFs, and to inform the public in a timely manner of the outcome of those studies; calls for the promotion of research into the development of technology that reduces radio frequency exposure;

28. Sees the European Green Deal as a significant contributing factor to cancer prevention in Europe, by means of reducing air, food, water and soil pollution and chemical exposure; calls for an evaluation of the impact of policies on cancer incidence to be integrated into the Farm to Fork Strategy, the Chemicals Strategy for Sustainability, the Zero Pollution and the Non-Toxic Environment Strategies; welcomes the upcoming revision of the EU’s air quality standards and calls on the Commission to align them with WHO guidelines as referred to in Parliament’s resolution of 25 March 2021 on the implementation of the Ambient Air Quality

\textsuperscript{48} OJ L 114, 27.4.2006, p. 38.
Directives\textsuperscript{52}; calls on the Commission to ensure that the common agricultural policy helps farmers to reduce the use of pesticides; encourages the research into, the use and the development of medicines that are safer for the environment, and encourages the implementation of efficient waste removal mechanisms that avoid polluting the environment, in line with the objectives of the Pharmaceutical Strategy for Europe;

29. Stresses the need for full implementation of the revised Drinking Water Directive\textsuperscript{53} and the implementation and enforcement of the Water Framework Directive\textsuperscript{54}, which will reduce the concentrations in surface and ground waters of certain pollutants that could contribute to cancer incidence;

30. Calls in particular for the strengthening of the information requirements on carcinogenicity under the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH)\textsuperscript{55} in order to enable the identification of all carcinogenic substances manufactured or imported, irrespective of their volume, in line with the Chemicals Strategy for Sustainability, and calls also for the registration, evaluation, authorisation and restriction of chemicals, including EDCs, under the REACH Regulation to be conducted in association with the IARC and the WHO assessments; welcomes the commitment of the Chemicals Strategy for Sustainability to extend the generic approach to risk management to ensure that consumer products do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative and toxic; calls on the Commission to swiftly implement the measures planned in the Chemicals Strategy for Sustainability to reduce citizens’ exposure to carcinogenic and endocrine-disrupting substances through all exposure pathways; calls on the Commission to devote particular attention to segments of the population that are particularly vulnerable to hazardous chemicals and to better take into account these vulnerable populations in the risk assessments of chemicals; stresses that information to consumers on exposure pathways in their everyday life is key to strengthening prevention, and welcomes in this regard the establishment of the Substances of Concern in Products database; calls on the EEA to produce a report together with the European Chemicals Agency on chemicals in the environment in Europe; calls for the report to assess the systemic nature of carcinogenic and EDCs within Europe’s production and consumption systems, their use in products, their occurrence in Europe’s environment, and the harm caused to human health, especially concerning cancer;

31. Considers that the next edition of the ECAC will have to take into account the latest knowledge on environmental carcinogens; calls on the Commission to propose without delay a revision of Article 68(2) of REACH, the Regulation on Food Contact Materials\textsuperscript{56}, the Regulation on Cosmetic Products\textsuperscript{57}, the Directive on Toy Safety\textsuperscript{58} and other relevant consumer product legislation to ensure that consumer products do not contain chemicals that cause cancer, in line with the Chemicals Strategy for Sustainability; calls, furthermore, for the

\textsuperscript{52} OJ C 494, 8.12.2021, p. 64.
regular revision of this legislation to take account of the development of new materials, trends and products; underlines that endocrine disruptors (EDs) are present in food, food contact materials, cosmetics, consumer goods, toys, as well as drinking water, and that exposure, even at low doses, can induce adverse effects in the short and long term, including cancer\(^{59}\); highlights that given the widespread exposure of the EU population to many suspected and known EDs and the fact that combined exposure to several EDs acting on similar or different pathways can have cumulative effects, there is a need to minimise exposure to EDs and to make EU regulation more consistent across sectors; encourages further research in order to determine the capacity of chemicals to act as endocrine disruptors;

32. Fully supports the Commission’s commitment under the Chemicals Strategy for Sustainability to amend the Regulation on the classification, labelling and packaging of chemicals (Regulation (EC) No 1272/2008\(^{60}\)) to introduce new hazard classes on, inter alia, EDs, including suspected EDs, and to update the information requirements in all relevant legislation to allow their identification;

33. Calls on the Commission to integrate the ‘benign by design’ approach into the regulatory requirements related to the production of chemicals and pharmaceuticals, in order to take a true precautionary approach to mitigating risks for our health, society and the environment;

34. Welcomes the publication of the new EU strategic framework on health and safety at work for the 2021-2027 period notably the ‘Vision Zero’ approach to work-related deaths, as well as the planned stock-taking occupational health and safety summit in 2023 to evaluate progress towards ‘Vision Zero’; stresses the need for the close and regular involvement of social partners and stakeholders in this strategy; regrets, however, the limited number of substances addressed in the strategy; encourages the constant analyses and research on new substances suspected of being carcinogenic, mutagenic and/or reprotoxic, the establishment of OELs for chemical agents for which they do not yet exist, and periodic revisions whenever this becomes necessary in the light of further recent scientific data and technical developments; welcomes the workers survey prepared by the European Agency for Safety and Health at Work (EU-OSHA) on exposure to cancer risk factors; stresses that more systematic human biomonitoring programmes in full compliance with data protection measures, both in occupational settings and non-occupational settings, can be one of several relevant sources of information on general chemical exposure effects and health impacts; calls therefore on the Commission to increase its ambition as a matter of urgency through ambitious and regular updates of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogenic or mutagens at work; to do so, calls on the Commission, following consultation of the Advisory Committee on Health and Safety, to present an action plan to achieve OEL values for at least 25 additional substances, groups of substances or process-generated substances by 2024; stresses, in this regard, the need for the Commission to increase the capacity for reviewing OELs and adding new ones, including through increased staffing in relevant units and authorities; recalls, in this context, that ongoing negotiations on the fourth revision of Directive 2004/37/EC are an opportunity to also include in Annex 1 work involving exposure to hazardous medicinal products meeting the criteria for classification as carcinogenic, mutagenic and/or toxic for reproduction category 1A or 1B set out in Annex I to Regulation (EC) No 1272/2008, in order to ensure the best possible general and individual protection measures for workers handling these products; reiterates its calls for a new coherent, transparent and risk-based system to be established for setting exposure limits and to better take into account workers’ exposure to a combination of substances; welcomes

the commitment by the Commission to add EDs as a category of substances of very high concern under Regulation (EC) No 1907/2006 (REACH Regulation) and to classify them under Regulation (EC) No 1272/2008; stresses that workers should also be protected from exposure to EDs; welcomes the Commission’s commitment to presenting in 2022 a legislative proposal to further reduce workers’ exposure to asbestos, a proven carcinogen (group 1) according to the IARC, which remains responsible for around half of all occupational cancers in Europe; reiterates in this regard Parliament’s requests in its resolution of 20 October 2021 on protecting workers from asbestos\textsuperscript{61}, in particular its call for a European strategy for the removal of all asbestos and its proposals for a better evaluation of the risks linked to non-occupational exposure to asbestos; asks Member States to facilitate recognition of and compensation for proven work-related cancers and to reinforce the monitoring of work-related exposure by labour inspectorates;

35. Encourages the Commission and the Member States to achieve the UN SDGs that target communicable diseases in order to promote the prevention of cancers related to infectious diseases; welcomes vaccination programmes in the fight against HPV transmission; insists that a gender-neutral and publicly-financed HPV vaccination programme be implemented in the Member States in order to ensure the elimination of all HPV-related cancers, and calls for 90% of girls to be fully vaccinated, and for a significant increase in the vaccination of boys, with the HPV vaccine by the age of 15 by 2030; urges that progress towards the goals of Europe’s Beating Cancer Plan on HPV vaccination be reported in the Cancer Inequalities Registry; calls on Member States to implement the Council recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases\textsuperscript{62} in order to reduce immunisation inequalities among vulnerable groups and to improve childhood immunisation; welcomes the Commission’s intention to propose a Council recommendation on vaccine-preventable cancers; stresses, in this context, the need for coordinated actions targeting carcinogenic viruses, such as HPV and the hepatitis B virus (HBV), in order to prevent their transmission; calls for more harmonisation of HPV and HBV vaccination within Member States’ national programmes, while ensuring the provision of information about vaccination and promoting equal access for vulnerable and at-risk adult groups; encourages the regular monitoring of current HPV and HBV vaccination at EU level using a tracking system similar to the COVID-19 vaccine tracker developed by the European Centre for Disease Prevention and Control (ECDC), that will also encourage Member States to adopt best practice and maintain momentum; calls on the Member States for data harmonisation, interoperability and enhanced development of national immunisation data systems; underlines that the ECDC should play a key role in tracking Member States’ progress; supports further research on vaccine development against other viruses such as the hepatitis C virus and the human immunodeficiency virus (HIV); considers that in the meantime therapeutic solutions ought to be used massively to reach the WHO’s goal of eradicating hepatitis C by 2030, and calls on the Commission to use financial resources under the Recovery and Resilience Fund to reach these targets by funding screening efforts; calls for cooperation with Member States and international organisations to combat the impact of misinformation on vaccination and to address vaccine hesitancy; calls for the EU4Health and other EU funding streams to be used for this purpose, including for supporting awareness-raising efforts for citizens, education providers and healthcare professionals, as well as for support to behavioural research under the Horizon Europe programme; recommends a strengthened application of the EU’s Code of Practice on Disinformation particularly with regard to vaccine misinformation;

36. Points out that recent data confirms that people suffering from chronic inflammation, including from rheumatic and musculoskeletal diseases (RMDs), are at a higher risk of

\textsuperscript{61} Texts adopted, P9_TA(2021)0427.
developing cancer and other malignancies; calls on the Commission and Member States to boost research on the relationship between chronic inflammation, cancer and RMDs;

37. Calls on the Commission and Member States to further invest in research into the causes of adult and also paediatric and adolescent cancers;

38. Highlights the importance of allocating appropriate funding to science and social humanities research in order to evaluate inequalities in access to standards of care and innovation in childhood cancer across Europe, which account for differences in survival rates of paediatric cancer patients of up to 20% among Member States, and of formulating mitigating measures in order to guarantee equal rights and access to treatment for all children and young people with cancer in Europe; regrets, in this regard, the disparities in terms of access to high-quality healthcare services among Member States, and also among different regions within Member States, and asks the Commission to address those disparities through the appropriate legislative measures in order to ensure equal rights in the EU;

39. Recommends that breastfeeding be encouraged so as to limit the risk of breast cancer in women by means of informing and educating mothers on the benefits of breastfeeding;

40. Points out that genetic predisposition to cancer linked to mutations of specific genes has been demonstrated; highlights that methods to detect these mutations are available, either at birth for early detection of certain paediatric cancers or over the course of a lifetime, especially for breast, ovarian and colorectal cancers, and that the detection of these mutations may help to prevent or detect early-stage cancer and guide treatment choices; recommends therefore that Member States support increased access for patients in all age groups to genetic testing coupled with medical counselling and advanced sequencing diagnostics by earmarking financing and creating clear pathways for fast and efficient reimbursement, and raise awareness about to what extent citizens can access such services in the Union; recommends boosting investment in infrastructure and skills related to genetic sequencing platforms and the training of specialised genetic counsellors in specific units, such as already exist in some centres; calls on the Commission to support research in genetics in order to find genotypes with higher likelihood of developing certain cancers, including childhood cancers, as diseases with short exposure to external agents;

41. Highlights that techniques such as molecular epidemiology can provide new insights into the gene-environment interactions in cancer compared to in regular epidemiology; points out that these insights, together with further studies in epigenetics, can be used to improve the understanding of risk factors contributing to cancer causes and increase early detection;

42. Strongly supports the planned revision of the ECAC in order to develop, share and implement best practices in cancer prevention programmes, with a dedicated focus on disadvantaged groups, and the launch of a user-friendly EU mobile application which supports people and covers from cancer prevention and education to care, as announced in the Plan; highlights that in addition to being available on mobile applications, all up-to-date information should also be made available in non-digital formats to ensure inclusiveness; stresses that the ECAC should be systematically evaluated by IARC and that the evaluation work should continue to be coordinated by the Commission;

43. Encourages the Commission and the Member States to further promote health literacy on cancer risks and determinants as well as digital literacy that is linked to it, to develop educational tools for prevention, and to support the creation of e-learning platforms and applications; calls for particular attention be paid to disadvantaged, vulnerable, socially excluded, and marginalised people, and underlines that specific awareness-raising campaigns
for groups with particular health literacy needs are essential; notes the importance of increasing health literacy on carcinogenic substances at work, and calls on the Commission and Member States to ensure that employers provide appropriate training; underlines that primary healthcare providers have an important role in health promotion among several population groups, since they can adapt their health promotion actions to the needs of patients in the light of patients’ digital skills, or even if they have no digital skills at all; considers cancer prevention to be a first step towards a European public health education policy;

44. Calls for the continuous strengthening of the Knowledge Centre on Cancer, which should be tasked with establishing a European roadmap for devising and coordinating large-scale prevention campaigns, in synergy with national programmes, and effective communication campaigns on health promotion in educational programmes (harmless behaviours, healthy nutrition, physical activity, transmission routes of carcinogenic viruses and vaccination and treatment opportunities for such infections, etc.), with a special focus on young people and disadvantaged groups; notes the importance of cooperating with national and local civil society organisations when developing the messaging for these campaigns;

45. Underlines that tobacco and harmful alcohol consumption, poor nutrition, a high body mass index, a sedentary lifestyle and environmental pollution are risk factors common to other chronic diseases; believes, therefore, that cancer prevention and risk reduction measures have to be implemented in the context of an integrated!chronic disease prevention programme, in close cooperation with the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases; calls for a stock-taking and prevention summit focusing on commercially-produced determinants of cancer and other chronic diseases, which would bring together the EU institutions, Member States, patient associations and civil society organisations active in the field of health;

46. Calls for the implementation of prevention programmes to be inclusive by involving regions and municipalities, citizens, the social partners, civil society and patient associations at all steps of the decision-making process, especially through the Conference on the Future of Europe;

II. Inclusive screening and detection of cancer

47. Deplores the frequent delays to and shortcomings in the timely diagnosis of symptomatic cancers related to a lack of information or adherence to cancer screening and detection processes; recognises the need to pay particular attention to the continuity of screening programmes and early detection and cancer care services during a health crisis (such as the COVID-19 crisis) or in situations where the capacity of the healthcare systems decreases; encourages the Commission and Member States to organise, in partnership with cancer stakeholders, public health campaigns to address any delays in screening, early detection and care that a health crisis might cause; stresses the importance of quick and up-to-date data on cancer screening programmes in order to enable swift reaction and follow-up in case of disruptions to regular screening capabilities with the goal of reducing the number of postponed screenings to an absolute minimum;

48. Regrets the inequalities between Member States in access to cancer screening, resulting in lower chances of survival due to late diagnosis of cancer, which represents an unacceptable discrimination of EU citizens based on their country of residence; underlines that in the case of breast cancer screening, differences in coverage are at least tenfold across the EU according to Eurostat; points out that the ‘Health at a Glance: Europe 2018’ publication noted that for cervical cancer screening, the difference between Member States in coverage of the target population ranges from 25% to 80%; notes that, for instance, only 18 Member States
reported having national or regional population-based screening programmes for breast, cervical and colorectal cancers, according to the most recent report by the IARC on the implementation of the 2003 Council Recommendations on screening; calls on the Commission to support projects, for example via EU4Health, Horizon Europe Mission on Cancer or other relevant programmes, to explore the barriers limiting the early detection and early diagnosis of cancer in Europe;

49. Invites Member States to work together, especially in cross-border regions and isolated areas (including mountain areas and urban areas remote from screening centres), to reduce social and geographical inequalities in cancer screening and early diagnosis services;

50. Supports the launch of a new EU-supported cancer screening scheme, as announced in the Plan, to help Member States to ensure that 90% of the EU population who qualify for breast, cervical and colorectal cancer screenings are offered screening by 2025; calls on the Commission to include other cancers in the scheme, based on the latest scientific evidence, with clear targets for each type of cancer; supports research on other types of cancers which may be effectively detected by screening; calls on the Commission to evaluate every two years the results of the cancer screening scheme in terms of equal access of the target population, to keep track of inequalities between Member States and regions, propose appropriate new measures and correlate screening programmes with the latest cancer screening research results, and if necessary, present measures for increasing the coverage of screening and prevention services in the Member States; urges the Member States and the Commission to report and monitor the achievement of screening targets in the Cancer Inequalities Registry;

51. Encourages Member States to promote cancer screening for breast, cervical and colorectal cancers, as part of organised population-based national and regional programmes, including in the remote and outermost regions, and to provide adequate resources for this; reiterates that, at the same time, there should be increased focus under the Plan on screening, diagnosis and treatment initiatives for cancers that cannot be prevented; encourages the Commission and the Member States to promote targeted screening for high-risk groups; strongly recommends that Member States develop a comprehensive screening policy which allows for timely screening when cancers with hereditary characteristics are detected; recommends that Member States establish research programmes into, and the development of, effective, accurate, non-invasive and innovative early diagnosis methods, such as biomarkers, for different types of cancer;

52. Calls on the Commission and the Member States to fully implement the European guidelines for quality assurance in cancer screening for breast, cervical and colorectal cancers and early detection services to minimise the diagnosis time for such cancers; recommends that inequalities within Member States regarding screening be addressed, possibly by making the criteria for cancer screening, legal frameworks and governance and quality assurance structures more stringent and science-based; considers that in order to address disparities in cancer screening, common standardised screening protocols are needed at EU level, going beyond best practice guidelines, e.g. on algorithms for the organisation of screening programmes and indicators for assessing the quality of screening programmes;

53. Encourages the improvement and harmonisation of cancer screening data collection to allow for an annual European report; encourages, furthermore, the regular monitoring of current screening programmes at EU level; highlights the need to link data sets on cancer incidence from screening programmes with occupational categories, which can help to identify appropriate preventive measures; considers that stepping up public health services (including financing, infrastructure and aspects involving health professionals) is key to improving cancer prevention, screening and diagnosis; stresses the importance of screening for and
collecting data on common cancer comorbidities in order to better anticipate them; underlines that scientific advances in cancer risk prediction should allow for the development of risk-appropriate screening programmes;

54. Stresses the need to closely monitor current and former hepatitis B and C patients to prevent cancer development;

55. Encourages the Commission to consider the possibility of facilitating a ‘second opinion’ system within the Cross-Border Healthcare Directive\(^{63}\) for difficult or atypical cancer cases, and recommends that the Member States introduce the right of patients to request that specialists from one Member State seek the advice of specialists from another Member State within a single coherent system;

56. Welcomes the process initiated by the Commission’s Group of Chief Scientific Advisors and the Scientific Advice Mechanism on the upcoming update of the 2003 Council recommendation on breast, cervical and colorectal cancer screening, which will take into account new screening tests and the most recent data on the best screening protocols (magnetic resonance imaging, HPV testing, risk-stratified approaches and risk calculators); emphasises that information on those screening programmes should be transmitted to the Joint Research Centre’s Knowledge Centre on Cancer (age of initiation and subsequent uptake, impact on survival, cost-effectiveness etc.) and that they should be regularly evaluated by the competent national authorities; calls on the Commission to develop EU guidelines for fostering research efforts in order to assess the inclusion of new science-based cancer screening programmes (including lung, prostate, stomach and ovarian cancers) and the role of artificial intelligence as part of the update of the Council recommendation in 2022, in close cooperation with the IARC, the WHO, healthcare professionals and patient organisations; calls for the evidence that proves the positive effect of targeted lung cancer screening on mortality to be recognised; encourages the Council, based on the outcome of the above-mentioned assessment, to consider including lung and prostate cancer screening in the update of the Council recommendation in 2022; calls, further to the opinion of the Commission’s Group of Chief Scientific Advisors and the 2022 update of the Council recommendation on cancer screening, for clear and tangible targets to be set for any new cancers that need to be tackled;

57. Advocates the launch by the Commission and the Member States of an EU platform for national screening centres, drawing on the experience of similar platforms for exchange and cooperation such as the European Network for Health Technology Assessment and the Heads of Medicines Agencies; recommends that this platform be entrusted with sharing expertise and implementing best practices, discussing common challenges, encouraging collaboration, training and capacity-building for improving quality in screening programmes, acting as a central hub for projects and initiatives on cancer screening supported by the EU, and maintaining in the long term the network of providers of data to the implementation report by the IARC on cancer screening;

58. Stresses the importance of increasing awareness about and the uptake of cancer screening and early detection among people in the EU via a Union-wide awareness-raising campaign as part of the European awareness days, motivation surveys and better implementation of existing communication campaigns; calls on the Commission and the Member States to support, fund and implement further actions aimed at raising awareness of cancer screening and promoting participation in screening both among the general population and to eligible residents via

direct notifications; encourages the Member States to actively work on educational strategies in primary healthcare centres; encourages research into behavioural adherence factors and obstacles impeding early detection and diagnosis of cancer to boost participation in screening programmes, supported by EU funding such as that provided under the Horizon Europe research programme;

59. Calls for reinforced cooperation with non-EU countries and especially with the broader European region to encourage the organisation of screening campaigns and early diagnosis programmes, in particular for women’s cancers and especially in low- and middle-income countries and for minority communities, while also taking into account the specifics of women’s cancers in those countries; stresses that this can mark an important contribution by the EU to the achievement of international goals in cancer, such as the WHO goal to eliminate cervical cancer as a public health problem;

60. Recognises the importance of health mediators, patient navigators and non-governmental organisations and calls for their inclusion in decision-making processes and resource allocation strategies; acknowledges the vital role they play, especially in prevention and vaccination campaigns, by helping to break down barriers between authorities and society, including vulnerable groups;

61. Calls on the EU and the Member States to reinforce cooperation with the WHO and to work towards the implementation of WHO policy recommendations and guidelines;

IIIa. Equal access to cancer care: towards best quality care

62. Deplores the fact that EU patients still face challenges in accessing healthcare services and participating in clinical trials in other Member States and that only a minority of patients, and not all healthcare professionals, are aware of the right of patients to seek cross-border healthcare under the two existing frameworks: the Cross-Border Healthcare Directive and the Social Security Regulation; calls for a reform of the Cross-Border Healthcare Directive, notably to allow for mobility and access to highly specialised equipment and care through the reinforcement of the national contact points by providing them with more budgetary resources, and to allow for the development of Commission guidelines setting acceptable and harmonised review and approval timelines to expedite time-to-treatment in the EU under the Social Security Regulation; calls for an increase in the number of information campaigns on patients’ rights to cross-border healthcare, including those aimed at health professionals, as well as the development of a one-stop-shop for information on the EU’s cross-border access pathways; emphasises the need to reduce logistic and linguistic barriers faced by patients when accessing healthcare in another EU Member State; stresses the need to provide patients with clear information on prior authorisation requirements that apply to certain Member States; underlines the need to provide particular financial support to low-income parents accompanying their child abroad for treatment; emphasises the need to facilitate the process through a holistic revision of the cross-border healthcare frameworks, giving equal weight to the Cross-Border Healthcare Directive and the Social Security Regulation, for patients who, in view of unmet needs and potential benefits, travel abroad for clinical trials and may face issues such as a lack of clarity on follow-up protocols after their return home and on coverage of costs related to their clinical trial participation by national insurance agencies; emphasises the need for clarification regarding access to cross-border clinical trials, as this is not clear in the Cross-Border Healthcare Directive; underlines that all costs related to a treatment should be financed before it begins to avoid the exclusion of low-income patients; calls on the

Commission to consider, in the context of the next revision of the existing frameworks, the setting up of a single set of authorisation and reimbursement rules for the access to cross-border healthcare, including a right to a second opinion; calls on the Commission and the Member States to work together to conduct regular evaluations of the Commission’s eHealth strategy from 2018 to ensure interconnected electronic health records, better interoperability, and improved data quality, privacy and security for cancer patients at regional, national and EU level, while ensuring strict adherence to patient health data privacy and security rules; notes the potential of the Cancer Inequalities Registry as a means of reporting and measuring improvement in these areas;

63. Notes the importance of rapidly administering treatment and providing the results of relevant medical exams to cancer patients in a timely fashion, since the more time this takes, the more the disease progresses, threatening the patient’s survival; regrets that in certain Member States, public resources are inadequate to guarantee timely detection and treatment, which leaves patients who depend on publicly provided social insurance with lower chances of survival, thus leaving them with no other option but the private sector;

64. Calls for the mutual recognition of health-related qualifications in cancer care across the EU and a common recognition scheme for non-EU countries to be considered, as requested in Directive 2005/36/EC, ensuring that it is facilitative for oncology-related specialties; calls for the development of upskilling programmes to enable those wishing to move into oncology to do so at any point in their career;

65. Calls for full recognition of medical oncology and paediatric oncology as specialist disciplines, the establishment of pan-European quality standards for administering and supervising medical treatments for cancer, both for adults and children, and the facilitation of patient access to cancer specialists so that they may benefit from innovations and access to early clinical trials on new promising drugs, health technologies and reference centres for complex treatments like cell and gene therapy; highlights the need to ensure that access to innovation in early clinical trials for relapsed or difficult-to-treat malignancies is covered by the relevant provisions;

66. Calls for surgical skills in the EU to be strengthened via the recognition of surgical oncology as a specialist discipline, the establishment of pan-European quality standards for cancer surgery, the facilitation of patients’ access to ‘high-volume’ centres for cancer surgery and access to innovative surgical procedures; calls for the recognition of high-quality surgery and highlights its importance in curing cancers detected at an early stage; stresses the need to promote the development of a core curriculum in surgical oncology as well as individual specialist training in surgical oncology, and calls for programmes to harmonise surgical oncology education in the EU; supports the development of clinical trials in surgical oncology as part of local-regional treatment and promotes greater investment of EU and national research and innovation funds in surgical oncology research; stresses the importance of standardised surgical oncology treatments to improve long-term quality of life for cancer survivors;

67. Supports the improvement of and increased and equal access to high-quality radiation therapy in the EU through the recognition of medical physics and radiation therapy as dedicated disciplines, the promotion of common education and training standards, increased EU funding
for Member States to expand their radiation therapy infrastructure, and greater investment of EU and national research and innovation funds in radiation therapy research;

68. Calls for the promotion of geriatric oncology as a branch that deserves special consideration and needs to be enriched by scientific research in order to ascertain best treatment and diagnostic methods for elderly patients; recalls that in the EU, over 60% of new cancer cases and over 70% of cancer deaths occur in people aged 65 and older; notes that this proportion is expected to increase as the population in the EU ages, thus representing a crucial challenge for healthcare systems; calls on the Commission and the Member States to urgently address this situation with concrete actions; specifically asks the Commission and the Member States to take action in order to facilitate clinical trials in the elderly, the implementation of multidisciplinary and comprehensive onco-geriatric care models in routine clinical pathways, and the creation of centres of excellence in geriatric oncology; calls on the Commission and the Member States to foster opportunities for the training and upskilling of the oncology workforce in the principles of geriatrics;

69. Calls on the Commission and the Member States to plan actions that promote, in the context of care and treatment, greater attention to the protection of patients’ fertility, in particular in the case of paediatric and juvenile cancers;

70. Welcomes the new action plan under the strategic agenda for medical ionising radiation applications, which will support the security of production capacities for and supply of radioisotopes through the replacement of the current ageing fleet and the implementation of existing technologies, notably reactors and particle accelerators, under existing financial instruments, avoid shortages of radioisotopes by facilitating the crossing of borders and exemptions for transportation, and enhance the quality and safety of radiation technology in medicine, which is currently not equally available in all EU Member States, through the evaluation of radioisotopes via health technology assessments, the harmonisation of market access, the affirmation of nuclear medicine as a fully independent medical specialty, the promotion of training standards, and investment in nuclear medicine research;

71. Calls on the Commission to promote, and on the Member States to strengthen, the role of general practitioners, paediatricians, nurses, primary care professionals and specialist physicians, given the important role they play in referring patients for diagnostic tests and to oncology specialists, as well as the role of specialised nutritionists or dieticians, psychologists and rehabilitation specialists during cancer treatment and follow-up care, in order to ensure access to the right treatment and care at the right time via an optimal care pathway; calls for the development of multidisciplinary teams to manage cancer patients throughout their treatment journey, and multidisciplinary decision-making in the framework of dedicated cross-discipline concertation meetings (consilium) bringing together various cancer specialists and primary care professionals; underlines the importance of constant training for health professionals to keep them updated on new cancer treatment options; calls for the role of treatment coordinator to be made more widespread in order to ensure that patient treatment is appropriately coordinated, and to give patients easy access to updated information related to cancer diagnosis and advice on how to use the health system;

72. Considers that the scope of Directive 2005/36/EC should be revised to allow for the mutual recognition of cancer nursing education and education for other medical staff supporting the treatment process;

73. Calls on the Member States to develop, within their national cancer control programmes (NCCPs), strategies that encompass and implement preventive measures against the risk of burnout among cancer care professionals; urges the Commission and EU-OSHA to pay attention to this concern, and stresses that they should be considered important implementation partners of the Plan in this respect;

74. Encourages, where feasible and safe, the use of ambulatory cancer treatments in order to preserve the quality of life of patients and their families; stresses, in particular, that ambulatory treatments for children should be promoted, provided that the relevant spaces/environments and medical devices available are designed in such a way as to cater for the needs of paediatric patients; stresses the role of pharmacists, oncologists and nurses in the multidisciplinary follow-up of patients taking oral anticancer medicines; calls on the Member States to implement or improve e-health technologies, telemedicine and telecare services to ensure the continuity of inpatient and outpatient cancer care as well as community care; urges the Commission to deploy Horizon Europe research funding to support the use of telemedicine and to assist with the establishment of evidence-based guidelines; calls for actions to ensure equal access to telemedicine services across the Member States, and for EU4Health and Digital Europe funding to support an increase in digital literacy for patients and healthcare professionals;

75. Calls on the Member States to provide integral and multidisciplinary palliative care services for cancer patients in order to ease their pain and discomfort, promoting comfort care and ensuring the presence of nurses or carers, while preserving their dignity and taking into account advance care planning and the autonomy of the patient; calls on the Commission to support and coordinate regular exchanges of information and the implementation of best practices on hospice and home palliative care at EU level; calls for the development of child-specific palliative care, especially in Member States where this type of care is not yet widely provided; encourages the Member States to address palliative care in their NCCPs, maximise the number of palliative units in each region in order to appropriately adjust their number to the needs of patients, minimise waiting times, and ensure sustainable funding and sufficient numbers of well-trained staff; considers that the EU regulatory framework for the recognition of professional qualifications should be broadened to allow for the standardisation of palliative care education and best practices of health professionals; emphasises the need for reference networks for palliative care and their integration with cancer pathways at all levels, namely specialist hospitals, primary healthcare centres, hospice and home care, as well as the need for hospital-territory integration; stress that patient access to supportive and palliative care (including psycho-oncology services) across the EU should be measured and reported via the Cancer Inequalities Registry; calls for deeper cooperation between healthcare systems and social assistance systems in all Member States;

76. Encourages the Commission and the Member States to adopt specific quality assurance criteria and schemes (including common standards of care, adequate organisation, infrastructure and competences, multidisciplinary practice, continuing education for professionals, patient education and participation in clinical research), and joint clinical guidelines to ensure accreditation standards are applied to public and private hospitals treating cancer patients, in order to guarantee efficient, safe and equal management of cancers all over the EU; insists that these criteria must adhere to the highest available standards of evidence-based science that have been published in peer-reviewed scientific journals; insists that both public and private institutions that meet the quality assurance criteria should be included in NCCPs as part of the Plan with the goal of providing the highest quality of cancer treatment to all patients across the EU; calls on the Member States to create maps of oncology health needs, coupling them with realistic mappings and inventories of their existing oncological infrastructure; takes the view that this mapping exercise will allow Member States to better
plan access to existing medical infrastructure, determine clear areas of action and prioritise the allocation of resources, and plan cross-border cooperation between the oncological reference centres;

77. Welcomes the planned establishment, as announced in the Plan, of an EU network linking recognised national comprehensive cancer centres (reference centres) in every Member State to facilitate the uptake of quality-assured diagnosis and treatments, including through training in, research on and the promotion of clinical trials across the EU; calls on the Member States and the Commission to support the establishment of such centres for rare cancers and cancers requiring complex treatments; calls on the Commission to identify existing centres of this type within the EU, to promote the establishment of at least one national comprehensive cancer centre in each Member State and to support the coordination of the network of these centres; stresses that the objectives of that network should include the reduction of inequalities and the strengthening of translational, clinical and outcome research; highlights that the promotion and development of translational research should be considered as an important core objective of the EU Network of Comprehensive Cancer Centres; notes that when developing this EU network, the Commission should consider the need to invest in state-of-the-art equipment and well-trained physicians and other healthcare specialists with various specialties, and recommends that a variety of well-developed cancer specialties and medical disciplines be involved from the start in the work of the envisioned EU Network of Comprehensive Cancer Centres to reinforce multidisciplinary cooperation, therefore improving outcomes for patients; calls on the Commission and the Member States to support the sustainability of pre-existing cross-border collaborations, such as the European Reference Networks and those relating to paediatric cancer; calls on the Commission to support the Member States by earmarking some of the budget in the cohesion and regional funds to support the establishment of these centres to ensure full coverage of the population;

78. Calls for the identification, reinforcement or creation in each Member State of an NCCP, in line with WHO guidance on NCCPs, consisting of a unique structure, possibly a national cancer institute, in charge of the implementation and follow-up of the respective NCCPs, with adequate objectives and resources; calls for the content of the NCCPs to be aligned as closely as possible with the Plan in order to facilitate the successful implementation of the latter; recommends that the NCCPs are set up in accordance with the European Guide for Quality National Cancer Control Programmes initiated by the European Partnership for Action Against Cancer (EPAAC) and calls for the inclusion of a dedicated paediatric cancer and rare cancers component in all NCCPs to ensure that appropriate resources are allocated and adequate implementation programmes are introduced to meet the specific needs of these patients; welcomes the setting up of a network of these organisations; stresses that NCCPs should include provisions on adequate staff capacities so as to guarantee a sufficient number of oncology workers in each Member State, commensurate with the overall population number;

IIIb. Equal access to cancer care and medicines in the EU

79. Calls on the Commission to strengthen the EU medicines market in order to improve equal access to treatment, including innovations and personalised medicine, reduce medicine shortages, overcome the problem of high prices for innovative technologies and treatments, encourage the use of generic and biosimilar medicines and improve cancer treatments for adults and children; calls on the Commission and the national competition authorities to assess the EU medicines market, focusing on acquisitions of SMEs by large pharmaceutical companies that undermine fair competition; encourages a multi-stakeholder dialogue on
access to medicines and innovations based on models such as ACCELERATE\textsuperscript{67} in the paediatric cancer sector and involving all relevant actors including academics, industry, health professionals and patient representatives;

80. Calls on the Member States to step up national research and production capacity for medicines and other health products, including by establishing national pharmaceutical laboratories, with a view to providing equal access to treatment, reducing medicine shortages and dependence on the pharmaceutical industry, securing cost-free access to innovative treatments and improving cancer treatments for adults and children; calls on the Member States, furthermore, to provide cost-free access to treatments and medicines used by cancer patients by means of their public health services and to consider medicine policies that provide cost-free access to medicine for users over the age of 65, the chronically ill and families in economic need;


82. Notes that cancer patients are frequently affected by medicine shortages and that severe disruptions in the supply of cancer treatments are highly detrimental to them, their carers and their families; calls on the Commission and the Member States to work together to prevent and manage shortages of all medicines and medical products and of cancer medicines in particular, including shortages of inexpensive essential cancer medicines; supports the development of a common basket of cancer drugs of which there may be shortages to ensure that patients have continuous access to appropriate treatment, based on transparently and appropriately defined patient needs;

83. Calls for the reinforcement and diversification of the supply chain, in particular that of cancer drugs, within the EU, close monitoring of supply tensions and shortages, and the creation of a strategic stockpile of such critical medicines, active ingredients and raw materials, particularly where the number of suppliers is limited; calls for EU pharmaceutical legislation to introduce a legal obligation for pharmaceutical companies to report information to the EMA on adequate safety stocks of essential cancer medicines; stresses the importance of the role of sustainable procurement practices in preventing medicine shortages; urges the Commission, in the context of the EU Public Procurement Directive\textsuperscript{70}, to develop guidelines to support public procurement practices in the pharmaceutical field for cancer drugs, in particular with regard to the implementation of the criteria for the most economically advantageous tender, aimed at ensuring long-term sustainability, competition and security of supply and stimulating investment in manufacturing;

84. Points out that generic and biosimilar medicines enable efficient and safe cancer care, increased competition, innovation and savings for healthcare systems, thus helping to improve access to medicines; calls for the introduction of a strategic objective in the Plan and the

\textsuperscript{67} https://www.accelerate-platform.org/
\textsuperscript{68} OJ L 311, 28.11.2001, p. 67.
NCCPs to actively promote the use of off-patent medicines, where appropriate and beneficial for patients; stresses that their market entry should not be hampered or delayed and their development process should be promoted and funded; calls on the Commission to ensure healthy competition on the expiry of intellectual property rights as a matter of urgency by ensuring the accessibility of biosimilar medicines from day one and removing all barriers to access to competition, for example through patent linkage, by banning intellectual property evergreening practices that unduly delay access to medicines and by allowing single global development;

85. Considers that Member States should converge on the evaluation of medical technologies; welcomes, therefore, the agreement on the Health Technology Assessment Regulation reached by the European Parliament and the Council on 22 June 2021 to support harmonised assessment of, and faster access to, innovative cancer diagnosis and treatments and considers that a more efficient decision-making process could, among other measures, play a role in facilitating it; welcomes that cancer medicines is one of the first medicinal product groups to be jointly assessed under the Health Technology Assessment Regulation; calls on the Commission and Member States to take further measures aimed at encouraging the uptake and use of Joint Clinical Assessments that are to be carried out under the regulation; highlights the existence of tools being used by the WHO to incorporate cancer medicines on the WHO Model List of Essential Medicines;

86. Recalls that all patients have the right to optimal treatment, regardless of their financial means, gender, age or nationality; notes with concern that there is a great disparity in the availability of and access to different cancer therapies, with unaffordability being one of the main reasons; insists, therefore, on the need to ensure equal access to safe, effective and affordable drugs, in particular cancer drugs, within the EU; calls on the Member States to consider joint price negotiation with pharmaceutical companies, as per the Beneluxa Initiative on Pharmaceutical Policy and the Valletta Declaration; calls on the Commission to make fair pricing and affordability of new treatments a core element of the Plan and the Pharmaceutical Strategy for Europe, notably by attaching conditionalities to EU public funding (e.g. under Horizon Europe and the Innovative Health Initiative), and to ensure that public investment in R&D is accounted for and that medicines resulting from publicly funded research are available at fair and affordable prices; underlines that this should also be the case for medicines benefiting from specific regulatory or market protection such as medicines developed to treat rare or paediatric cancers; calls for more transparency throughout the pharmaceutical system, especially regarding pricing components, reimbursement criteria and the actual (net) prices of medicines in different Member States to ensure fairer prices and bring public accountability to the pharmaceutical sector;

87. Strongly advocates the extension of joint procurement procedures, especially for (ultra) rare, paediatric and novel cancer medicines and treatments, diagnostic procedures, companion diagnostic tests, and cancer-preventing vaccines like the HPV and hepatitis B vaccines, to counter shortages and improve affordability and access to cancer treatments at EU level; notes that joint procurement procedures should improve response times and be transparent; highlights that joint public procurement should not hinder patient access and medical innovation;

88. Calls on the Commission to support a regulatory framework which strengthens incentives for rare cancer treatment in the EU to effectively address existing shortcomings; underlines that patent systems all over the world are drafted in a way that for a specific period of time – i.e. only for the duration of the patent – only the inventor is allowed to commercially exploit their patent, whereas thereafter the invention can be freely produced by anyone; calls on the Commission to develop new targeted incentives to ensure equitable access to cancer
medicines also in areas where the development of products would otherwise not be sustainable;

89. Calls on the Commission to submit a proposal for the revision of Council Directive 89/105/EEC on the transparency of measures regulating the prices of medicinal products in order to ensure effective controls and full transparency of the procedures used to determine the price of and reimbursement amount for medicines, in particular cancer medicines, in Member States; encourages the competent authorities to ask pharmaceutical companies to provide information on research and development costs, including the financing from public resources, prior to market authorisation, as well as on the tax benefits and subsidies they have received; requests that the calculation of drug costs take into account the use of public funds; calls on the EMA to increase the number of audits in order to assess pharmaceutical companies’ compliance with the requirements on transparency;

90. Notes that huge advances in biology have revealed that cancer is an umbrella term for more than 200 diseases, and that precision or personalised medicine can be made available through the drug targeting of various mutations; considers that precision or personalised medicine, consisting of a treatment choice based on individual tumour biomarkers reflecting genotypes or phenotypes, is a promising way to improve cancer treatment; encourages the Member States, therefore, to develop personalised medicine across the EU through cooperation among them and to promote the implementation of regional molecular genetics platforms and facilitate equal and rapid access to advanced diagnostics and personalised treatment for patients, in full respect of data privacy and ensuring that patients are informed and consent to the use of their health data for research; notes that the fragmentation and classification of cancers based on specific genotypes should not lead to them being defined as ‘artificial rare diseases’ with the aim of increasing financial compensation;

91. Recalls that in the context of personalised medicine, gender-based medicine and therapies are considered to be effective treatment strategies for curing cancer, taking into consideration differences between men and women at the biological, genetic and musculoskeletal levels; calls on the Commission and the Member States to facilitate the development of gender-based treatment for cancer, in line with the indications coming from medical practitioners and physicians;

92. Welcomes the Genomic for Public Health project and the establishment of a roadmap to personalised prevention in the Plan to identify gaps in research and innovation and support an approach to map all known biological anomalies leading to cancer susceptibility, including hereditary cancers, which amount to between 5 and 10 % of cancer cases;

93. Calls for the full and rapid application of Regulation (EU) No 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use; considers that the application of the regulation would facilitate the launch of large clinical trials across Europe carried out in a harmonised, efficient and coordinated manner at European level in order to facilitate research into cancer drugs and improve the quality of life of cancer patients and their families; considers, furthermore, that the regulation should be applied in a consistent manner in all Member States with the aim of rationalising procedures for carrying out clinical research; highlights the importance of undertaking a fresh review of opportunities to reduce the administrative burden associated with clinical trials; calls for long-term learning from the

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COVID-19 pandemic on future forms of international trial cooperation and information sharing;

94. Points out that the PRIME scheme launched by the EMA can be a highly efficient instrument to enhance support for the development of innovative medicines in oncology, so that they can reach the patient sooner;

95. Calls for a more sustainable environment, including as regards financial support, for conducting research into and analysing existing research about the repurposing of medicines for cancer treatment, especially by third parties with no commercial intent, and for the creation of an additional project that uses high-performance computing to rapidly test existing molecules and new drug combinations, starting with high unmet needs, such as treatment for cancers with a poor prognosis, metastatic cancers and rare cancers;

96. Highlights the importance of addressing the issue of the off-label use of medicines, including inexpensive medicines and medicines used for rare cancers; calls on the Commission to analyse the existing situation concerning the off-label use of medicines;

97. Acknowledges that many upcoming technologies will require complex regulations (cell and gene therapies, for example); considers that the Union should fund, incentivise and ensure a regulatory process that actively encourages research and innovation, anticipates the needs of researchers in academia, industry and at clinics, actively informs and guides them on regulatory processes, prepares the ground for future technologies, evaluates those technologies step by step and fosters the entry of safe and effective new treatments into the market;

98. Reiterates the importance of generating and reporting strong evidence on the efficacy and safety profiles of medicines, both in clinical trials and in post-market entry follow-up studies; supports the development of clinical trials on the use of new and affordable cancer drugs in adults and children; supports the development of multi-centric clinical trials across Europe for the discovery of improved forms of treatment and care for patients, including children and older patients; underlines that authorities must ensure transparency, compliance with study conduct requirements and the early communication of relevant data to the EMA and the general public;

99. Takes note of the Commission’s legislative proposal to establish a Health Emergency Preparedness and Response Authority (HERA); notes that, by 2023 and every two years thereafter, the Commission should carry out an in-depth review of the implementation of the operations of HERA, including its structure, governance, funding and human resources; notes that these reviews must address, in particular, any need to modify HERA’s structure, including but not limited to the possibility of upgrading it to a stand-alone agency, revising its mandate and understanding the financial implications of any such modification; notes that the Commission should report on the findings of the reviews to the European Parliament and the Council and that these findings should be made public; notes that these reviews should be accompanied, where appropriate, by a legislative proposal to address the outlined issues, fully respecting the European Parliament’s role as co-legislator; considers that if HERA is upgraded to a stand-alone agency, it could, at that point, be able to anticipate, incentivise, co-develop and facilitate rapid, equal and sustainable access to cancer innovations for cancer patients, including diagnostic procedures as well as companion diagnostic tests; considers that HERA could, in the long term, closely collaborate with public and private entities to plan, coordinate and build an ecosystem of private and public capabilities that can provide suitable emergency frameworks for EU access to key raw materials in case of global supply shocks;
100. Stresses the need to promote the innovation of life-saving cancer treatments; calls therefore on the Commission to create a pharmaceutical legislation framework for oncological medicines and therapies that promotes real breakthrough innovations and not the so-called ‘me too’ pharmaceuticals, which are just another substance with the same use without major benefits or highly expensive pharmaceuticals that offer only minor improvements for patients; calls for a large consortium of public authorities, private companies and NGOs, including patient and survivors associations and academia, to work together to guarantee the accessibility and affordability of cancer treatment options requiring complex technologies, for instance, complex treatments like cell therapy (CAR T cells), gene therapy, adoptive immunotherapy through the use of tumour genome extracts (messenger RNA) and nanotechnologies; stresses that, to facilitate the wider utilisation of innovative therapies, the EU and the Member States must not only do their best to finance currently available therapies but also support the development of more cost-efficient methods; believes that lowering the costs of the most innovative and effective therapies will increase their wider availability to the benefit of patients in the EU and beyond; calls for securing equal access to innovative therapies, both in densely populated urban regions and smaller rural or remote areas;

IIIc. Equal access to multidisciplinary and quality cancer care: towards a better response to the impact of health crises on cancer patients

101. Underlines that the COVID-19 crisis has had, and is still having, a significant impact on cancer patients’ survival and quality of life at all stages of the disease, due to delays in prevention activities such as vaccination, postponements of prevention schemes, clinical trials, screenings, referrals, diagnoses, surgical procedures and treatments, shortages in the supply of medicine and other medical supplies, specialised workforce shortages, reduced communication with health professionals and patients’ fear of infection; highlights that evidence suggests that clinicians across Europe saw 1.5 million fewer cancer patients in the first year of the pandemic and performed an estimated 100 million fewer cancer screening tests, and therefore, one million citizens in the EU may presently be undiagnosed with cancer as a consequence of the COVID-19 pandemic;73

102. Considers that the COVID-19 pandemic was a real stress test for the EU’s health systems; underlines that the main lesson learned should be the need to invest in the public health sector and to build an emergency strategy to allow Member States to react in a coordinated manner against any future health crises; stresses that vulnerable groups, including cancer patients, are particularly exposed during a health crisis; stresses that specific measures under this emergency strategy should be aimed at the protection of vulnerable groups, including cancer patients, who cannot wait until the end of the crisis; stresses that these specific measures should support the development, production and stockpiling of products to protect these vulnerable groups;

103. Calls on the Commission and the Member States to diligently collect data via suitable registries to monitor the effects of vaccines against COVID-19 in vulnerable populations, including patients with cancer, and their subsequent immune responses;

104. Notes with concern that the COVID-19 pandemic has exacerbated pre-existing health workforce shortages; acknowledges the urgency of ensuring a sufficient number of specialised health professionals in cancer care; reiterates that specific measures under the emergency strategy should be aimed at addressing workforce shortages through the recruitment of health professionals, in both primary and specialised care, and their retraining, should they be

specialists in other fields; suggests that the Cancer Inequalities Registry may serve as a tool in measuring and reporting on pre-existing workforce shortages; underlines that new approaches to human-centred healthcare are required in order to ensure access to diagnostics, therapeutics and quality public health services for all; stresses the need for work on a skill mix in order to optimise the response to staffing needs in the health sector; supports the exchange of good practices between Member States in this regard; calls on the Commission and the Member States to create online training platforms for healthcare professionals such as carers, and to create therapeutic care programmes granting qualifications and recognising their competences;

105. Deplores the fact that patients still face many difficulties in accessing quality, public healthcare services since many oncology departments at public hospitals are suffering from workforce shortages and a lack of capacity; calls, therefore, for the creation of high-quality radiotherapy departments and modern oncology centres at public hospitals, based on European guidelines and in line with the most recent scientific evidence;

106. Calls on the Member States and relevant authorities to recognise the pivotal role of informal carers, integrate them into health and care teams and empower them with the possibility of making informed choices regarding available supportive measures with the support of healthcare professionals; recognises that the pandemic has exacerbated the crucial role of informal carers, who provide most of the daily care for cancer patients and who face a clear lack of practical and policy support, including as regards social rights, training, psychological help, information and recognition; points to the high percentage of informal carers among the EU population and to the disparities regarding the way in which they are supported and how their rights are recognised across Member States; calls on the Commission to consider the formalisation of informal care, which would ensure the recognition of a certain minimum standard of rights, especially for those who are providing long-term care;

107. Advocates the development of a digital health communication channel to monitor symptoms remotely and ensure continued cancer treatment in out-of-hospital care; calls for permanent access to medical consultations, psychosocial services and contact between the patient and health professionals and between the attending health professional and the patient’s family, to be guaranteed through the use of telemedicine and telecare and their integration into healthcare systems, in health threat-free environments in hospitals, or, where possible and safe, in pharmacies; calls for the stimulation of the development of therapeutics that can support a transition to home care;

108. Asks for enhanced communication between health professionals, patients, survivors, caregivers, parents and public authorities regarding the effectiveness and safety of health interventions, in particular cancer screening, diagnosis and treatment, and for increased awareness campaigns for prevention in times of crises;

109. Calls on the Commission and the Member States to adopt European prevention and management plans as part of a coherent and holistic contingency strategy to prevent and address shortages of medicines, devices, products and staff in times of health crises; underlines the responsibilities of market authorisation holders and wholesale distributors with respect to relevant EU legislation;

IV. Strong support to cancer patients, survivors and caregivers

110. Stresses that cancer patients should not suffer a ‘double punishment’ in their daily lives; calls for the adoption of an anti-discrimination directive, as well as for the fair and equal
implementation of directives on financial services, such as the Consumer Credit Directive\(^\text{74}\), without any discrimination against cancer patients and survivors;

111. Notes that there is a need to focus on the quality of life for a rising number of chronic cancer patients whose illnesses cannot be cured but may be stabilised for a number of years; emphasises the importance of specific EU recommendations to improve the quality of life of patients and survivors, including via comprehensive supportive care integrated into cancer care starting with the diagnosis and continuing throughout the course of the disease (including pain relief, psychological services, adapted physical activity, scientific evidence-based complementary therapies, access to education, nutritional support, social assistance encompassing all day-to-day tasks such as household help or childcare, access to reproductive health and the restoration of aesthetic integrity) and access to specialised supportive centres; asks the Member States to recognise sequelae (physical or mental disabilities), as well as social discrimination, including in the workplace; asks the Commission to propose guidelines for the Member States to address the importance of establishing comprehensive coverage systems that guarantee that these needs are met; recognises that cancer is a financially burdensome disease, even beyond cancer treatments; calls on the Commission to set up a platform for the exchange of best practices in palliative care and to support research on palliative care;

112. Calls on the Commission to consider an EU strategy on care and caring to ensure appropriate, accessible and high-quality long-term care;

113. Highlights the fact that scientifically recognised integrative medicine approved by public health authorities can bring benefits to patients in relation to the parallel effects of several diseases, such as cancer, and their treatment; stresses the importance of developing a holistic, integrative and patient-centred approach and encouraging, where appropriate, the complementary use of these therapies under the supervision of healthcare professionals;

114. Underlines that the results of cancer treatment can be hampered by malnutrition, therefore optimal nutritional care is an essential part of cancer care; calls on the Member States to develop recommendations for incorporating clinical nutrition into all aspects of cancer care, including treatment, support and research; considers that, wherever indicated, cancer patients must be provided with clinical nutritional support by a dietitian specialist to be included in the multidisciplinary team; welcomes, therefore, the planned inter-speciality training on nutrition support and calls on the Commission and the Member States to develop minimum standards for continuous training on nutritional care for the multidisciplinary workforce; recommends that nutrition management be an integral and ethical part of all clinical research involving cancer patients; recommends, furthermore, that proper nutritional support be included in the cancer patients' Charter of Rights;

115. Strongly urges the Member States to ensure that all cancer patients are fully informed about the possibility of fertility preservation procedures prior to the start of active treatment; calls for the development of guidelines at EU level for health professionals, defining the age at which cancer patients should be informed about the availability of reproductive health procedures; encourages, furthermore, the Member States to make provision for all cancer patients covered by compulsory national health insurance to be reimbursed for such services by national health insurance schemes;

116. Encourages the Member States to take into account the frequent exhaustion of the families and relatives of cancer patients and to provide them with psychological and socioeconomic

\(^{74}\) OJ L 133, 22.5.2008, p. 66.
assistance, especially to the most vulnerable, and rest periods in the workplace, throughout the course of the disease, as well as with bereavement support; encourages, furthermore, the development of integrated, adequate and accessible support schemes for cancer patients and their families, that take health, community and social services into account;

117. Recalls that patient empowerment and health literacy is crucial for the European cancer strategy and that patient-centredness and participatory decision-making must be at the heart of treatment and care development processes; encourages the promotion of well-informed patients who are actively involved in their own treatment and calls for the therapeutic education of caregivers and patients and their empowerment in the care programmes; considers that a specifically tailored methodology should be used for the training and empowerment process of paediatric patients, given their specific characteristics and needs; calls for participatory decision-making, with personalised and understandable evidence-based information to be provided to patients, as an integral part of the NCCPs, supported by the Plan; calls for the support of such initiatives and actions to empower cancer patients through EU funding, especially the EU4Health Programme;

118. Acknowledges the central role of independent patients’ and carers’ associations in relation to patient advocacy and accompaniment, services provided to cancer patients and caregivers, dissemination of health literacy, awareness raising and ongoing support both at EU and national level; calls on the Commission and the Member States to take into account the formal participation of these associations, as well as their requests and recommendations, when formulating cancer-related policies and legislation, and to provide them with public support in the form of both operating grants and project-related grants in order to guarantee their independence from private funding; calls on the Commission to set clear criteria according to which public financial support can be awarded; considers that paediatric patients should play a role, both individually and collectively, in improving healthcare and research procedures for all patients by contributing with their specific experiences; takes the view, therefore, that adequate learning and educational tools should be developed and properly financed to plan and ensure the involvement of children;

119. Stresses the importance of securing proper compensation claim options for workers in cases of occupational cancer; calls on the Member States to fully implement the Commission recommendation of 19 September 2003 on occupational diseases and ensure that proper compensation claim options exist for workers in cases of occupational cancer, which would secure every worker a chance to be properly compensated after being exposed to harmful substances or affected by work-related cancer; calls on the Commission to create a minimum list of occupational diseases with comparable recognition criteria across the EU;

120. Calls on the Member States to improve the reintegration of cancer survivors into social activities and the labour market, helping them transition into new professional roles in case sequelae prevents them from continuing in the same job and facilitate the return of paediatric cancer survivors to school or higher education; notes the general undervaluation of aftercare compared to equally important cancer prevention; recalls the recommendations and tools developed by the CHRODIS+ Joint Action to foster patients’ retention at work, ability to return to work and their reintegration into the labour market and encourages the Commission to support the implementation of these recommendations and tools across the Member States; advocates specific EU recommendations for measures for cancer survivors to prevent the recurrence of primary cancer and the development of new cancers as well as measures for their rehabilitation, including specific provisions for long-term follow-up care for childhood cancer survivors as they transition into adulthood; stresses the need for medical and psychological aftercare for cancer survivors;
121. Considers that EU-OSHA should be mandated to play a stronger role in promoting good practices in Member States with respect to the integration of cancer patients and survivors into the workplace and their protection from discrimination; looks forward to the new study, announced in the Plan, on the return to work of cancer survivors, which will map national employment and social protection policies and identify obstacles and the remaining challenges;

122. Underlines the essential role of labour inspectorates in securing compliance with health and safety legislation and preventing work-related cancers; calls on the Member States to strengthen labour inspectorates and ensure that they are adequately funded; emphasises that monitoring and verification is of particular importance for mobile workers; calls for the fastest possible implementation of the European Labour Authority (ELA) and for it to be made operational as soon as possible, and calls for the ELA to provide real labour inspection power in cross-border cases and monitor compliance with health and safety legislation; calls on the Commission and the Member States to involve the ELA in cross-border situations to secure proper enforcement of health and safety legislation;

123. Urges the Commission to pay attention to shifts in the EU labour market, and secure sufficient funding for proper data collection; believes that extensive and thorough information and data collection is of the absolute importance and is a continued priority for the Commission in order to respond with necessary legislative and non-legislative initiatives concerning the prevention of work-related cancers; stresses the need to establish comprehensive national registers for all Member States, which would enable EU-wide data collection on carcinogen exposure and stresses that these registers should cover all relevant carcinogens; calls for close cooperation between EU institutions, Member States, EU-OSHA and relevant stakeholders, while also strongly involving social partners; calls for making use of the collected data to follow up with necessary legislative and non-legislative measures to combat work-related cancers;

124. Supports the upcoming roll-out of a Cancer Survivor Smart Card, as announced in the Plan, to all European cancer survivors, especially survivors of childhood and adolescent cancers, for whom the Survivorship Passport model exists as a basis, which will summarise their clinical history, including patients’ own experience, and facilitate and monitor follow-up care; stresses the sensitive nature of individual health data and hence the need for the Smart Card to be fully protected under the EU’s General Data Protection Regulation (GDPR);

125. Considers that insurers and banks should not take into account the medical history of people who have been affected by cancer; calls for national legislation to ensure that cancer survivors are not discriminated against compared to other consumers; notes the Commission’s intention to engage with businesses to develop a code of conduct to ensure that developments in cancer treatments and their improved effectiveness are reflected in the business practices of financial service providers; supports, in parallel, the promotion of advances made in France, Belgium, Luxembourg and the Netherlands, where cancer survivors enjoy the ‘right to be forgotten’; requests that by 2025, at the latest, all Member States should guarantee the right to be forgotten to all European patients 10 years after the end of their treatment, and up to five years after the end of treatment for patients whose diagnosis was made before the age of 18; calls for the introduction of common standards for the right to be forgotten under the relevant provisions on consumer protection policy of the Treaty on the Functioning of the European Union, in order to remedy the fragmented national practices in the area of creditworthiness assessment and ensure equal access to credit for cancer survivors; calls for embedding the

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right to be forgotten for cancer survivors into relevant EU legislation to prevent discrimination and improve cancer survivors’ access to financial services;

126. Calls on the Commission to promote the European Code of Cancer Care Practice launched by the European Cancer Organisation, which is an empowering and informative tool to ensure that the best available care is provided to European patients;

127. Sees an urgent need for a European charter of the rights of cancer patients; calls for this charter to take the cancer care pathway (i.e. access to prevention, initial diagnosis and throughout their treatment) into account at every stage and for it to apply equally to all EU citizens, regardless of the country or region in which they live;

V. Challenges in cancer among children, adolescents and young adults

128. Welcomes the childhood cancer spotlight initiatives announced by the Commission; calls for clear policy requirements on paediatric cancer research needs; calls on the Member States and the Commission to redress the unequal allocation of investment to paediatric cancers; considers that a clear and specific EU funding stream should be dedicated to paediatric cancer research and treatment and that budget allocations should be earmarked across all relevant EU programmes; highlights the importance of supporting international academic research platforms focusing on paediatric cancers, informed by research performed by other relevant actors;

129. Notes that the current bureaucratic workload of trial activation in Europe is too burdensome for many rare diseases including childhood cancers because investigator-led trials suffer from a lack of commercial sponsorship and many non-commercial organisations are still unwilling to undertake the role of sponsor at a pan-European level for multinational trials in children; calls on the Commission to review the existing legislation, in this regard, and to facilitate multinational trials for children;

130. Calls for the promotion of bone marrow donation in the Member States so that the lives of thousands of people diagnosed with leukaemia can be saved, a number that is constantly increasing and which includes many children, since it is the most common childhood cancer; highlights that bone marrow transplantation is the only hope for many people affected by leukaemia and other blood diseases, and that three out of four patients will not have a compatible family member, so they will need a donor;

131. Calls on the Commission and the Member States to focus on ensuring equal and geographically balanced access to the best specialist diagnostics and multidisciplinary treatments for children with cancer and to improve cancer treatment outcomes in all Member States; considers that the academic specialty and the professional figure of the paediatric oncologist should be recognised in all Member States; believes that every patient who has experienced cancer as a child or adolescent should receive ongoing medical care and monitoring even after reaching adulthood, and therefore calls for measures to make cooperation between paediatric and adult health professionals more flexible; encourages the exchange of knowledge on the course of cancers among children and adolescents;

132. Stresses the need for comprehensive population-based childhood cancer registries based on internationally agreed childhood cancer classification systems, to ensure high-quality comparable data across Europe; reiterates the need for publishing, on at least an annual basis, the number of cancer cases in children and adolescents in the Union and in each Member State;
133. Calls for adolescents and young adults (AYAs) with cancer to be recognised at EU level as a particular group with specific medical and psychosocial needs, and for the creation of school programmes dedicated to them;

134. Underlines the need to effectively address mental health issues in children and AYA cancer patients and survivors; calls on the Commission and the Member States to ensure equal access to and availability of appropriate psychosocial support measures for this group of patients;

135. Stresses the need to strengthen the right to cross-border care for children and AYA cancer patients when the best treatment is not available in their country of residence, and ensure that access to innovation via clinical trials for relapsed or difficult-to-treat malignancies is covered by the relevant legislation, by enhancing the sustainability of existing cross-border collaborations including the European Reference Networks (ERNs), in particular the ERN on paediatric cancer; emphasises the need for clarification regarding access to cross-border clinical trials, which is not clearly specified in the Cross-Border Healthcare Directive;

136. Notes that both regulations on paediatric and orphan medicinal products have fostered the development and availability of medicines for patients with rare diseases and for children, and have redirected private and public investments towards previously neglected areas; calls for an ambitious revision of the regulations on paediatric and orphan medicinal products in order to ensure the development of and affordable access to innovative cancer drugs, identify the most important drugs to meet the needs of children with poor prognostic cancers, support academic research and SME involvement, reduce delays so that children can have faster access to paediatric drugs and gene and cell therapies, stimulate competition by adapting the regulatory framework and encouraging investments in off-patent orphan and paediatric medicines, and address limited access to certain essential medicines due to drug shortages and the high price of innovative medicines; recommends an increase of 20% in the available new paediatric cancer drugs by 2027, as well as an increase in the accessibility of personalised medicine; considers, consequently, that a clear obligation to include paediatric research should be considered as a condition for an application for funding; calls on the Commission, where appropriate, in dialogue with the Member States, to work on a system that favours access to real breakthrough innovations for paediatric cancer patients; calls on the Commission to facilitate the repurposing of medicines that fail in adults when there is scientific and preclinical rationale, and to provide more effective and tailored incentives to foster the development of medicines for cancer in children and the First-in-Child development of new paediatric anticancer medicines; calls on the Commission to encourage timely paediatric medicine development and reduce delays, such as by means of early proportionate rewards allocated incrementally and not exclusively at the end of the supplementary protection certificate; calls on the Commission to remove Article 11(b) of the Paediatric Regulation in the upcoming review to allow paediatric cancer medicine development to be driven by science and the medicine’s mechanism of action;

137. Calls for the creation of an EU-level advisory group of stakeholders dedicated to childhood and AYA cancers, which would support the goal-driven and coherent implementation of relevant actions across the Plan, Horizon Europe, the Pharmaceutical Strategy for Europe and EU4Health Programme;


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on work-life balance for parents and carers\textsuperscript{78}, which introduces leave for carers and the possibility to request flexible working time arrangements so that workers have the right to carers’ leave of five working days per year in order to provide personal care or support to a relative or to a person who lives in the same household as the worker and who is in need of significant care or support for a serious medical reason, as defined by each Member State;

139. Welcomes the creation of an EU Network of Youth Cancer Survivors announced by the Commission;

140. Supports the recommendation of the JARC for the roll-out of a European unique patient identifier, the Survivorship Passport, and guidelines on long-term surveillance and the transition from paediatric to adult care, in order to ensure the monitoring of long-term outcomes in childhood cancer survivors in a cross-border setting; stresses the need for the right to be forgotten’ to be fit for purpose for this population;

\textit{VI. Challenges of rare adult cancers}

141. Acknowledges that rare adult cancers are a public health challenge; recalls that patients affected by rare adult cancers share the challenges linked to the rarity and uncommon nature of their disease, including long delays to diagnosis, and sometimes misdiagnosis, and difficulty accessing timely and adequate care and treatments; notes that patients often feel alone and isolated and suffer from a greatly reduced quality of life, and that their carers are also significantly and negatively impacted; calls for the Cancer Inequalities Registry to integrate information on rare cancers, which amount to about 24 \% of new cancer cases occurring in all age groups;

142. Supports the introduction of a dedicated flagship initiative on rare adult cancers within the Plan to tackle the specific challenges faced by this patient community and make the best use of the recommendations set out in the Rare Cancer Agenda 2030 to foster research and improve care in each step of the rare cancer patient journey; stresses the importance of ensuring that rare adult cancers are included in all initiatives across the four pillars of the Plan;

143. Calls for dedicated funding for rare adult cancer research projects under Horizon Europe, including under the Mission on Cancer (for instance, under UNCAN.eu – the European Initiative to Understand Cancer), to develop targeted therapies and support the development of databases, registries and biobanks relevant to rare adult cancers;

144. Stresses the difficulty of diagnosing rare adult cancers in a more timely way; recommends, therefore, easier and quicker access to molecular testing that can help patients receive an accurate diagnosis and targeted therapy, and even access to relevant clinical trials where appropriate; stresses, moreover, that research on biomarkers is critical in this area;

145. Calls for increasing awareness as regards rare adult cancers among primary and secondary healthcare professionals and implementing adequate referrals to specialised multidisciplinary expert centres at both national and European level;

146. Encourages the Member States to establish national networks for rare adult cancers to optimise the referral of patients to specialised centres in a timely fashion and facilitate interactions with

\textsuperscript{78}\textsuperscript{78} OJ L 188, 12.7.2019, p. 79.
ERNs to maximise the exchange of multidisciplinary knowledge and high-quality care, as well as to foster clinical research;

147. Calls for improving access to clinical trials and compassionate use programmes for rare adult cancer patients; regrets that it continues to be very difficult for rare adult cancer patients from many countries to access compassionate use programmes and trials abroad; calls for a better implementation of EU schemes for rare adult cancer patients to access healthcare abroad, and considers that national healthcare systems should facilitate access to trials and compassionate use programmes for patients with rare adult cancers who have few treatment options;

148. Encourages novel regulatory approaches to enable rare adult cancer patients to access new innovative therapies under safe monitoring, while facilitating the collection of real-world data in addition to data collected in clinical trials;

149. Emphasises the need to include rare adult cancers in the ‘inter-specialty cancer training programme’ that also includes specialised nursing training, in conjunction with ERNs for rare adult cancers; emphasises the need to support educational programmes targeting rare adult cancer patients, carers and patient representatives in conjunction with ERNs to increase the level of health literacy and ultimately help patients and their families to make informed choices about treatment options and follow-up care;

150. Acknowledges the specificities of rare adult cancers in programmes dedicated to improving the quality of life of cancer patients, survivors and carers; calls on the Commission and the Member States to implement specific training for professionals other than healthcare providers (e.g. social workers, case managers, etc.), who are taking care of rare adult cancer patients; stresses that rare adult cancer patients need to receive adequate psychological support, rehabilitation and monitoring of long-term side effects of treatments by professionals who understand their rare disease and its specificities; recommends that all patients with rare adult cancers also be provided with a survivorship care plan; considers that carers for rare adult cancer patients (often family members) also need access to specific psychosocial support to cope with the severity and complexity of the disease, and the significant burden of care that they take on;

151. Calls on the Member States to include a specific section on the management of rare adult cancers in their NCCPs (along with a dedicated section on cancers in children) as recommended in the Rare Cancer Agenda 2030; considers that these specificities should be acknowledged in dedicated sections in all NCCPs, including relevant synergies with rare disease national plans, to foster research and improve care management and care pathways for these patients, from primary care up to highly specialised multidisciplinary healthcare centres that are a part of or in close contact with the relevant ERNs; notes that, to date, many of the Member States’ NCCPs do not sufficiently include rare cancers in adults and paediatric cancers;

152. Urges relevant national authorities to involve rare adult cancer patient organisations as partners in NCCPs to voice the needs and expectations of rare adult cancer patients, and to actively participate in the implementation of dedicated measures for rare adult cancers;

B. Tools for action

I. Holistic research and its implications
153. Stresses that the Plan should be implemented in close cooperation with the Mission on Cancer under Horizon Europe and its objectives of promoting EU investment in cancer research, public production and innovation; welcomes the fact that Horizon Europe will fund research infrastructures, cloud computing and European Innovation Council actions; calls on the Commission to consider paediatric cancer as a topic for a European partnership under Horizon Europe’s next strategic programme; recommends that appropriate funding be given to projects under Horizon Europe dedicated to new paediatric cancer medicines in order to fill the existing gap in paediatric medicines;

154. Recalls that multidisciplinary cancer research, and its translation into everyday clinical practice, is fundamental to ensuring continuous improvements in cancer prevention, diagnosis, treatment and follow-up care for survivors; welcomes, therefore, the launch of Horizon Europe partnerships to translate scientific knowledge into innovations that reach patients; asks the Commission to closely follow the activity of the Horizon Europe partnerships and the translation of research into real added value for current medical practice;

155. Welcomes the Commission’s communication on a new European Research Area for Research and Innovation, which sets out the strategic objectives and actions to be implemented in close cooperation with the Member States; supports the target of investing 3% of EU GDP in research and development which will help to promote research excellence across the EU and enable research results to reach the scientific community, society and the real economy; deplores the significant inequalities in research funding across the EU; calls on the Member States to adopt a pact on research and innovation in Europe that includes the commitment to increase public spending on research and innovation to 1.25% of the GDP by 2030 in a coordinated manner across the EU;

156. Calls on the Member States to promote and ensure attractive scientific careers for researchers in Europe, with a particular focus on women; calls on the Member States to establish a well-structured scientific workforce and infrastructure, and to ensure continuous funding for their research centres; welcomes that the proposed innovative health initiative will help create an EU-wide research and innovation ecosystem, promoting cooperation between the health industry, academia and other stakeholders to translate scientific knowledge into innovations that address prevention, diagnosis, treatment and management of diseases, including cancer;

157. Reiterates its call for sustainable and adequate funding for competitive European research on cancer; stresses that such research should aim to address areas of highly unmet needs and should be conducted across all parts of the cancer care continuum, including for all treatment modalities; calls on the Member States to increase by at least 20% the mobilisation of public research on therapeutic, diagnostic and screening cancer innovations, covering all patient populations concerned; calls, furthermore, for Horizon Europe and national research programmes to support research into paediatric and orphan medicines through innovation prize funds; considers that the conditions for access to public funding should be revised, ensuring transparency of the contracts stipulated between public and private entities as well as conditionalities as regards the accessibility and affordability of new innovations when projects are successful;

158. Supports the recommendation by the Conquering Cancer Mission Board to establish a research programme tasked with identifying effective cancer prevention strategies and methods with regard to commercial determinants of health and exposure to occupational carcinogens; supports the recommendation for the creation of a Policy Support Facility to

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enhance knowledge-sharing and support the implementation of cancer-related prevention policies at EU, national and local level;

159. Calls on the Member States and the Commission to establish programmes to provide the necessary support for the recently consolidated European cell-based interceptive medicine community that will create and integrate breakthrough cellular and artificial intelligence technologies to understand early events in cancer and therapy response, and use this knowledge to improve patient outcomes; supports the creation of a platform for cell-based interceptive medicine to coordinate and establish synergies between research, innovation and multi-sectoral activities; stresses the need for investment in research and innovation approaches to create innovative cell-based early detection and personalised treatment strategies for cancer;

160. Stresses the need for independent and multidisciplinary research on cancer ‘from bench to bedside’, that is from the laboratory to applied studies in patients, and also for the regular re-evaluation of the effectiveness of medicines already on the market; stresses the need for the results of this research to be made public in a transparent and simple way; calls for the establishment of measures to limit the health risks posed by disinformation and misinformation, especially on social media, with special attention to measures protecting children and young people; calls for support for science dissemination initiatives;

161. Stresses the importance of investing in the development of non-animal new research methodologies, such as in silico and organoids, in order to shorten preclinical observation periods, increase efficiency in research, and reduce unnecessary and often less reliable experiments on animals; underlines that non-animal methods for testing the carcinogenicity of environmental chemicals, such as testing strategies focused on the underlying biological mechanisms that lead to cancer, should provide more relevant information than the animal-based methods currently in use for chemical safety assessment, thus enabling authorities to take swifter measures to limit exposure to harmful chemicals that could lead to cancer;

162. Calls on the Member States to make a strong commitment to encouraging public-private cooperation, driven by public health needs, and breaking down the barriers to competitiveness across the EU;

163. Considers the significant potential impact of the use of artificial intelligence, ‘big data’ algorithmic analysis and other modern technologies in diagnosis and decision-making for cancers in the coming years; underlines that the combination of real-world data, mathematical modelling, artificial intelligence and digital tools will significantly help to develop innovative treatments in a more cost-efficient way, and potentially reduce the number of patients required for clinical trials and the use of animals in research; encourages the Commission and the Member States to promote the knowledge of cancer biology through the implementation of genomics and informatics infrastructures; urges all implementation partners to be ever mindful of the principles of data privacy and security, trust, transparency, patient centricity and patient involvement at all times;

164. Highlights the crucial importance of clinical research and calls on the Member States to facilitate the conciliation of patient care with research and innovation initiatives, especially in smaller centres, reducing the workload and the ratio of patients per health professional;

165. Calls for research into the potential positive impact of artificial intelligence and modern technologies in cancer diagnosis, monitoring, decision-making and care; welcomes the launch of the Genomics for Public Health project which will give secure access to large amounts of
genomic data to be used in P4 medicine (preventive, predictive, personalised and participatory);

166. Supports the creation of new digital resources and platforms, such as the European Cancer Imaging Initiative, and the strengthening of the European Cancer Information System, which will enable competent authorities to make good use of artificial intelligence applied to big data in the years to come; stresses the need for equal and transparent access to the information included in these platforms;

167. Welcomes the launch of the ‘Cancer Diagnostic and Treatment for All’ flagship initiative under the Plan, which aims to improve access to innovative cancer diagnosis and treatment and promote the use of the ‘next generation sequencing’ technology for quick and efficient genetic profiles of tumour cells, allowing researchers and clinicians to share cancer profiles and apply the same or similar diagnostic and therapeutic approaches to patients with comparable cancer profiles; stresses the need to consider personalised treatments based on well-designed clinical trials with proven added therapeutic value for patients;

168. Welcomes the planned Partnership for Personalised Medicine, announced in the Plan and to be funded under Horizon Europe, which will identify priorities for research and education in personalised medicine, support research projects on cancer prevention, diagnosis and treatment, and make recommendations for the roll-out of personalised medicine approaches in daily medical practice; stresses the need to establish a well-defined, globally consistent terminology for personalised medicines that would streamline investment in research and benefit the health literacy of patients; supports the establishment of a roadmap for personalised prevention allowing for the identification of gaps in research and innovation and for the mapping of all known biological anomalies leading to cancer susceptibility, including hereditary and environmental factors and paediatric issues; calls these solutions to potentially be made accessible through public healthcare systems;

169. Calls for enhanced capacity-building, infrastructure, collaboration and funding of research on non-profit clinical trials to improve treatment strategies, with a focus on the elderly as well as on vulnerable and underrepresented patient populations, including women and children; calls for EU support for the health system and treatment optimisation agenda;

170. Calls on the Commission and the Member States to promote studies dedicated to human and social sciences, in particular those addressing health inequalities at the different stages of cancer diseases, as well as research on optimising the organisation of cancer treatment, the financing of healthcare services and providers, the organisation of the delivery of healthcare services, and the functioning of management institutions; calls for the studies to include inequalities in cancer care that are related to factors such as gender, age and socioeconomic status, with a particular focus on marginalised and vulnerable groups in society;

171. Calls on the Commission and the Member States to support the development of European multicentre clinical trials, in particular in the case of low-incidence cancers and/or cancers with reduced treatment options, and to strengthen multinational cooperation and the conduct of cross-border clinical trials, building on existing structures where appropriate, such as the European Clinical Research Council in the paediatric cancer sector, and to encourage the engagement of smaller countries; highlights, furthermore, the need for all EU cancer policy initiatives to be coordinated towards defined and shared aims;

172. Supports clinical research to evaluate the feasibility, efficacy and cost-effectiveness of non-treatment-related interventions, such as studies on health determinants (including environmental factors) and quality of life;
173. Strongly believes that patients and independent patient associations, as well as parents and carers, should be involved in defining research priorities and endpoints for clinical trials, in order to ensure that the trials address the unmet needs of European patients, including quality of life as the primary endpoint; considers that the final results of the trials should be communicated to the participating patients and to the public; calls for paediatric patients to be involved in the definition of unmet needs to provide input into the design of the clinical trials protocol, improve communication with the target population and enhance methods for the dissemination of findings; stresses that the extent to which transparency provisions within the Clinical Trials Regulation are being met should be kept under surveillance and regularly reported on;

174. Advocates more robust scrutiny of clinical trials and more transparency in the process of research into and the development of cancer treatments, including the establishment of a portal to allow patients access to information on the available clinical trials in Europe; calls for transparency on the access to, and use of, data from clinical trials at EU level, including those that have been abandoned; underlines that this should also include information tailored to children and young patients;

175. Recommends that research be a parameter of the Cancer Inequalities Registry in order to measure and monitor inequalities with respect to access to clinical trials as well as to better understand and respond to regional and national disparities in trial activity, and to track improvement from initiatives to be taken up via the Plan, such as the EU Network of Comprehensive Cancer Centres;

176. Highlights that gender-associated differences in cancer research should be taken into consideration, both at preclinical and clinical stages, to describe differences in the physiopathology of the disease and related comorbidities, and in drug pharmacokinetics/pharmacodynamics, among others;

177. Applauds the 2021 Porto Declaration on Cancer Research that highlights opportunities for a comprehensive translational cancer research approach with the potential to achieve a ten-year cancer-specific survival for 75% of patients diagnosed in 2030 in Member States with well-developed healthcare systems; urges the Commission to be actively involved and play a leading role in achieving this goal;

178. Welcomes the fact that the Marie Sklodowska-Curie Actions will continue educating and training researchers in cancer prevention, prediction, detection, diagnosis and treatments;

II. Shared knowledge

179. Considers that the sharing of expertise, data, training programmes and communication tools is needed to improve the knowledge of cancer among health professionals, researchers and patients; highlights that cross-sector and cross-border collaboration and knowledge-sharing is crucial for further enhancing the quality of cancer care in the EU; notes that data-sharing is key to applying artificial intelligence and machine learning tools to research provided that there is human oversight, as well as to enable the digital transformation of healthcare, to tackle disparities in cancer prevention, diagnosis, and treatment around Europe and to optimise the use of healthcare systems resources by increasing efficiency and thus allowing for wider availability of oncological care data, including in less urbanised and more remote areas; stresses the sensitive nature of health data; calls for full compliance with Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection
Regulation\(^{80}\) to avoid unnecessary restrictions on cross-border healthcare; stresses the need for a harmonised interpretation and implementation of the GDPR, especially by data protection authorities, including its Recitals 33 and 157, and its interaction with the Clinical Trials Regulation, once applicable, including Recital 29 and Article 28 (2) of that regulation, across the EU to facilitate scientific research; requests the European Data Protection Board to ensure that its guidelines concerning health research are updated with the aim of fostering research, and calls on the Commission to make concrete proposals by the end of 2022;

180. Asks the Commission to assess the functioning of the ERNs, especially their role in gathering and sharing expertise and best practices, thus rationalising patient referral in the management of rare cancers, which affect an estimated 5.1 million patients across Europe and require cooperation on a large scale; emphasises the importance of the ERNs with regard to overcoming health inequalities and ensuring safer and high-quality treatment across EU borders;

181. Calls on the Commission and the Member States to secure appropriate and sustained long-term funding for the ERNs, and to integrate them into national health systems; calls for the funding to cover, inter alia, compensation of virtual consultations, support for twinning and education programmes, and effective reimbursement of patient travel in line with the Cross-Border Healthcare Directive when this is required, in order to foster improved standards of care and equal access to the best possible interventions to all patients who require them across Europe; calls also for support for the roll-out, upgrade and smooth functioning of digital infrastructure that simplifies and facilitates access to the ERNs, as well as for the creation of an EU health data strategy to improve current rare disease registries in a common and uniform data space; stresses the need to guarantee funding for the continued functioning of the ERNs through the EU4Health Programme, Horizon Europe, the European Semester programme, structural funds, and through Article 195 of the Financial Regulation; supports the expansion of the four existing ERNs (PaedCan on paediatric cancers, EURACAN on rare adult solid cancer, EuroBloodNet on rare haematological diseases including rare haematological malignancies and GENTURIS on genetic tumour risk syndromes) to include rare, complex, poorly curable cancers and paediatric cancers, as this could facilitate equal access for patients, including children and AYA, to the best available care across Europe and would improve the functionality of the ERNs and health outcomes in rare disease patient populations;

182. Believes that the further development and optimisation of the ERNs will require the participation of all Member States in existing ERNs, with each Member State having at least one ‘full’ or ‘affiliate’ member in each ERN and in each sub-clinical domain/thematic network of ERNs, the facilitation of the individual patient journey through the effective collaboration of national contact points with ERNs, the evaluation of the functioning of the ERNs by sharing data on their performance and networking in the field of rare cancers, the deployment of efficient telemedicine tools allowing for the sharing of case records and imaging results in a secured fashion to discuss complex rare cancer cases, and the allocation of adequate and long-term funding, both at Union (EU4Health) and national level;

183. Calls on the Member States to give due consideration to the importance of non-governmental local, regional and national organisations in uniting cancer patients, survivors and their relatives, in terms of their participation in the knowledge-sharing process, in the fight against cancer, in terms of legislative support, and in terms of the provision of separate funding for these organisations, especially those involved in programmes to combat cancer;

184. Encourages Member States to support a dedicated and tailored approach to rare cancers in adults and paediatric cancers, taking stock of EU initiatives, and to fully integrate ERNs into their national healthcare systems; calls for the creation of common and consistent protocols governing the collection of data, and for the creation of a single set of definitions explaining the data collected; calls for rare cancer patient organisations to be associated with the ERNs and the European reference centre;

185. Recalls that the Joint Research Centre has taken an active role in supporting the activities and harnessing the data of cancer registries; considers that the mandate, funding and political support for the Joint Research Centre to continue and accelerate its coordinating work with cancer registries should be strengthened, particularly in terms of the collection of patient outcomes and real-world evidence and the identification of cancer clusters, and their integration in existing cancer registries;

186. Welcomes the development of a European research infrastructure entirely dedicated to paediatric research, including oncology, that will facilitate basic, preclinical and transnational paediatric research that underpins the availability of clinical trials and medicines for children;

187. Welcomes the launch of the Knowledge Centre on Cancer in 2021 in order to contribute to the exchanges and coordination of scientific and technical initiatives related to cancer at EU level; considers that the knowledge centre should involve all stakeholders (representatives of each NCCP, patients’ and caregivers’ associations, learned societies, relevant EU bodies and agencies, representatives of economic operators, etc.); believes that this knowledge centre should be based on data screening, ERN reports and cancer registries; considers that its mission should be clearly defined and include:

(a) coordinating the network of all NCCPs;

(b) producing a European roadmap to trigger large-scale prevention campaigns and educational programmes on health promotion;

(c) coordinating the establishment of common quality criteria to guide the national accreditation of screening programmes, cancer registries and cancer care centres;

(d) developing, on the basis of the latest scientific evidence, clinical practice guidelines and quality assurance schemes to improve the entire care pathway for all cancer types, and in particular for rare and paediatric cancers;

(e) drafting annual reports and establishing frameworks to improve data collection from screening programmes, cancer registries and ERNs at EU level;

(f) presenting studies on the impact of prevention and diagnosis, including estimates concerning the reduction of economic costs generated through increased investment in prevention and diagnosis;

(g) coordinating the exchange of best practices and results between the ERNs and the Comprehensive Cancer Centres;

(h) generating a comprehensive model based on the Plan and Horizon Europe, and with input from patients and carers, in order to identify research priorities and possibly enable the development of a coordinated and efficient cancer research force in Europe;
(i) facilitating the sharing of anonymised data, collected in a European Cancer Cloud, for clinicians and researchers, as well as for entities developing health services and modern technological solutions for cancer patients;

(j) supporting common training programmes for health professionals, patients and caregivers;

(k) delivering updated, certified and transparent information to citizens and professionals on cancer causes, treatments and EU legislation;

(l) monitoring the level of implementation of relevant recommendations in the Member States’ NCCPs, and regularly making available the results of this monitoring;

(m) proposing measurable and reproducible indicators for the main outcomes outlined in the Plan;

188. Recalls that researchers have to work together to find the best possible treatment especially for patients suffering from rare cancer, but that they are facing serious obstacles; calls therefore for the Commission to systematically look, via its scientific advice mechanism or through the appointment of a Special Envoy on cross-border cancer research, at all the obstacles in cross-border cancer research and cooperation, including regulation, in order to promote cross-border cancer research;

189. Recommends the creation of at least one cancer registry in each EU region, including remote and outermost regions; considers it pivotal to ensure the smooth functioning of the cancer registries; supports the strengthening of the capacity of national cancer registries to collect standardised patient-reported outcomes, to better map the lifestyles of EU citizens, including socioeconomic conditions, occupational information, environmental factors, and other data, and to identify the causes of inequalities in cancer incidence, prevalence and survival; stresses the essential need to collect data collaboratively across all Member States; calls for the comparability of data sources and the interoperability of regional and national cancer registries via the harmonisation of the scope and quality of data collection, and for secure access to such data; calls for mandating national cancer registries to analyse disparities in morbidity and to make recommendations to national cancer councils and the Joint Research Centre on the need for interventions; calls for the use of modern epidemiological and molecular genetics methods to analyse the prevalence of cancer and to identify its causes; calls for the implementation of specific cancer registries for paediatric malignancies in line with the International Classification of Childhood Cancer; calls for improved access to clinical trials and compassionate use for rare adult cancer patients;

190. Strongly supports the creation of a Cancer Inequalities Registry at European level, as announced in the Plan, in order to identify trends, disparities, inequalities and inequities between and within Member States; believes that this registry will help to identify challenges and specific areas of action so as to guide investment and intervention, and facilitate research into inequalities, at EU, national and regional level; calls for the Registry to be made accessible to the public; stresses the need for the Registry to also cover social inequalities such as those related to socioeconomic status, occupation and gender;

191. Calls on the Commission to promote the publication of scientific results in open access, to make them easily available to all health professionals and researchers;

192. Supports the Commission’s intention to enable cancer patients to securely access and share electronic health records across borders; considers that the Commission could lay the
foundation for the European Health Data Space, in association with Digital Health Europe, by collecting, analysing and exchanging anonymised medical data (from cancer registries, hospitals, academic clinical trials and cohorts) and biological data (from blood and tumour samples) in a European Cancer Cloud; underlines that a harmonised interpretation of the GDPR in all Member States is the foundation for new data-sharing initiatives such as the European Health Data Space; encourages the use of health data for research purposes (data altruism); welcomes the planned creation of a virtual European Cancer Patient Digital Centre under Horizon Europe’s Mission on Cancer in order to support a standardised approach to the participation of willing patients in the deposit and exchange of their standardised and uniformly defined health data; recommends the inclusion of patients in any actions related to the storage and use of health data for policy-making and research purposes; welcomes the planned expansion of the European Cancer Information System before 2022;

193. Calls for improved standards in the education and training of health professionals; encourages common and multidisciplinary training programmes for health professionals in close collaboration with European learned societies; welcomes the launch of an inter-specialty cancer training programme at every stage of the treatment and care pathway, including diagnosis, treatment, complications and comorbidities, survivorship and end-of-life care;

III. Financing Europe’s Beating Cancer Plan

194. Emphasises that the Plan should not only be seen as a political commitment to driving change but as a set of concrete and ambitious initiatives that will support, coordinate and complement Member States’ efforts to reduce the physical and mental suffering caused by cancer; encourages the Commission to optimise the coherent implementation of the initiatives outlined in the Plan, with clear guidance for Member States regarding concrete actions against unequal access to cancer diagnosis and treatment, as well as adequate funding, especially in order to address unequal access; underlines, however, the differing capacity of Member States to absorb the funds dedicated to healthcare programmes thus far; calls on the Commission to provide Member States with guidance and a clear overview of the dedicated EU resources, the specifically defined pathways that link the actions outlined in the Plan with the EU funding mechanisms identified in it, and the possible synergies and complementarities between the EU4Health Programme and others – such as Digital Europe, Horizon Europe, NextGenerationEU/Recovery and Resilience Facility, structural and cohesion funds – in order to enhance equitable access to quality diagnosis and care, ensure adequate investment in cancer prevention and innovation, and improve the resilience of health systems; emphasises the importance of cohesion funds in achieving equality of access to healthcare, in particular in less developed parts of the EU, including rural regions, by investing in health infrastructure and workforce;

195. Calls on the Member States to ensure that sufficient funds are allocated for the appropriate implementation of the Plan and of their respective NCCPs; considers that no more than 30 % of the Plan should be allocated to the implementation of the NCCPs;

196. Welcomes the funding plan of EUR 4 billion and notes the complementarity of the sources of funding as set out in the Plan itself; notes that the proposed budget should be seen as a first step towards the realisation of all actions under the Plan; recalls that the Plan will benefit from different sources of funding, such as the EU4Health, Horizon Europe and Digital Europe programmes, cohesion policy funds, and the Recovery and Resilience Facility; highlights the need to include the fight against cancer across all funding sources in a coherent and transparent manner; stresses, in particular, the importance of enhancing cancer research, innovation and prevention and the need to dedicate more funds to them; stresses the need for regular revision of the proposed budget allocation for the Plan, with a view to potentially
increasing it when possible; stresses the need for the mobilisation of these funds by the Member States so that they are in line with the needs identified by each country, and are geared towards benefiting public interest and public health services;

197. Instructs its President to forward this resolution to the Council, the Commission, the European Economic and Social Committee, the European Committee of the Regions, the governments and parliaments of the Member States, and the World Health Organization.
II. Mandate of the Special Committee on Beating Cancer (BECA)
SETTING UP A SPECIAL COMMITTEE ON BEATING CANCER AND DEFINING ITS RESPONSIBILITIES, NUMERICAL STRENGTH AND TERM OF OFFICE

1. Committee mandate

European Parliament

2019-2024

TEXTS ADOPTED

P9_TA(2020)0160

Setting up a special committee on beating cancer, and defining its responsibilities, numerical strength and term of office

European Parliament decision of 18 June 2020 on setting up a special committee on beating cancer, and defining its responsibilities, numerical strength and term of office (2020/2682(RSO))

The European Parliament,

– having regard to the proposal from the Conference of Presidents,
– having regard to the Commission communication of 11 December 2019 on ‘The European Green Deal’ (COM(2019)0640),
– having regard to its resolution of 15 January 2020 on the European Green Deal\(^\text{81}\),
– having regard to EU funding for Research and Innovation 2021-2027 (Horizon Europe),
– having regard to the dedicated Horizon Europe mission on cancer;
– having regard to the Council recommendation 2003/878/EC of 2 December 2003 on cancer screening\(^\text{82}\).

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\(^{81}\) Texts adopted, P9_TA(2020)0005.

\(^{82}\) OJ L 327, 16.12.2003, p. 34.
having regard to the Council conclusions of 22 May 2008 on reducing the burden of cancer,

having regard to the report of May 2017 on the implementation of the Council Recommendation on cancer screening,

having regard to the European guidelines on screening for breast cancer, cervical cancer and bowel cancer,

having regard to the United Nations Sustainable Development Goals,

having regard to its resolution of 10 April 2008 on combating cancer in the enlarged European Union\(^{83}\),

having regard to its resolution of 6 May 2010 on the Commission communication on Action Against Cancer: European Partnership\(^{84}\),

having regard to the European Code Against Cancer (fourth edition),

having regard to the activity and the conclusions of the all-party interest group MEPs Against Cancer (MAC),

having regard to Rule 207 of its Rules of Procedure

A. whereas European cooperation in prevention, diagnosis, treatment, research and other areas clearly benefits the fight against cancer;

B. whereas the Treaty on the Functioning of the European Union (TFEU) provides a number of legal bases for EU action on health, including Article 114, whereby the highest level of protection concerning health, safety, environmental protection and consumer protection, in the internal market should be ensured, in particular taking account of any new development on the basis of scientific facts, Article 168, whereby a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities, and Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health, Article 181, which requires the EU and the Member States to coordinate their research and technological development activities so as to ensure that national policies and Union policy are mutually consistent and supports initiatives aiming at the establishment of guidelines and indicators, and the exchange of best practice, and Article 191, whereby Union policy on the environment shall contribute to protecting human health on the basis of the precautionary principle, without prejudice to the Member States’ competence in the field of health;

C. whereas cancer is the second leading cause of mortality in the Member States after cardiovascular diseases; whereas in 2015, 1.3 million people died from cancer in the EU-28, which equated to more than one quarter (25.4 %) of the total number of deaths; whereas cancer affects people differently according to age, gender, socio-economic status, genetics and other

\(^{83}\) OJ C 247E, 15.10.2009, p. 11.

\(^{84}\) OJ C 81E, 15.3.2011, p. 95.
factors; whereas demographic changes will increase the incidence of cancer in the coming decades;

D. whereas cancer does not only affect the individual patient, but also the patient’s loved ones, their families, friends, communities and care-givers; whereas the challenges, psycho-social needs and demands of these groups, in particular the impact on mental health, also require attention;

E. whereas the World Health Organization (WHO) identifies a number of key preventable risk factors, namely tobacco, physical inactivity, unhealthy diet and obesity, alcohol use, HPV and hepatitis B and C and Helicobacter pylori (H. pylori) infections, environmental pollution, including chemical exposure and air pollution, occupational carcinogens and radiation; whereas, according to the WHO, 30-50% of all cancer cases are preventable; whereas prevention offers the most cost-effective long-term strategy for the control of cancer; whereas the prevention of virus-related cancers may rely on vaccination; whereas cancer prevention programmes should be conducted within the context of an integrated chronic disease prevention programme since most individual determinants are risk factors common to other chronic diseases; whereas the fight against environmental pollution will be part of the zero-pollution ambition as proposed in the political agenda of the Commission;

F. whereas genetic predisposition to cancer due to mutations of specific genes has been demonstrated; whereas the detection of these mutations is available and personalised screening offers an efficient way to reduce the risk of certain cancers;

G. whereas cancer-screening programmes can, if implemented in the right manner, render huge benefits and play their part in the wider context of cancer control;

H. whereas Member States are struggling with cancer prevention and treatment as the economic impact of cancer is significant and on the increase;

I. whereas public funded research represents a key source of scientific advances; whereas a robust world-leading life-science industry is also important to ensure private research and development, which is crucial in the fight against cancer but it is essential that policy-makers set the right framework so that innovation will benefit all patients and protect the population at large; whereas the public and private sector should collaborate on this;

J. whereas cancer remains one of the main challenges European citizens will face in the future as it is predicted that more than 100 million Europeans will be diagnosed with cancer over the next 25 years; whereas it is of utmost importance for both national and European policymakers to act towards the implementation of stronger cancer control and contributing to the well-being of all Europeans;

K. whereas there are considerable inequalities between and within Member States with regard to cancer prevention, screening treatment facilities, implementation of evidence-based best-practice guidelines, and rehabilitation;

L. whereas prices of medicines can be unaffordable for some individuals and healthcare systems, with cancer medicines often particularly expensive; whereas a study has found that from 2010 to 2020, total cancer expenditure is estimated to have increased by 26%, while spending on
1. Decides to set up a special committee on beating cancer, vested with the following responsibilities:

(a) looking at actions to strengthen the approach at every key stage of the disease: prevention, diagnosis, treatment, life as a cancer survivor and palliative care, ensuring a close link with the research mission on cancer in the future Horizon Europe programme and with a focus on EU competence;

(b) listening to the current evidence and data available and react by identifying policies and priorities that meet patients’ needs;

(c) evaluating the possibilities where, in accordance with the TFEU, the EU can take concrete steps to fight cancer and where only recommendations to the Member States and exchange of best practices are possible and focus on the concrete actions;

(d) evaluating scientific knowledge on the best possible prevention of cancer and identifying specific actions, including the strict implementation of current legislation and the identification of future measures in the fields of tobacco control, measures to reduce obesity and improve nutritional choices, measures to reduce alcohol use, measures to increase vaccination and treatment for infections, measures to reduce chemical exposure including cumulative impacts, air pollution as mentioned in the European Green Deal and exposure to carcinogens in the workplace, and measures to protect against radiation; evaluating where possible the quantifiable effects of such measures;

(e) analysing and assessing early detection of cancer in the form of screening programmes to ensure that future revisions of the recommendation are incorporated rapidly and efficiently;

(f) evaluating the best possible way of supporting research to strengthen prevention, diagnosis, treatment and innovation, especially with a view to achieving the new mission on cancer within Horizon Europe; focusing on areas where Member States alone cannot be successful enough, for example regarding childhood cancer or rare cancers;

(g) looking, in particular at ways to support non-profit clinical trials to improve the treatment in areas which the pharmaceutical industry is not investigating because there is limited profitability;

(h) assessing the current framework of the pharmaceutical legislation and evaluating if changes are needed to better incentivise genuine innovation and breakthrough treatments for patients, in particular to evaluate possibilities to improve cancer treatment in children and in order to harmonise in the EU the science-based evaluation of efficacy, added value and cost-benefit ratio of each cancer medicine including HPV vaccines and e-health applications;

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(i) evaluating the possibility of actions, including legislation, to guarantee the development of common standards to enhance the interoperability of health care systems including cancer registers and the necessary eHealth structures to address the different issues of specialised therapies, including avoiding unnecessary travel for patients;

(j) evaluating the implementation of the Cross-Border Healthcare Directive and, if necessary, propose improvements to allow patients to see those specialists best suited for their treatment without imposing an unnecessary burden;

(k) analysing and assessing the functioning of the European Reference Networks, including their role in gathering and sharing knowledge and best practices in the field of rare cancers prevention and control;

(l) evaluating the possibility of EU action to facilitate the transparency of treatment prices to improve the affordability and accessibility of cancer medicines, to avoid drug shortages, and to reduce inequalities between and within Member States;

(m) evaluating the possibility, in accordance with the TFEU, of improving patients’ rights, including their rights over their personal data (the right to be forgotten), and their right to non-discrimination – in order to continue their employment and return to work – to access preserved fertility and reproductive treatments, to lifelong surveillance and to optimal palliative care, and to avoid any psychological or financial discrimination due to genetic predisposition to cancers;

(n) evaluating the possibility of improving the quality of life for patients and their families;

(o) evaluating the possibilities of supporting research in palliative care and of triggering a more intensive exchange of best practice in hospice and palliative care;

(p) making any recommendations that it considers necessary with regard to the Union policy on combatting cancer in order to achieve a high level of protection of human health based on the patient oriented approach; to undertake visits and hold hearings to this end with the other EU institutions and relevant agencies, and with international and national institutions, non-governmental organisations and relevant industries, taking into consideration the perspective of a range of stakeholders including practitioners, patients and their loved ones; to recommend how specific EU funds should be mobilised to achieve those goals;

2. Stresses that any recommendation of the special committee shall be presented to and, if necessary, followed up by Parliament’s competent standing committee;

3. Decides that the powers, staff and available resources of Parliament’s standing committee with responsibility for matters concerning the adoption, monitoring and implementation of Union legislation relating to the area of responsibility of the special committee will not be affected or duplicated and thus remain unchanged;

4. Decides that, whenever the special committee work includes the hearing of evidence of a confidential nature, testimonies involving personal data, or exchanges of views or hearings with authorities and bodies on confidential information, including scientific studies or parts thereof granted confidentiality status under Article 63 of Regulation (EC) No 1107/2009 of the
European Parliament and of the Council 86, the meetings shall be held in camera; decides further that witnesses and experts shall have the right to make a statement or provide testimony in camera;

5. Decides that the list of people invited to public meetings, the list of those who attend them and the minutes of such meetings shall be made public;

6. Decides that confidential documents that have been received by the special committee shall be assessed in accordance with the procedure set out in Rule 221 of its Rules of Procedure, decides further that such information shall be used exclusively for the purposes of drawing up the final report of the special committee;

7. Decides that the special committee shall have 33 members;

8. Decides that the term of office of the special committee shall be 12 months, except where Parliament extends that period before its expiry, and that the term shall start running from the date of its constituent meeting.

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2. Letter to the President of the European Parliament, David Sassoli regarding the prolongation of the mandate and his approval hereof

Dear President,

On 18 June 2020, the European Parliament decided to set up the BECA Special Committee to focus on the huge challenge of cancer in Europe. The committee’s constitutive meeting took place on 23 September 2020 and since then BECA has held hearings with numerous experts, submitted a Working Document to the Commission, launched a public consultation on the issue of COVID19 and cancer and held two Exchanges of Views with the Commissioner for Health and Food Safety. This has all been carried out in the context of the current health crisis, which has naturally made committee meetings, hearings, discussions between Members and experts, and fact-finding missions either more burdensome or impossible to carry out. While the committee has done its utmost to put cancer patients at the heart of its work, it has unfortunately been impossible to invite patients physically to the Parliament and hear from them directly.

On 3 February 2021, the Commission presented Europe’s Beating Cancer Plan. The Cancer Plan is an ambitious and wide-ranging document that covers every stage of the disease and sets out ten flagship actions and numerous supporting actions, including legislative changes, new EU initiatives and mobilisation of EU funding. There are some elements that have been discussed for a long time, some elements that are new ideas and require further development, and some elements that Members may feel are missing and need to be addressed. The BECA committee wants to respond to this Cancer Plan in the best way possible and hold more discussions with the Commission and experts on these topics, which will sadly affect almost all Europeans directly or indirectly in their lifetimes.

Therefore, the BECA Coordinators decided on 5 February 2021, that considering the magnitude of work still ahead, and the challenges of the current working environment, an extension to the committee’s term of office should be requested. Pursuant to Article 207(2) of
Parliament’s Rules of Procedure, the term of office of a special committee may not exceed 12 months unless extended before its expiry.

Therefore, I would like to request a three-month extension of the BECA committee’s term of office. I will keep you informed on the progress of the work of the BECA committee and come back to you in case there are new elements influencing on our activities.

I would be grateful if this request could be added to the agenda at the forthcoming meeting of the Conference of Presidents for consideration and subsequent decision at plenary level.

Yours sincerely,

[Signature]

Bartosz ARLUKOWICZ

Cc: Antonio Tajani, Chair of the Conference of Committee Chairs
3. Prolongation of the BECA mandate: Announcement by the President in Plenary (09.03.2021)

The President informed the House that no objections had been raised to the requests by the Special Committee on Foreign Interference in all Democratic Processes in the European Union, including Disinformation and the Special Committee on Artificial Intelligence in a Digital Age for a six-month extension of their terms of office, or to the request by the Special Committee on Beating Cancer for a three-month extension of its term of office, announced in plenary the previous day, Monday 8 March 2021 (minutes of 8.3.2021, item 9).

The extensions were deemed to be approved.
III. Composition of the Committee
1. BECA Bureau

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## 2. BECA Coordinators

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3. BECA Rapporteur & Shadow Rapporteurs

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IV. Working Method
At their meeting of 12 October 2020, the coordinators of the Special Committee on Beating Cancer decided on the following working methods, to be divided into two key phases:

- A “hearings” or reflection phase, primarily devoted to public hearings and exchanges of views, lasting until the presentation of the draft report on 15 July 2021;
- An “assessment” phase, devoted mainly, but not exclusively, to the drafting of the report, the tabling of the amendments, and the negotiations on compromise amendments.

1. Reflection phase

In line with the BECA mandate, the committee studied the state of play throughout the whole cancer pathway and explored possible actions for the improvement of prevention and care. BECA meetings were used for gathering as much information and expertise for the report as possible through public hearings or exchanges of views with experts and key stakeholders. The hearings centred around six broad topics: research, prevention, detection, shared knowledge and expertise, equal access to treatment and support to patients and caregivers. The committee additionally addressed topical issues, such as breast cancer awareness on the occasion of the 2020 Breast Cancer Awareness Month; it also conducted a public consultation on the impact of COVID-19 on cancer prevention and care, and discussed the results of the consultation.

2. Assessment phase

The presentation of the draft report at the BECA meeting of 15 July marked the start of the “assessment phase” of the BECA committee, devoted to exchanges of views on the draft report, tabling and consideration of amendments and working on compromise amendments ahead of the vote on 9 December 2021.
3. Timeline
V. Working Document
WORKING DOCUMENT

on Inputs of the Special Committee on Beating Cancer (BECA) to influence the future Europe’s Beating Cancer Plan

Special Committee on Beating Cancer

Rapporteur: Véronique Trillet-Lenoir
This document aims to share some inputs of the Special Committee on Beating Cancer (BECA) to influence the future Europe’s Beating Cancer Plan.

1. CONTEXT

Cancer is a critical public health issue, one of the first causes of death in most European countries, which leads to the deaths of 1.4 million people each year in Europe, including 6000 children. Nearly 4 million people develop cancer every year and more than 12 million cancer survivors face the difficult return to a “normal life”.

Cancer patients need to be at the centre when dealing with all stages of the disease. Cancer is responsible for intense suffering of patients and their families, and it is a clear concern for governments, which are confronted with the growing economic burden of this disease and its related treatments on national health and social systems, budgets, productivity and growth of the economy.

Although there has been a slight decrease in mortality rates thanks to steps forward in screening campaigns and treatments, the number of cases diagnosed is increasing, notably due to longer life expectancies, and to better detection via screening. However, these increasing trends are not fully explained by a growing and ageing population as there is a complex interplay of multiple risk factors in the causes and mechanisms of cancer. According to the International Agency for Research on Cancer (IARC), new cancer cases are projected to increase from 3.9 million in 2018 to 4.7 million by 2040, with the highest rates predicted in the elderly population. There is evidence of gender differentiation in different cancer types.

There are significant disparities in terms of incidence, access to diagnosis, treatment and mortality from one country to another, and from one region to another in a given country. The 5-year survival rate from cancer is roughly 54% (80% for children), but these figures vary from 38 to 64% from one country to another, and there is as much as a 20% difference in children's survival rates among European countries. Inequalities and disparities are also identified between gender, social classes, demographic and ethnic groups (including marginalized groups), and with respect to the age of patients.

The current health crisis of COVID-19 has affected cancer at all stages of the disease and poses an ongoing challenge for patients, researchers and medical professionals.

2. METHODS

In order to reduce the incidence of cancer, to help patients live a longer and better life, and to pursue a reduction in health inequalities, Europe’s Beating Cancer Plan could follow this specific methodology:

- to catalogue, publish and analyse current legislative and financial instruments on cancer and the opportunities for Europe’s Beating Cancer Plan to build upon these and/or other successful
European initiatives developed by the cancer community itself (e.g. by European and international level healthcare professional and patient organisations);

- to determine general and specific objectives and estimate their respective strengths, weaknesses, opportunities and threats;

- to identify and compare the various actions already taken by Member States in establishing their National Cancer Control Plans and impact assessments of these plans;

- to propose a list of measures for actions, revised or new legislation, incentives, guidelines and recommendations;

- to clarify which measures fall under European legislative competences, and which can be achieved either through recommendations to Member States or by voluntary measures;

- to define the competent authorities (European, national, regional, local) required for the implementation of the different measures;

- to indicate the most recently available scientific data underpinning the proposed measures, as well as data currently lacking that should be addressed in the context of Europe’s Beating Cancer Plan, the EU Cancer Mission and the EU4Health programme;

- to consider for each measure the potential implications for the different public and private stakeholders, including various patient associations, European learned institutions, social partners, Non-Governmental Organizations involved in the cancer field and medical companies;

- to assess the feasibility and estimate the required financial resources for the different measures;

- to define measurable and reproducible impact indicators accordingly.

3. POSSIBLE DOMAINS OF ACTIONS - For a coordinated and effective fight against cancer

a. Areas of action

   i. Global prevention

More than 40% of all cancers are preventable through coordinated actions on individual, social, environmental and commercial health determinants. The European Code Against Cancer is an initiative of the European Commission developed by the IARC to inform people about actions they can take for themselves or their families to reduce their risk of cancer. Successful cancer prevention requires these individual actions to be supported by governmental policies and actions.
Many significant health inequalities exist within the EU in regards to cancer prevention. Prevention policy must be enshrined in a framework of social justice in order to account for the inequalities vulnerable and low-income populations face in terms of preventable risk factors.

**Tobacco use**, in particular cigarette smoking, is the main risk factor for cancer death in Europe. Various measures to fight against smoking appear heterogeneous and inconsistently implemented. Overall, the WHO Europe region is the global area with the highest tobacco consumption, with major discrepancies between Member States, as the proportion of smokers varies by a factor of up to 5 from one country to another.

**Harmful alcohol consumption**, whether or not in combination with tobacco-smoking, provokes a significant increase in many different types of cancers. Overall, the level of alcohol consumption is high and varies from 10 to 12 litres per person per year among EU countries.

Cancer is the first cause of work-related death in Europe. **Exposure at work** accounts for 8% of cancer, according to a 2018 ETUI report, and is responsible for up to 150 500 cancer cases each year. The elimination of carcinogens and mutagens and the reduction of workers' exposure in production processes will decrease the number of occupational cancers. The fraction of cancers attributable to occupation is often underestimated, owing to the very long exposure time period required for cancer to be clinically detectable, and thus to be declared as an occupational disease by the public health authorities.

Promising advances have been made regarding the prevention of cancers related to infectious diseases, in particular national vaccination programmes in the fight against human papilloma virus (HPV) that can induce uterine cervix cancer in women and an increased number of anogenital and oropharyngeal cancers in both sexes. The majority of Member States have introduced vaccination campaigns but not all have organized programmes, and the targeted populations vary. Major discrepancies appear in the level of vaccination coverage between Member States, from less than 30% to more than 70% (the required level for population effectiveness). Vaccination against Hepatitis B is recommended by IARC for newborns.

An individual’s cancer risk can also be reduced by adopting **healthy nutritional habits** from their dietary intake (high intake of fruits and vegetables, grain and pulses; low intake of sugar, saturated fatty acids, sugary drinks and processed meat; reduction of red meat) and keeping a **healthy body weight**. The Farm to Fork strategy will contribute in this regard.

Regular **adapted physical activity** is helpful in the prevention, and reduction of recurrences, of some cancers.

**Radiation from the sun** contains invisible ultraviolet (UV) radiation which can lead to skin cancer. Exposure to radioactive substances is a known risk factor for cancers and attention should also be paid to other environmental radioactive agents such as radon.

The detection of a **genetic predisposition** to breast and colorectal cancers is possible and may help
with prevention, early detection or even prophylactic measures.

**Environmental pollution** in the air, food, water and soil, and exposure to chemicals including dangerous and carcinogenic substances are risk factors for cancer. Improved implementation of existing EU environmental legislation, better research on the correlation between the environmental factors and cancer, as well as commitments under the implementation of the **European Green Deal** with its zero pollution ambition for a toxic-free environment will contribute to cancer prevention in Europe via the reduction of these risk factors. There is not yet a reliable measurement of the health impact of such policies in Europe.

Tobacco and alcohol, poor nutrition, high body mass index and sedentary lifestyles are also risk factors common to **other chronic diseases**.

**Health promotion** requires specific attention to vulnerable populations in order to avoid any type of discrimination towards cancer patients, especially during times of economic, social or public health crises.

### ii. Screening and early detection

Lack of information, non-adherence to, and non-provision of cancer screening detection processes frequently lead to delays in cancer diagnoses.

In 2003, the Council issued a set of recommendations on the establishment of cancer screening programmes in EU Member States. Recommendations include a shared commitment to implement systematic population-based national (or regional) screening programmes for breast cancer, colorectal cancer and uterine cervix cancer. Their implementation is far from complete and significant inequalities remain in terms of access to quality-assured cancer screening. Only 18 Member States have national or regional population-based screening programmes for these tumours. Development and implementation of these programmes also differs between countries. Early detection is a key factor for beating cancer. Big differences exist in the length of time for diagnosis as well as in the process of follow-up after successful treatment. New innovative imaging screening strategies and early blood detection technologies are currently being evaluated in many types of cancers.

### iii. Equal access to patient-oriented treatments

Cancer treatment and care involve a very wide range of treatment modalities.

Surgery is a key component of cancer treatment and contributes significantly to improved cancer survival in Europe. Surgery has the potential to cure most solid tumours and therefore remains the primary treatment option in cancer. Yet only 25% of patients worldwide are receiving safe, timely, affordable, and high-quality surgical care.
Radiation therapy is essential in more than half of all cases of cancer and has a clear curative impact in many cancer types. However, studies suggest that at least one in four people needing radiation therapy does not receive it. Across Europe, there is a 6 to 7-fold variation in the access to radiation therapy equipment and a 3 to 5-fold variation in available personnel and workload.

Most recent advances in the field of cancer treatment are related to the availability of innovative new drugs thanks to better knowledge of cancer molecular mechanisms. The total expenditure for cancer-related drugs in the EU is around €13 billion per year.

The strengthening of the European Medicines Market could guarantee equal access to affordable treatments and innovations, reduce the risk of shortages of medicines, allow shared evaluation of medical devices and medicines, increase the transparency on price-fixing procedures, overcome the high prices of innovative treatments and improve cancer treatments and best practices in adults and children. Shortages particularly affect cancer medicines and some patients are forced to stop their treatment.

Age-specific care taking into account specific needs is not yet available whenever needed. The growing use of targeted therapies requires common molecular diagnostic techniques.

EU patients still face challenges in accessing healthcare. The best quality care in cancer relies on rapid access to the finest skills and tools in terms of diagnosis without delay, optimal and tailored treatment, follow-up and quality of life at every stage of the disease. Every patient in Europe, wherever she or he may live, and regardless of the social background, expects to be given the same chances to beat cancer and benefit from adequate coordination between all health, medical and non-medical professionals, specialists and general practitioners from both the private and public sectors, as well as recent advances in outpatient treatments, maximizing the potential of digital health, and optimal supportive care, including palliative care during the end-of-life stage.

The EU has a role in many areas related to patient access to specialized multidisciplinary and multiprofessional cancer teams, including through professional qualification recognition legislation, legislation pertaining to workforce conditions and safety, as well as workforce planning and classification activity.

According to OECI (Organization of European Cancer Institutes), there are approximately 280 to 300 cancer centres in the EU. Only 80 to 100 of those are in a recognised accreditation programme to fulfil the requirements for the “comprehensive cancer centres” label. However, only 34 so far have been designated as “Comprehensive Cancer Centres” (CCCs).

While 49% EU nationals feel well informed about healthcare reimbursement in their own country, 17% feel the same about another EU country and only 10% are aware of the availability of cross border healthcare.
iv. Strong support to patients and caregivers (including family caregivers)

Cancer patients often suffer “double punishment” in their daily lives. They face various problems such as physical trauma, mental health and difficulties in returning to school, work or leisure, and work-life balance. They also often lack medical, psychological, social and financial support, as do their families and caregivers during treatment. Additionally, individuals with occupational cancer can suffer especially from the lack of recognition of their work-related disease. Caregivers do not have a recognized legal status in all Member States.

The mobilization of various healthcare specialists, support from patient associations and advocacies are helpful. Children, adolescents and young adults may require specific assistance, notably regarding treatment to restore fertility. Rehabilitation, including restoration of esthetic integrity, is a key issue to support cancer related quality of life. Too many insurers and banks indeterminately take into account the medical history of people who were affected by cancer. Four Member States have implemented the “right to be forgotten” after cancer cure.

b. Possible action tools

i. Holistic research and innovation

Horizon Europe’s Cancer Mission has published its inspiring report in the context of the Europe’s Beating Cancer Plan. As stated in the recommendations of the European Academy of Cancer Sciences - and reiterated in the declaration of the Trio Presidency of the European Union (EU) - to reduce the enormous cancer burden requires a joint program covering the whole cancer research/care continuum as well as the establishment of interconnected high-quality infrastructures.

Valid and useful findings rely on independent, adequately financed and cross-sector multidisciplinary and highly cooperative cancer research, “from bench to bedside”, that is from the laboratory to applied studies involving patients. The unmet expectations of European patients may be addressed through fundamental, translational, clinical or interventional studies.

Better knowledge of cancer biology requires the implementation of genomics and bioinformatics infrastructures. In this regard, there is a huge potential for the use of Artificial Intelligence as a transformative technology in the diagnosis and treatment of cancers in the coming years.

Clinical research may evaluate the feasibility, efficacy and cost-effectiveness of non-treatment related interventions such as studies on health determinants both before, during and after the disease or on quality of life. Non-profit, clinical trials, including academic trials, may improve treatment strategies. Early phase 1 trials on new drugs are a valuable means to improve access to innovative new treatments, such as personalised therapy and precision oncology, in adults, children. Access to promising clinical trials is often not guaranteed because of age-related requirements or geographical origin.

Human and social sciences may be required, in particular those addressing health inequalities throughout the different stages of cancers. Research programmes could be developed to identify
effective cancer prevention strategies and methods to provide up-to-date knowledge to the EU and the Member States.

Patient groups are increasingly involved in the elaboration of clinical trials. Some Member States offer the possibility of patient-reported outcomes (PROMs). Communication portals to allow patients access to available clinical trials already exist or are being developed in many European countries.

ii. Shared knowledge

Shared expertise

The 24 European Reference Networks (ERNs) aim to connect healthcare professionals around Europe with expertise on rare diseases which allows them to discuss patients’ records and provide the best diagnostic and treatment options in these complex situations. Two of them are currently dedicated to rare cancers.

Shared data

Cancer registries are a very important source of objective cancer data to evaluate cancer burden and help design cancer control plans. The European Network of Cancer Registries (ENCR) currently gathers 178 individual registries across Europe, including non-EU countries, but it appears that registration is hampered by significant disparities in their quality and coverage.

Independent collection, sharing and analysis of anonymized clinical and biological “big data” is crucial to better understand cancer mechanisms, cancer determinants, cancer predispositions, and treatment resistances. Some countries have already set up national databases. An optimal critical mass is needed to ensure efficiency, independence and competitiveness of data sharing.

The experts of the Mission Board for Cancer have proposed 2 different types of platforms:

- European Initiative to Understand Cancer (UNCAN), a European platform that would integrate patient data, samples and biomarkers, shedding light on how tumours start, develop and spread.

- European digital centre for cancer patients to create a standardised and interoperable virtual (patient-controlled) health data network, a global knowledge centre on cancer prevention, health promotion, diagnosis, treatment and supportive care. Also a contact point to provide guidance and support to survivors and to feed into oncology research

Generating more real-world data is important in order to provide evidence of how treatments are actually used in clinical practice.
Shared training

Some common training programmes for health professionals are developed in close connection with European learned institutions. Preventive measures may also be useful to prevent the burnout of cancer care professionals. Interdisciplinary and multidisciplinary health workforce education has shown efficiency.

The potential of genomic medicine and use of artificial intelligence makes it necessary to specialise in medical training and to extend specialised profiles within medical activity.

Educating and training of patients and family caregivers enhances empowerment and health (digital) literacy, known factors that improve quality of life.

Shared communication

Adequate and updated guidelines for health professionals, as well as clear and validated information to citizens are key for public education and the fight against misinformation. They are already available in some Member States, but not all.

The European institutions do not currently provide for any structure dedicated to the coordination of such networking tools on expertise, training and communication.
VI. Draft Report
DRAFT REPORT

on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy
(2020/2267(INI))

Special Committee on Beating Cancer

Rapporteur: Véronique Trillet-Lenoir
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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy
(2020/2267(INI))

The European Parliament,

– having regard to its decision of 18 June 2020 on setting up a special committee on beating cancer, and defining its responsibilities, numerical strength and term of office,

– having regard to the working document of its Special Committee on Beating Cancer of 27 October 2020 entitled ‘Inputs of the Special Committee on Beating Cancer (BECA) to influence the future Europe’s Beating Cancer Plan’,

– having regard to the Commission communication of 3 February 2021 on Europe’s Beating Cancer Plan (COM(2021)0044),

– having regard to the Commission communication of 11 December 2019 on the European Green Deal (COM(2019)0640),

– having regard to its resolution of 15 January 2020 on the European Green Deal,

– having regard to the EU’s Framework Programme for Research and Innovation 2021-2027 (Horizon Europe) and the dedicated Horizon Europe Mission on Cancer,

– having regard to the Commission communication of 20 May 2020 entitled ‘A Farm to Fork Strategy for a fair, healthy and environmentally friendly food system’ (COM(2020)0381),


– having regard to its resolution of 10 July 2020 on the Chemicals Strategy for Sustainability,

– having regard to its resolution of 10 July 2020 on the EU’s public health strategy post-COVID-19,

– having regard to the public consultation synopsis report of its Special Committee on Beating Cancer of 19 April 2021 entitled ‘The impact of the COVID-19 pandemic on cancer prevention, health services, cancer patients and research: lessons from a public health crisis’,

– having regard to the Commission communication of 11 November 2020 entitled ‘Building a

89 Texts adopted, P9_TA(2020)0005.
91 Interim report of the Mission Board for Cancer entitled ‘Conquering cancer: Mission possible’.

– having regard to Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-202794,

– having regard to Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme95,

– having regard to the UN Sustainable Development Goals (SDGs), in particular SDG 3 on good health and well-being,

– having regard to the fourth edition of the European Code Against Cancer,

– having regard to the activity and conclusions of the all-party interest group MEPs Against Cancer (MAC),

– having regard to Rule 54 of its Rules of Procedure,

– having regard to the report of Special the Committee on Beating Cancer (A9-0000/2021),

A. whereas Europe’s Beating Cancer Plan should effectively respond to the call for progress by the families and doctors of the 1.3 million people who die from cancer each year in Europe, including 6 000 children, the crucial needs of patients who are currently in need of efficient and innovative treatments, the rightful expectations of more than 12 million cancer survivors facing the difficult return back to a ‘normal life’, the clear will of future generations to be protected against health threats, and the concern of governments facing a growing economic burden from cancer and its related treatments;

B. whereas Europe represents less than 10 % of the world’s population, but accounts for a quarter of all cancer cases, and whereas cancer is the second leading cause of death in Europe after cardiovascular diseases; whereas although there has been a slight decrease in mortality rates thanks to screening campaigns and therapeutic innovation, the number of cases diagnosed is nevertheless increasing, notably due to longer life expectancies, which results in ageing populations; whereas almost three quarters of all cancer diagnoses in the EU occur in people aged 60 or above;

C. whereas cancer illustrates social injustice in healthcare, as differences in cancer survival rates across the EU Member States exceed 25 %; whereas EU citizens are unequal in terms of prevention, unequally protected against risk factors, unequally educated in terms of healthy behaviours and unequally equipped against misinformation; whereas EU citizens are unequal in terms of timely access to quality care from Member State to Member State and from region to region in any given country; whereas after recovery or when in remission, EU citizens are unequal in their ability to return to work, to be financially independent and to return to a

harmonious familial, social and emotional life;

D. whereas specific national or regional cancer policies have been set up in most Member States, whose missions and budgets are heterogeneous;

E. whereas the goal of Europe’s Beating Cancer Plan should not only be to fight against a crucial public health issue and to help patients live longer and better lives, but should also be to initiate a reduction in health inequalities and inequities and lower the social and economic burden of the disease; whereas the Commission should promote a patient-centred and citizens’ rights-based approach by integrating considerations of justice, sustainability, equity, solidarity, innovation and collaboration at the very core of Europe’s Beating Cancer Plan;

F. whereas health literacy includes the acquisition of knowledge and skills, awareness of rights and the confidence to take action to improve personal and community health; whereas actions to promote health literacy under the Plan should focus on empowering patients and citizens; whereas all efforts to increase health literacy should take into account people with learning disabilities, as well as ensure that the necessary information is available in common non-EU languages in order to reach migrants and new arrivals;

G. whereas the Plan should be implemented in close association with the recommendations and actions of the International Agency for Research on Cancer (IARC), the UN SDGs for global health, and the recommendations and guidelines of the World Health Organization (WHO), and should acknowledge as a priority the EU’s solidarity and partnership with low- and middle-income countries;

H. whereas addressing cancer could be used as a model for other non-communicable diseases, and whereas patients with other chronic diseases should therefore also benefit from the achievements of Europe’s Beating Cancer Plan;

I. whereas a common policy driven at European level is absolutely essential for progress in the area of cancer; whereas the primary responsibility for health protection and healthcare systems lies with the Member States;

J. whereas a comprehensive, multidisciplinary and coordinated approach to addressing social, individual, environmental and commercial health determinants is needed at regional, national and European level in order to support actions targeting all aspects of cancer (prevention, detection, treatment, palliative care and reintegration) through the effective mobilisation of key tools such as research and knowledge sharing; whereas new technologies and artificial intelligence have high potential for improvements in the field of cancer research;

K. whereas the ‘Health in All Policies’ and ‘One Health’ approaches should be promoted further, and efforts to fight cancer should be integrated into all EU policies;

L. whereas the EU and its Member States should mobilise their forces and provide adequate incentives and sustainable budgets so as to achieve the ambitious objective of conquering the cancer burden and the fatality of cancer in Europe;

M. whereas Europe’s Beating Cancer Plan could therefore represent the first step towards a real European Health Union;
A. Areas of action

I. Cancer prevention in all European policies

1. Strongly believes that preventive actions against cancer should be implemented in all European policies and funding programmes;

2. Calls on the Commission and Member States to design and implement effective prevention measures at national and EU level, based on best practices, independent expertise and guidance;

3. Acknowledges that more than 40% of all cancers are preventable through coordinated actions on social, individual, environmental and commercial health determinants;

4. Supports the aim of the Horizon Europe Cancer Mission to avert more than 3 million additional premature deaths over the 2021-2030 period, by accelerating progress in cancer prevention and control programmes and creating more equal access to these programmes;

5. Deplores the significant health inequalities in the EU as regards cancer prevention; insists on the need to pay special attention to vulnerable and marginalised populations in order to ensure their access to cancer prevention services;

6. Acknowledges that tobacco use, in particular cigarette smoking, is by far the largest preventable cause of cancer in the EU, as the cause of 15-20% of European cancer cases and the main risk factor for cancer death in Europe (27% of cancer fatalities equalling 700,000 cancer deaths annually in the EU); recalls that major differences exist across the EU since the proportion of smokers varies more than fivefold from one country to another;

7. Strongly supports the goal of a ‘tobacco-free generation’, as set out in Europe’s Beating Cancer Plan, where less than 5% of the population uses tobacco by 2040, compared to around 25% today;

8. Welcomes the Commission’s intention to review the Tobacco Products Directive\textsuperscript{96}, the Tobacco Products Tax Directive\textsuperscript{97} and the legal framework on cross-border purchases of tobacco by private individuals in order to introduce the following:

   a) an increase in minimum excise duties for all tobacco products, which could result in a reduction in tobacco use, notably among young people;

   b) a requirement for plain packaging and the obligation to include health warnings on 80% of the front and back of cigarette packaging;

   c) a ban on flavourings in all tobacco products to reduce the appeal of these products to non-smokers and young people;

   d) an authorisation for Member States to introduce a ban on plastic cigarette filters on health and environmental grounds;

   e) the continuation of evaluations of the health risks related to electronic cigarettes and the


establishment of a list of substances contained and emitted by these products at European level, based on the model published by the French Agency for Health Security;

9. Calls for the rapid implementation of the WHO Framework Convention on Tobacco Control, paying specific attention to the protection of public health policies from the vested interests of the tobacco industry.

10. Supports the Commission’s proposal to update the Council recommendation of 30 November 2009 on smoke-free environments to extend its coverage to emerging products, such as e-cigarettes and heated tobacco products, and to extend smoke-free environments, including outdoor spaces;

11. Recalls that ethanol and acetaldehyde in alcoholic beverages are classified as carcinogenic to humans by the IARC, and that in Europe an estimated 10% of all cancer cases in men and 3% of all cancer cases in women are attributable to alcohol consumption;

12. Welcomes the Commission’s target of achieving a reduction of at least 10% in the harmful use of alcohol by 2025; encourages the Commission and the Member States to promote actions to reduce and prevent alcohol-related harm within the framework of a revised EU alcohol strategy; supports the provision of better information to consumers by improving the labelling of alcohol beverages to include prominent warning labels and introducing the mandatory indication of the list of ingredients and nutritional information; calls for the prohibition of alcohol advertising at sport events and for the prohibition of alcohol sponsorship of sport; considers it important to protect children from commercial communication on alcohol consumption, as well as product placement and sponsorship of alcohol brands, especially in the digital environment; calls for the strong monitoring of the implementation of the revised Audiovisual Media Service Directive; encourages the allocation of public funds for national and European awareness campaigns; supports the planned review of EU legislation on the taxation of alcohol and on cross-border purchases of alcohol by private individuals and a review of alcohol pricing policies, including increasing taxes on alcoholic beverages;

13. Emphasises the role of a healthy diet in cancer prevention and that individual cancer risks can be reduced by an appropriate intake of fruits and vegetables, and therefore welcomes the upcoming revision of the ‘EU school fruit, vegetables and milk scheme’; asks the Commission and the Member States to help consumers to make informed, healthy and sustainable choices about food products via the adoption of harmonised, mandatory front-of-pack nutrition labelling, such as the Nutri-Score; welcomes the focus on healthy nutrition in the EU Child Guarantee and calls for a new EU Action Plan on Childhood Obesity; supports fiscal measures to make fresh foods (such as pulses, grains and vegetables) more affordable and accessible at national level, especially for people with low incomes; encourages Member States to use pricing policies, such as value added tax differentiation, and marketing controls to influence demand for, access to and the affordability of food and drink low in saturated fats, trans-fats, salt and sugar; supports Member States in restricting the

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advertising of ultra-processed food products and sugary and sweetened beverages, including on social media;

14. Calls on Member States, regional and local governments, and civil society representatives to promote and facilitate the practice of sports activities, which is known to limit both the incidence and the recurrence of cancer, as well as mental health problems, and favour social inclusion;

15. Welcomes the launch of the EU’s ‘HealthLifestyle4all’ campaign involving the promotion of sports, physical activity and healthy diets, in addition to other key sectors;

16. Points out that radiation from the sun contains invisible ultraviolet (UV) radiation which can lead to skin cancer; supports the strengthening of protection against exposure to UV radiation at EU level, especially in the framework of occupational health and safety legislation for outdoor workers; calls on the Member States to fully implement the rules on artificial tanning devices (sunbeds)\(^\text{102}\) and to work together towards the phasing out of sunbeds for cosmetic purposes;

17. Acknowledges that around 2% of the European cancer burden can be attributed to ionizing radiation and that indoor exposure to radon and its decay products is the second leading cause of lung cancer in Europe; looks forward to the results of the Euratom Research and Training Programme\(^\text{103}\), which will improve knowledge on exposure to radon, and the proposed countermeasures to reduce its accumulation in dwellings; encourages Member States to regularly update their national plans to reduce exposure to radon, as requested in the Directive on Exposure to Radioactive Sources\(^\text{104}\); calls on the Commission to introduce measures to protect workers exposed to ionising radiation such as airline crews, nuclear power plant workers and health professionals working in the radiology, radiotherapy or nuclear medicine sectors;

18. Sees the European Green Deal as a contributing factor in cancer prevention in Europe, via the reduction of air, food, water and soil pollution and of chemical exposure; calls for an evaluation of the impact of policies on cancer incidence to be integrated into the Farm to Fork Strategy and the Chemical, Zero Pollution and Non-Toxic Environment Strategies; welcomes the upcoming revision of the EU’s air quality standards to align them with WHO guidelines; calls on the Commission to ensure that the common agricultural policy reduces the intake of pesticide residues; encourages the use and development of medicines that are safer for the environment;

19. Looks forward to the implementation of the revised Drinking Water Directive\(^\text{105}\) and the implementation and enforcement of the Water Framework Directive\(^\text{106}\), which will reduce the concentrations in surface and ground waters of certain pollutants that could contribute to

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cancer incidence;

20. Calls for the registration, evaluation, authorisation and restriction of chemicals under the REACH Regulation\(^{107}\) to be conducted in association with the IARC assessments; calls on the Commission to adopt effective guidance and legislation to reduce citizens’ exposure to carcinogenic substances;

21. Considers that the next review of the European Code Against Cancer (ECAC) will have to take into account the latest knowledge on environmental carcinogens; calls for the regulation on food contact materials\(^{108}\) to be reviewed in order to reduce exposure to carcinogens and endocrine disruptors;

22. Recalls that exposure at work is responsible for at least 120 000 deaths from cancer each year in the EU; looks forward to the forthcoming new EU Strategic Framework on Health and Safety at Work for the 2021-2027 period, the regular update of Directive 2004/37/EC of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work\(^{109}\), and the addition of further binding occupational exposure limits within that directive; welcomes the Commission’s commitment to presenting a legislative proposal to further reduce workers’ exposure to asbestos in 2022; asks Member States to facilitate recognition of and compensation for proven work-related cancers; stresses the need to ensure the best possible general and individual protection measures for healthcare workers handling anti-cancer drugs;

23. Encourages the Commission and the Member States to promote the prevention of cancers related to infectious diseases; recalls that human papillomavirus (HPV) is a sexually transmitted infection associated with uterine, cervical and oropharyngeal cancers; welcomes the vaccination programmes in the fight against HPV transmission; notes and regrets major discrepancies in vaccination coverage between Member States, ranging from less than 30 % to more than 70 % (with the required level of population immunity being at 70 %); insists that a gender-neutral HPV vaccination programme be implemented in the Member States to ensure the elimination of all HPV-related cancers; considers it important to draw up further recommendations to better implement these programmes; calls for more harmonisation of HPV and hepatitis B vaccination within Member States’ national programmes, while ensuring the provision of information about and equal access to vaccination; supports further research into the most effective vaccination schedules against other carcinogenic viruses such as hepatitis C; calls for collaboration with Member States and international organisations to combat the impact of misinformation on vaccination and address vaccine hesitancy;

24. Recommends that breastfeeding be encouraged to limit the risk of breast cancer in women;

25. Points out that genetic predisposition to cancer linked to mutations of specific genes has been demonstrated; highlights that methods to detect these mutations are available, especially for breast and colorectal cancers, and may help to prevent or detect early-stage cancer; recommends investments in infrastructures and skills in genetic sequencing platforms and the training of specialised genetic counsellors;

26. Strongly supports the planned revision of the ECAC and the launch of an EU mobile app for


\(^{109}\) OJ L 158, 30.4.2004, p. 50.
cancer prevention and care, as announced in Europe’s Beating Cancer Plan, in order to develop, share and implement best practices in cancer prevention and care programmes, with a focus on disadvantaged groups; stresses that the ECAC should be systematically evaluated and that the evaluation work should be coordinated by the IARC;

27. Encourages the Commission and the Member States to promote health literacy as regards cancer risks and determinants, to develop educational tools for prevention and to support the creation of e-learning platforms and applications; considers cancer prevention to be a first step towards a European public health education policy;

28. Calls for the creation of a virtual European Cancer Institute, which would be in charge of establishing a European roadmap to devise and coordinate large-scale prevention campaigns and effective communication campaigns on health promotion in educational programmes (harmless behaviours, healthy nutrition, physical activity etc.) with a special focus on young people and disadvantaged groups;

29. Underlines that tobacco and alcohol consumption, poor nutrition, a high body mass index and a sedentary lifestyle are risk factors common to other chronic diseases; believes, therefore, that cancer prevention has to be implemented in the context of an integrated chronic disease prevention programme, in close cooperation with the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases;

30. Calls for the implementation of prevention programmes to be inclusive, by involving citizens, civil society and patient associations, especially through the Conference on the Future of Europe;

II. Inclusive screening and detection of cancer

31. Deplores the frequent delays to cancer diagnosis related to a lack of information or adherence to cancer screening and detection processes; recognises the need to pay particular attention to the continuity of screening programmes and early detection in the context of a health crisis (such as the COVID-19 crisis);

32. Notes that, for instance, only 18 Member States reported that they had national or regional population-based screening programmes in place; regrets the inequalities between Member States in access to breast cancer screening, which differs at least tenfold across the EU according to Eurostat;

33. Invites Member States to work together to reduce inequalities in cancer screening and early diagnosis services, especially in cross-border regions;

34. Supports the launch of a new EU-supported Cancer Screening Scheme, as announced in Europe’s Beating Cancer Plan, to help Member States to ensure that 90% of the EU population who qualify for breast, cervical and colorectal cancer screenings are offered screening by 2025;

35. Encourages Member States to promote cancer screening for breast, cervical and colorectal cancers as part of organised population-based national and regional programmes, including in the remote and outermost regions, and provide adequate resources; recommends that Member States roll out programmes for early clinical detection of oral and skin cancers;

36. Calls for the full implementation by Member States of the European guidelines for quality
assurance in cancer screening for breast, cervical and colorectal cancers and early detection services, to minimise the delay to diagnosis for such cancers; recommends that inequalities within Member States regarding screening be addressed, possibly by making the criteria for cancer screening, as well as the legal frameworks, governance and quality assurance structures, more stringent;

37. Encourages the improvement and harmonisation of cancer screening data collection to allow for an annual European report; encourages, too, the regular monitoring of current screening programmes at EU level; underlines that scientific advances in cancer risk prediction should allow for the development of risk-appropriate screening programmes;

38. Welcomes the upcoming update of the 2003 Council recommendation on breast, cervical and colorectal cancer screening\textsuperscript{110} to take into account new screening tests and the most recent data on the best screening protocols (magnetic resonance imaging, HPV testing); emphasises that those programmes should be regularly evaluated by the competent national authorities; calls for research efforts to be fostered in order to assess, in close cooperation with the IARC and the WHO, the possible inclusion of new science-based cancer screening programmes (including lung, prostate, stomach and ovarian cancers) in the recommendation;

39. Advocates the launch of a platform for national screening centres to share expertise and implement best practices, discuss common challenges and encourage collaboration, based on the model of the European Network for Health Technology Assessment (EUnetHTA);

40. Stresses the importance of increasing the uptake of cancer screening and early detection among EU citizens through European Awareness Days, motivation surveys and better implementation of existing communication campaigns;

41. Calls for reinforced cooperation with third countries to encourage the organisation of screening campaigns, in particular for women’s cancers and notably in low- and middle-income countries;

III.a. Equal access to cancer care: towards best quality care

42. Deplores the fact that EU patients still face challenges in accessing healthcare services in other Member States and that only a minority of patients are aware of their right to seek cross-border healthcare; emphasises the need for better implementation of, and an improved financial model for, the Cross-border Healthcare Directive\textsuperscript{111} to allow for mobility and access to highly specialised equipment and care through the reinforcement of the National Contact Points (NCPs) by providing them with more budgetary resources, and calls for an increase in the number of information campaigns on patients’ rights to cross-border healthcare; emphasises the need to facilitate the process, through the revision of the Cross-border Healthcare Directive, for patients who travel abroad for clinical trials and face issues such as a lack of clarity on follow-up protocols after their return home and on coverage of costs related to their clinical trial participation by national insurance agencies; calls on the Commission and the Member States to work together to conduct regular evaluations of the Commission’s eHealth Strategy from 2018 to ensure interconnected electronic health records for cancer patients at regional, national and European level;

43. Calls for consideration of mutual recognition of medical qualifications in cancer care across the EU;

44. Calls for full recognition of medical oncology as a specialist discipline, the establishment of pan-European quality standards for administering and supervising medical treatments for cancer, and the facilitation of patients’ access to cancer specialists so that they may benefit from innovations and access to early clinical trials on new promising drugs;

45. Calls for surgical skills in the EU to be strengthened via the recognition of surgical oncology as a specialist discipline, the establishment of pan-European quality standards for cancer surgery, the facilitation of patients’ access to ‘high-volume’ centres for cancer surgery and access to innovative surgical procedures;

46. Supports the improvement of high-quality radiation therapy in the EU through the recognition of medical physics and radiation therapy as dedicated disciplines, the promotion of common education and training standards, and the greater investment of EU and national research and innovation funds in radiation therapy research;

47. Welcomes the upcoming new action plan under the Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA)\(^\text{112}\) which will support the security of supply of radioisotopes for cancer diagnosis and care and enhance the quality and safety of radiation technology in medicine;

48. Calls on the Commission to promote, and on Member States to strengthen, the role of general practitioners, paediatricians and primary care professionals, given their importance in patient referral to diagnostic tests and oncology specialists, as well as during cancer treatment and follow-up care; calls for the development of multidisciplinary decision-making in the framework of dedicated concertation meetings bringing together various cancer specialists;

49. Considers that the EU regulatory framework for the recognition of professional qualifications should be broadened to allow for the standardisation of cancer nursing education;

50. Calls on the Member States to take preventive measures against the risk of burnout among cancer care professionals;

51. Encourages, where possible and safe, the use of ambulatory cancer treatments in order to preserve the quality of life of patients; calls on Member States to implement or improve e-health technologies and telemedicine services to ensure the continuity of cancer care;

52. Calls on the Member States to provide optimal relief for advanced-stage cancer patients at the end of their lives in order to ease their pain and discomfort while preserving their dignity; supports more intensive exchanges and the implementation of best practices on hospice and palliative care at EU level; encourages Member States to assess the number of palliative units in each region and to ensure sustainable funding and sufficient and well-trained human resources;

53. Encourages the Commission and the Member States to adopt specific quality assurance criteria (including adequate organisations, infrastructures and competences, multidisciplinary practice, continuing education for professionals, patient education and participation in clinical research) for accreditation standards to be applied to public and private hospitals treating cancer patients, in order to ensure the efficient, safe and equal management of cancers all over

\(^{112}\) Commission staff working document entitled ‘Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA)’ (SWD(2021)0014).
the EU;

54. Welcomes the planned establishment, as announced in Europe’s Beating Cancer Plan, of an EU network linking recognised National Comprehensive Cancer Centres (reference centres) in every Member State to facilitate the uptake of quality-assured diagnosis and treatments, including training, research and promotion of clinical trials across the EU; calls on the Commission to identify such existing centres within the EU, to promote the establishment of at least one comprehensive cancer centre in each Member State and to support the coordination of the network of these centres via a European Cancer Institute;

55. Calls for the identification, reinforcement or creation in each Member State of a National Cancer Control Programme (NCCP), consisting of a unique structure, possibly a National Cancer Institute, in charge of the implementation and follow-up of the respective NCCPs, with adequate objectives and resources; recommends that the NCCPs are set up in coherence with the European Guide for Quality National Cancer Control Programmes initiated by the European Partnership for Action Against Cancer (EPAAC); welcomes the setting up of a network of these organisations coordinated by the European Cancer Institute;

III.b. Equal access to cancer care: towards a European Medicines Market

56. Calls on the Commission to strengthen the European medicines market in order to guarantee equal access to treatment, reduce medicine shortages, overcome the problem of high prices for innovative treatments, and improve cancer treatments for adults and children;


58. Notes that cancer patients are frequently affected by medicine shortages; calls on the Commission to present a specific strategy for managing shortages of all medicines and medical products in Europe and of cancer medicines in particular; supports the development of a common basket of the cancer drugs of which there may be shortages to ensure that patients have continuous access to appropriate treatment;

59. Calls for the reinforcement and diversification of the supply chain, in particular that of cancer drugs, within the EU, close monitoring of medicine tensions and shortages, and the creation of a strategic stockpile of such medicines;

60. Points out that generic and biosimilar medicines enable efficient and safe cancer care, increased competition and savings for healthcare systems, thus helping to improve access to medicines for patients; stresses that their market entry should not be hampered or delayed;

61. Considers that Member States should converge on the evaluation of medical technologies; welcomes, therefore, the provisional agreement on the Health Technology Assessment (HTA) Regulation reached by the European Parliament and the Council on 22 June 2021 to support harmonised access to innovative cancer diagnosis and treatments;

62. Insists on the need to ensure equal access to affordable drugs, in particular cancer drugs,

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within the EU; calls for collective negotiation on the price of medicines with pharmaceutical industries, as per the Beneluxa Initiative on Pharmaceutical Policy and the Valetta Declaration; considers that pharmaceutical companies should respect conditionalities on charging an affordable price for medicines developed in the framework of publicly funded research;

63. Strongly advocates the extension of joint procurement procedures for cancer medicines to improve affordability and access to cancer treatments at EU level;

64. Calls for a review of data exclusivity in the authorisation process of medicines\textsuperscript{115}, i.e. the period of time within which the marketing authorisation holder of a medicine enjoys exclusive access to the results of preclinical tests and clinical trials, so that compulsory licensing can allow for the market entry of cancer treatments in the event of a health crisis (such as the COVID-19 crisis) or to overcome the rising cost of specific treatments;

65. Calls on the Commission to submit a proposal for the revision of Directive 89/105/EEC on the transparency of measures regulating the prices of medicinal products\textsuperscript{116} in order to ensure effective controls and full transparency of the procedures used to determine the price and reimbursement of the cost of medicines, in particular cancer medicines, in Member States; calls for pharmaceutical companies to provide information on financing with public resources, as well as on the tax benefits and subsidies they have received; requests that the calculation of drug costs should take into account the use of public funds; calls on the European Medicines Agency (EMA) to increase the number of audits in order to assess pharmaceutical companies’ compliance with the requirements on transparency;

66. Notes that huge advances in biology have revealed that cancer is an umbrella term for more than 200 diseases, and that precision or personalised medicine can be made available through the drug targeting of various mutations; considers that precision or personalised medicine, consisting of a treatment choice based on individual tumour biomarkers, is a promising way to improve cancer treatment; encourages Member States, therefore, to promote the implementation of regional molecular genetics platforms and facilitate equal and rapid access to personalised treatment for patients;

67. Calls for the full and rapid application of Regulation (EU) No 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use\textsuperscript{117}; considers that the application of the regulation would facilitate the launch of large clinical trials carried out in a harmonised, efficient and coordinated manner at European level in order to facilitate research into cancer drugs and improve cancer patients’ and their families’ quality of life;

68. Calls for a more sustainable environment for conducting research into the repurposing of medicines for cancer treatment and for the creation of an additional project that uses high-performance computing to rapidly test existing molecules and new drug combinations, starting with treatment for cancers with a poor prognosis and rare cancers;

69. Supports the development of clinical trials on the use of new cancer drugs in adults and


\textsuperscript{117} OJ L 158, 27.5.2014, p. 1.
70. Welcomes the Commission’s intention to adopt a legislative proposal to establish a Health Emergency Preparedness and Response Authority (HERA) in order to anticipate, incentivise, co-develop and facilitate rapid, equal and sustainable access to cancer innovations for cancer patients; calls for a large consortium of public authorities, private companies and NGOs, including patient associations, to work together to guarantee the accessibility and affordability of cancer treatment options requiring complex technologies, for instance, cellular therapy (CAR T cells), adoptive immunotherapy through the use of tumour genome extracts (messenger RNA) and nanotechnologies;

III.c. Equal access to cancer care: towards a better response to the impact of health crises on cancer patients

71. Underlines that the COVID-19 crisis has had, and is still having, a significant impact on cancer patients’ survival and quality of life at all stages of the disease, due to delays in screening, referral and surgical procedures, treatment postponement, shortages in the supply of medicines and other medical supplies, specialised workforce shortages and reduced communication with health professionals;

72. Considers that the COVID-19 pandemic was a real stress test for the EU’s health systems; underlines that the main lesson learned should be the need to build an emergency strategy to allow Member States to react accordingly in times of any future health crises; stresses that specific measures under this emergency strategy should be aimed at the protection of vulnerable groups, including cancer patients;

73. Notes with concern that the COVID-19 pandemic has exacerbated pre-existing health workforce shortages; acknowledges the urgency of ensuring a sufficient number of specialised health professionals in cancer care; reiterates that specific measures under the emergency strategy should be aimed at addressing workforce shortages through the recruitment of health professionals;

74. Advocates the development of a digital health system to monitor symptoms and ensure cancer treatment and care at home; calls for permanent access to medical consultations and psychosocial services to be guaranteed through the use of telemedicine or in health threat-free environments in hospitals;

75. Asks for enhanced communication between health professionals, patients and public authorities regarding the effectiveness and safety of health interventions, in particular cancer screening, diagnosis and treatment, and for increased awareness campaigns in times of crises;

76. Calls on the Commission and the Member States to adopt European prevention and management plans to address cancer drug shortages in times of health crises;

IV. Strong support to cancer patients, survivors and caregivers

77. Stresses that cancer patients should not suffer a ‘double punishment’ in their daily lives; calls for the adoption of an anti-discrimination directive, as well as for the fair and equal implementation of directives on financial services, such as the Consumer Credit Directive118,

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without any discrimination against cancer patients and survivors;

78. Emphasises the importance of specific EU recommendations to improve the quality of life of patients, including via supportive care (pain relief, psychological services, adapted physical activity, nutritional support, social assistance, access to reproductive health and restoration of aesthetic integrity); asks Member States for recognition of sequelae (physical or mental disabilities), as well as social discrimination;

79. Encourages Member States to take into account the frequent exhaustion of the families and relatives of cancer patients and to provide them with psychological assistance and rest periods in the workplace;

80. Recalls that patient empowerment is crucial for the European cancer strategy and that patient-centeredness and participatory decision-making must be at the heart of treatment and care development processes; encourages the therapeutic education of caregivers and patients and their empowerment in the care programmes;

81. Acknowledges the positive role of patients’ associations in relation to patient advocacy and accompaniment; calls on the Commission and the Member States to take into account their requests and recommendations when formulating cancer-related policies and legislation and to provide them with public support in order to guarantee their independence from private funding;

82. Calls on the Member States to improve the reintegration of cancer survivors into the labour market and to facilitate the return to school of paediatric cancer survivors; advocates specific EU recommendations for measures for cancer survivors to prevent the recurrence of primary cancer and the development of new cancers and for their rehabilitation;

83. Considers that the European Agency for Health and Safety at Work should be mandated to play a stronger role in promoting good practices in Member States with respect to the integration of cancer patients and survivors into the workplace and their protection from discrimination; looks forward to the new study, announced in Europe’s Beating Cancer Plan, on the return to work of cancer survivors, which will map national employment and social protection policies and identify obstacles and the remaining challenges;

84. Supports the upcoming roll-out of a Cancer Survivor Smart Card, as announced in Europe’s Beating Cancer Plan, to all European cancer survivors, especially survivors of childhood and adolescent cancers, which will summarise their clinical history, including patients’ own experience, and facilitate and monitor follow-up care;

85. Considers that insurers and banks should not take into account the medical history of people who have been affected by cancer; calls for national legislation to ensure that cancer survivors are not discriminated against compared to other consumers; notes the Commission’s intention to engage with businesses to develop a code of conduct to ensure that developments in cancer treatments and their improved effectiveness are reflected in the business practices of financial service providers; supports, in parallel, the promotion of advances made in France, Belgium, Luxembourg and the Netherlands, where cancer survivors enjoy the ‘Right to be Forgotten’; requests that by 2025, at the latest, all Member States should guarantee the Right to be Forgotten to all European patients ten years after the end of their treatment, and five years after the end of treatment for patients whose diagnosis was made before the age of 18; calls for the introduction of common standards for the Right to be Forgotten under the relevant provisions on consumer protection policy of the Treaty on the Functioning of the European Union, in order to remedy the fragmented national practices in the area of creditworthiness
assessment and ensure equal access to credit for cancer survivors;

86. Calls on the Commission to support the European Code of Cancer Care launched by the European Cancer Organisation (ECO), which is an empowering and informative tool to ensure that the best available care is provided to European citizens and patients;

87. Sees an urgent need for a European charter of the rights of cancer patients; calls for this charter to define the rights of cancer patients at every stage of their care pathway, i.e. access to prevention, initial diagnosis and throughout their treatment, and for it to apply equally to all EU citizens, regardless of the country or region in which they live;

V. Challenges in cancer among children, adolescents and young adults

88. Calls for clear policy requirements on paediatric cancer research needs; calls on Member States and the Commission to redress the unequal allocation of investment to paediatric cancers; considers that a clear and specific EU funding stream should be dedicated to paediatric cancer research and budget allocations earmarked across all relevant EU programmes;

89. Calls on the Commission and the Member States to focus on ensuring equal access to the best specialist diagnostics and multi-disciplinary treatment for children with cancer, and to improve cancer treatment outcomes in all Member States; considers that the professional figure of the paediatric oncologist should be recognised in all Member States;

90. Calls for adolescents and young adults (AYAs) with cancer to be recognised at EU level as a particular group with specific medical and psychosocial needs;

91. Stresses the need to strengthen the right to cross-border care for children and AYA cancer patients when the best treatment is not available in their country of residence;

92. Calls for an ambitious revision of the regulations on paediatric\(^\text{119}\) and orphan\(^\text{120}\) medicinal products in order to ensure access to innovative cancer drugs, identify the most important drugs to meet the needs of children with poor prognostic cancers, reduce delays so that children can have faster access to paediatric drugs, and address limited access to certain essential medicines due to drug shortages and the high price of innovative medicines; recommends an increase of 20 % in the available new paediatric cancer drugs by 2027;

93. Calls for the creation of an EU-level advisory group of stakeholders dedicated to childhood and AYA cancers, which could support the goal-driven and coherent implementation of relevant actions across Europe’s Beating Cancer Plan, Horizon Europe and the Pharmaceutical Strategy;

94. Calls on the Member States to fully transpose Directive (EU) 2019/1158 of 20 June 2019 on work-life balance for parents and carers\(^\text{121}\), which introduces leave for carers and the possibility to request flexible working time arrangements;

95. Welcomes the creation of an EU Network of Youth Cancer Survivors announced by the

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Commission;

96. Supports the recommendation of the Joint Action on Rare Cancers for the roll-out of a European unique patient identifier, in order to ensure the monitoring of long-term outcomes in childhood cancer survivors in a cross-border setting;

B. Tools for action

I. Holistic research

97. Stresses that Europe’s Beating Cancer Plan should be implemented in close cooperation with the Cancer Mission under Horizon Europe and its objectives of promoting EU investment in cancer research and innovation;

98. Recalls that cancer research, and its translation into everyday clinical practice, is fundamental to ensuring continuous improvements in cancer prevention, diagnosis, treatment and follow-up care for survivors; welcomes, therefore, the launch of Horizon Europe partnerships to translate scientific knowledge into innovations;

99. Reiterates its call for sustainable and adequate funding for competitive European research on cancer; calls for at least a 20% increase in the mobilisation of public and private research on therapeutic and diagnostic cancer innovations;

100. Stresses the need for independent and multidisciplinary research on cancer ‘from bench to bedside’, that is from the laboratory to applied studies in patients; urges the establishment of measures to limit misinformation, especially on social media;

101. Calls on Member States to make a strong commitment to encouraging public-private cooperation and breaking down the barriers to competitiveness across the EU;

102. Considers the significant potential impact of the use of artificial intelligence and modern technologies in diagnosis and decision-making for cancers in the coming years; encourages the Commission and the Member States to promote the knowledge of cancer biology through the implementation of genomics and informatics infrastructures;

103. Welcomes the launch of the Genomics for Public Health project which will give secure access to large amounts of genomic data to be used in 4P medicine (preventive, predictive, personalised and participatory);

104. Supports the creation of new digital resources and platforms, such as the European Cancer Imaging Initiative, and the strengthening of the European Cancer Information System, which will enable competent authorities to make good use of artificial intelligence applied to big data in the years to come;

105. Welcomes the launch of the ‘Cancer Diagnostic and Treatment for All’ flagship initiative under Europe’s Beating Cancer Plan, whose aim is to improve access to innovative cancer diagnosis and treatment and promote the use of the ‘next generation sequencing’ technology for quick and efficient genetic profiles of tumour cells, allowing researchers and clinicians to share cancer profiles and apply the same or similar diagnostic and therapeutic approaches to patients with comparable cancer profiles;
106. Welcomes the planned Partnership for Personalised Medicine, announced in Europe’s Beating Cancer Plan and to be funded under Horizon Europe, which will identify priorities for research and education in personalised medicine, support research projects on cancer prevention, diagnosis and treatment, and make recommendations for the roll-out of personalised medicine approaches in daily medical practice; supports the establishment of a roadmap for personalised prevention allowing for the identification of gaps in research and innovation and for the mapping of all known biological anomalies leading to cancer susceptibility, including hereditary factors;

107. Encourages research on non-profit clinical trials to improve treatment strategies, with a focus on the elderly;

108. Calls on the Commission and the Member States to promote studies dedicated to human and social sciences, in particular those addressing health inequalities at the different stages of cancer diseases;

109. Considers that the Commission and the Member States should support the development of European multicentre clinical trials;

110. Supports clinical research to evaluate the feasibility, efficacy and cost-effectiveness of non-treatment-related interventions, such as studies on health determinants (including environmental factors) and quality of life;

111. Strongly believes that patient associations should be involved in defining research endpoints for clinical trials, in order to ensure that the trials address the unmet needs of European patients; considers that the final results of the trials should be communicated to the participating patients and to the public;

112. Advocates more transparency in the process of research into and the development of cancer treatments, including the establishment of a portal to allow patients access to information on the available clinical trials in Europe;

II. Shared knowledge

113. Considers that the sharing of expertise, data, training programmes and communication tools is needed to improve the knowledge of cancer among both health professionals and patients; stresses the sensitive nature of health data and calls for full compliance with Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation));

114. Asks the Commission to assess the functioning of the European Reference Networks (ERNs), especially their role in gathering and sharing expertise and best practices, thus rationalising patient referral in the management of rare cancers, which affect an estimated 5.1 million patients across Europe and require cooperation on a large scale;

115. Emphasises the need to secure sustained long-term funding for the ERNs; supports the expansion of the ERNs to specific types of cancer (rare, complex, poorly curable) and paediatric cancers;

116. Believes that the revamping of ERNs will necessarily involve the participation of all Member States in existing ERNs, with each Member State having at least one ‘full’ or ‘affiliate’ member in each ERN, the facilitation of the individual patient journey through the effective collaboration of national contact points with ERNs, the evaluation of the functioning of the ERNs by sharing data on their performance and networking in the field of rare cancers, the deployment of telemedicine tools allowing for the sharing of case records and imaging results, and the allocation of adequate and long-term funding, both at Union (EU4Health) and national level;

117. Encourages Member States to support a dedicated and tailored approach to rare cancers in adults and paediatric cancers, taking stock of EU initiatives, and to fully integrate ERNs into their national healthcare systems;

118. Recalls that the Joint Research Centre has taken an active role in supporting the activities and harnessing the data of cancer registries; considers that the mandate, funding and political support for the Joint Research Centre to continue and accelerate its coordinating work with cancer registries should be strengthened;

119. Welcomes the launch of a Knowledge Centre on Cancer in 2021, announced in Europe’s Beating Cancer Plan, in order to contribute to the exchanges and coordination of scientific and technical initiatives related to cancer at EU level; believes that this knowledge centre should be based on data screening, ERN reports and cancer registries, and be part of a European Cancer Institute;

120. Recommends the creation of at least one cancer registry in each EU region, including remote and outermost regions; supports the strengthening of the capacity of national cancer registries to collect data (including lifestyle and socio-economic information) to better identify the causes of inequalities in cancer incidence, prevalence and survival; asks Member States to ensure the comparability of data sources and the interoperability of regional and national cancer registries;

121. Strongly supports the creation of a Cancer Inequalities Registry at European level, announced in Europe’s Beating Cancer Plan, in order to identify trends, disparities, inequalities and inequities between and within Member States; believes that this registry will help to identify challenges and specific areas of action so as to guide investment and intervention at EU, national and regional level;

122. Supports the Commission’s intention to enable cancer patients to securely access and share electronic health records across borders; considers that the Commission could lay the foundation for the European Health Data Space, in association with Digital Health Europe, by collecting and analysing anonymised medical data (from cancer registries, hospitals, academic clinical trials and cohorts) and biological data (from blood and tumour samples) in a European Cancer Cloud hosted by a European Cancer Institute; encourages the use of health data for non-commercial purposes (‘data altruism’); welcomes the planned creation of a virtual European Cancer Patient Digital Centre under Horizon Europe’s Mission on Cancer in order to support a standardised approach to the participation of willing patients in the deposit and exchange of their health data; recommends the inclusion of patients in any actions related to the storage and use of health data for policy-making and research purposes; welcomes the planned expansion of the European Cancer Information System before 2022;

123. Calls for improved standards in the education and training of health professionals; encourages common and multidisciplinary training programmes for health professionals in close collaboration with European learned societies; welcomes the launch of an inter-specialty
cancer training programme, which will involve cooperation between Member States via a European Cancer Institute;

**III. Creation of a European Cancer Institute**

124. Calls for the creation of a virtual European Cancer Institute, involving all stakeholders (representatives of each NCCP, patients’ and caregivers’ associations, learned societies etc.), in charge of the following missions:

a) coordinating the network of all NCCPs;

b) producing a European roadmap to trigger large-scale prevention campaigns and educational programmes on health promotion;

c) coordinating the establishment of common quality criteria to guide the national accreditation of screening programmes, cancer registries and cancer care centres;

d) hosting the planned Knowledge Centre on Cancer; drafting annual reports and establishing frameworks to improve data collection from screening programmes, cancer registries and ERNs at EU level;

e) coordinating the exchange of best practices and results between the ERNs and the Comprehensive Cancer Centres;

f) generating a comprehensive model based on Europe’s Beating Cancer Plan and Horizon Europe in order to identify research priorities and possibly enable the development of a coordinated and efficient cancer research force in Europe;

g) facilitating the sharing of anonymised data, collected in a European Cancer Cloud, for clinicians and researchers;

h) supporting common training programmes for health professionals, patients and caregivers;

i) delivering updated, certified and transparent information to citizens and professionals on cancer causes, treatments and EU legislation;

j) monitoring the level of implementation of relevant recommendations in the Member States’ NCCPs;

k) proposing measurable and reproducible indicators for the main outcomes outlined in Europe’s Beating Cancer Plan;

**IV. Financing Europe’s Beating Cancer Plan**

125. Emphasises that Europe’s Beating Cancer Plan should not only be seen as a political commitment to driving change but as a set of concrete and ambitious initiatives that will support, coordinate and complement Member States’ efforts to reduce the suffering caused by cancer; stresses that, in order for the initiatives outlined in the Plan to be translated into concrete actions, these initiatives have to be adequately funded; underlines, however, the differing capacity of Member States to absorb the funds dedicated to healthcare programmes.
thus far;

126. Calls on the Member States to ensure that enough funds are allocated for the appropriate implementation of the Plan and of their respective NCCPs; considers that no more than 30% of Europe’s Beating Cancer Plan should be allocated to the implementation of the NCCPs;

127. Welcomes the funding plan of EUR 4 billion and notes the complementarity of the sources of funding as set out in the Plan itself; recalls that the Plan will benefit from different sources of funding, such as the EU4Health, Horizon Europe and Digital Europe programmes, cohesion policy funds, and the Recovery and Resilience Facility; highlights the need to include the fight against cancer across all funding sources in a coherent and transparent manner; stresses, in particular, the importance of enhancing cancer research and cancer prevention and the need to dedicate more funds to them;

128. Instructs its President to forward this resolution to the Council, the Commission, the European Economic and Social Committee, the European Committee of the Regions, the governments and parliaments of the Member States, and the World Health Organization.
VII. Amendments and Compromise Amendments
1. An overview of the legislative process

Drawing conclusions from the public hearings and consultations, and from the debates in the committee, and responding to Europe’s Beating Cancer Plan that the Commission put on the table in February 2021, the Rapporteur prepared the draft report and presented it to the committee for an exchange of views on 15 July 2021.

The draft report elaborates upon four areas of actions:

(i) cancer prevention in all European policies;
(ii) inclusive screening and detection of cancer;
(iii) equal access to cancer care: quality of care, the potential of the European medicines market, and the impact of health crises on cancer patients and building back better after the crises; and
(iv) strong support to cancer patients, survivors and caregivers. Incentivising research; promoting knowledge sharing via the European Reference Networks, the Knowledge Centre on Cancer and the Commission’s JRC; and securing adequate financing also featured at prominent place in the draft report.

Link to the Draft report on “Strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy”

Further to the presentation of the draft report, the deadline for tabling amendments was set for 14 September 2021. Pursuant to the Rules of Procedure, only full or substitute members of the BECA Committee could table amendments, or their co-signature was needed on amendments signed by other Members. In total, 1537 amendments were tabled, which the Committee debated in two sessions on 14 October 2021 and 8 November 2021.

Link to the amendments tabled:
- Amendments 1 - 335
- Amendments 336 - 538
- Amendments 539 - 853
- Amendments 854 - 1183
- Amendments 1184 - 1537

Given the large number of amendments and the relevance of the topics they covered, the Rapporteur proposed to the Shadows to negotiate compromise amendments ahead of the committee vote. As usual, the purpose of compromise amendments is to find a common ground in terms of policy ambitions and wording that is acceptable to all political groups or at least to the majority of the groups. Three Shadows meetings were organised for this purpose between October and December 2021, and the Rapporteur and the Shadows managed to come to agreement on a comprehensive package of 144 compromise amendments.
On prevention, early detection and treatment, the compromises aim to develop new synergies between Europe’s Beating Cancer Plan and the EU4Health Programme, the Pharmaceutical Strategy, the Chemicals Strategy and the updated European Industrial Strategy. Alcohol and tobacco consumption, exposure to dangerous chemicals at work, air quality and lifestyle habits, as well as health literacy, access to screening, the revision of cancer screening programmes are among the key issues the compromise amendments deal with. The facilitation of access to cross-border healthcare for patients and the reimbursement of the related costs, and the maintenance and broadening of the scope of the European Reference Networks are also addressed in details.

For research and innovation, the compromises highlight opportunities for the creation of more national and cross-border clinical trials. The unique needs of childhood, adolescent, and other rare cancers are considered, together with a call for incentives to encourage innovation in these areas. The compromises also cover possibilities for joint evaluation, negotiation and purchase of cancer medicines and thereby opportunities to improve accessibility and affordability of essential and innovative cancer medicines.

Link to the compromise amendments
2. Compromise Amendments

European Parliament
2019-2024

Special Committee on Beating Cancer

2020/2267 (INI)

01.12.2021

FINAL

COMPROMISE AMENDMENTS

on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy
(2020/2267(INI))

Special Committee on Beating Cancer

Rapporteur: Véronique Trillet-Lenoir
MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION
on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy
(2020/2267(INI))

Compromise amendment on Paragraph -1 (new)
Replacing amendments 181-183, 205

Motion for a resolution

1. Welcomes Europe's Beating Cancer Plan and calls on the Commission to seek new synergies between the Plan and the EU4Health Programme, the Pharmaceutical Strategy, the Chemicals Strategy and the updated European Industrial Strategy; considers that such a comprehensive cancer framework would contribute to preventing, early detecting and curing cancer; calls on the Commission to work towards developing a common cancer policy which includes, where necessary, proposals for draft legislation;

A. Areas of action

I. Cancer prevention in all European policies

Compromise amendment on Paragraph 1
Replacing amendments 184-193, 206, 199, 202

Motion for a resolution

1. Strongly believes that preventive actions against cancer should be implemented in all European policies and funding programmes;

Draft compromise amendment

1. Strongly believes that comprehensive preventive actions against cancer, through measures supporting the elimination or reduction of harm caused by modifiable risk factors, should be implemented across all European policies and funding programmes;

calls on the Commission and the Member States to integrate public awareness raising campaigns about cancer prevention into all relevant policies;
calls on the Commission to streamline the
objectives of Europe’s Beating Cancer Plan into all relevant sectoral policies;
strongly believes that preventive actions should be evidence based;
therefore, calls on the Commission and Member States to increase the funding for scientific research into the causes of cancer and the efficiency and implementation of preventive measures;

Compromise amendment on Paragraph 2
Replacing amendments 194-204

Motion for a resolution
2. Calls on the Commission and Member States to design and implement effective prevention measures at national and EU level, based on best practices, independent expertise and guidance;

Draft compromise amendment
2. Calls on the Commission and Member States to design and implement effective prevention measures at national and EU level, that are based on independent scientific expertise, best practices and lessons learnt, and clinical guidance;
in this regard calls, in particular, for the implementation of the European Code Against Cancer (ECAC) to reduce cancer risks pursuant to latest scientific evidence, and for regular updates to the ECAC on a cycle that is based on continuous monitoring and evaluation;

Compromise amendment on Paragraph 3
Replacing amendments 207, 209-214, 366, 485, 511

Motion for a resolution
3. Acknowledges that more than 40 % of all cancers are preventable through coordinated actions on social, individual, environmental and commercial health determinants;

Draft compromise amendment
3. Acknowledges that more than 40 % of all cancers are preventable through coordinated actions on behaviour-related, biological, environmental, work-related, socio-economic and commercial health determinants;
calls for more attention to be dedicated to maintaining a healthy lifestyle to prevent cancer and reduce recurrence of certain cancers;
Compromise amendment on Paragraph 4
Replacing amendments 216-221

Motion for a resolution

4. Supports the aim of the Horizon Europe Cancer Mission to avert more than 3 million additional premature deaths over the 2021-2030 period, by accelerating progress in cancer prevention and control programmes and creating more equal access to these programmes;

Draft compromise amendment

4. Supports the aim of the Horizon Europe Cancer Mission to avert more than 3 million additional premature deaths over the 2021-2030 period, by accelerating progress in cancer prevention and control programmes, striving for equal opportunities in access to these programmes;
calls on the Commission to allocate adequate funding to the Horizon Europe Cancer Mission and other relevant programmes (such as 'Science and Policy for a Healthy Future' - HBM4EU) in order to achieve this objective;

Compromise amendment on Paragraph 5
Replacing amendments 222-237, 717, 1210

Motion for a resolution

5. Deplores the significant health inequalities in the EU as regards cancer prevention; insists on the need to pay special attention to vulnerable and marginalised populations in order to ensure their access to cancer prevention services;

Draft compromise amendment

5. Deplores the significant health inequalities and inequities in the EU as regards cancer prevention; insists on the need to identify as well as to pay special attention to vulnerable, marginalised, socially excluded populations, people living in remote areas (such as in rural, isolated or outermost regions far from medical centres), in order to ensure their access to cancer prevention services;

considers in this regard that cancer prevention also needs to be framed in the context of social justice, entailing the need for systemic changes through population-wide public policies beyond changes in individual behaviour;

Compromise amendment on Paragraph 7
Replacing amendments 244-249

**Motion for a resolution**

7. Strongly supports the goal of a ‘tobacco-free generation’, as set out in Europe’s Beating Cancer Plan, where less than 5% of the population uses tobacco by 2040, compared to around 25% today;

**Draft compromise amendment**

7. Strongly supports the goal of a ‘tobacco-free generation’, as set out in Europe’s Beating Cancer Plan, where less than 5% of the population uses tobacco by 2040, compared to around 25% today;

- urges the Commission to establish interim goals that are constantly monitored and promoted also at national level, and are reported within the Cancer Inequalities Registry in order to best direct efforts to achieve the overall target;

- calls on the Commission to fund programmes that promote smoking cessation;

- calls on the Commission to back cooperation between Member States in exchanging the best and most effective practices for reducing smoking;

Compromise amendment on Paragraph 8
Replacing amendments 250-271, 291-297, 303-308, 312-313

**Motion for a resolution**

8. Welcomes the Commission’s intention to review the Tobacco Products Directive\(^{10}\) , the Tobacco Products Tax Directive\(^{11}\) and the legal framework on cross-border purchases of tobacco by private individuals in order to introduce the following:

- an increase in minimum excise duties for all tobacco products, which could result in a reduction in tobacco use, notably among young people;

**Draft compromise amendment**

8. Welcomes the Commission’s intention to review the Tobacco Products Directive\(^{10}\) , the Tobacco Products Tax Directive\(^{11}\) and the legal framework on cross-border purchases of tobacco by private individuals, and urges the Commission to take appropriate measures and to bring forward legislative proposals, in order to introduce the following:

- an increase and an upward convergence in minimum excise duties for all tobacco products and their final market price, which would improve prevention by reducing tobacco uptake and use, notably among current smokers, and prevent young people from starting smoking;
(b) a requirement for plain packaging and the obligation to include health warnings on 80% of the front and back of cigarette packaging;

(c) a ban on flavourings in all tobacco products to reduce the appeal of these products to non-smokers and young people;

(d) an authorisation for Member States to introduce a ban on plastic cigarette filters on health and environmental grounds;

(e) the continuation of evaluations of the health risks related to electronic cigarettes and the establishment of a list of substances contained and emitted by these products at European level, based on the model published by the French Agency for Health Security;


Compromise amendment on Paragraph 8a (new)
Replacing amendment 290

Motion for a resolution

Draft compromise amendment

8 a. Calls for the evaluation and review of currently used measurement methods for tar, nicotine and carbon monoxide in tobacco and related products, based on independent and recent scientific research;
Compromise amendment on Paragraph 8b (new)
Replacing amendments 274, 275, 276, 277, 278

Motion for a resolution

Draft compromise amendment

8 b. Calls for the full implementation by Member States of the obligations under the Single Use Plastics Directive (Directive (EU) 2019/904) as regards filters in tobacco products containing plastics to address environmental and health concerns;

Compromise amendment on Paragraph 8c (new)
Replacing amendments 279-289, 298

Motion for a resolution

Draft compromise amendment

8c. Calls on the Commission to pursue the scientific evaluations of the health risks related to electronic cigarettes, heated tobacco products and novel tobacco products, including the assessment of risk of using these products compared to consuming other tobacco products, and the establishment of a list of substances contained in and emitted by these products at European level;

considers that electronic cigarettes could allow some smokers to progressively quit smoking;

considers at the same time that e-cigarettes should not be attractive for minors and non-smokers; therefore, calls on the Commission to evaluate, in the framework of the Tobacco Products Directive, which flavours in e-cigarettes are in particular attractive to minors and non-smokers, and propose a ban on these, as well as on all characteristic flavours in heated tobacco products and novel tobacco products;
Compromise amendment on Paragraph 9
Replacing amendments 299-302

Motion for a resolution

9. Calls for the rapid implementation of the WHO Framework Convention on Tobacco Control, paying specific attention to the protection of public health policies from the vested interests of the tobacco industry.

Draft compromise amendment

9. Calls for the rapid and complete implementation of the WHO Framework Convention on Tobacco Control (FCTC) and the WHO Protocol to Eliminate Illicit Trade in Tobacco Products, paying specific attention to the FCTC Article 5.3 and its guidelines on protection of public health policies from the vested interests of the tobacco industry;

urges the Commission to implement specific rules of conduct for all its officials and other servants when interacting with the tobacco industry, in line with the European Ombudsman’s decision in case 852/2014/LP;

Compromise amendment on Paragraph 11
Replacing amendments 317-335, 361, 363, 365

Motion for a resolution

11. Recalls that ethanol and acetaldehyde in alcoholic beverages are classified as carcinogenic to humans by the IARC, and that in Europe an estimated 10% of all cancer cases in men and 3% of all cancer cases in women are attributable to alcohol consumption;

Draft compromise amendment

11. Recalls that ethanol and acetaldehyde from ethanol metabolism in alcoholic beverages are classified as carcinogenic to humans by the IARC, and that in Europe an estimated 10% of all cancer cases in men and 3% of all cancer cases in women are attributable to alcohol consumption;¹ underlines that the lower the amount of alcohol consumed, the lower the risk of developing cancer is;

recalls that alcohol consumption is a risk factor for many different cancers, such as oral cavity, pharynx, larynx, oesophagus, liver, colorectal and female breast cancer;

recalls the study referred to by WHO which recognises that there is no safe level of alcohol consumption when it comes to cancer prevention, and stresses the need to take this into account when devising and implementing cancer prevention policy;²

¹ Scoccianti C., Cecchini M., Anderson A.S. et al., European Code against Cancer 4th Edition:
Compromise amendment on Paragraph 12
Replacing amendments 336-359

Motion for a resolution

12. Welcomes the Commission’s target of achieving a reduction of at least 10% in the harmful use of alcohol by 2025;

encourages the Commission and the Member States to promote actions to reduce and prevent alcohol-related harm within the framework of a revised EU alcohol strategy\(^\text{13}\);

supports the provision of better information to consumers by improving the labelling of alcohol beverages to include prominent warning labels and introducing the mandatory indication of the list of ingredients and nutritional information;

calls for the prohibition of alcohol advertising at sport events and for the prohibition of alcohol sponsorship of sport;

considers it important to protect children from commercial communication on calls for the prohibition of alcohol advertising at sport events when those

Draft compromise amendment

12. Welcomes the Commission’s target of achieving a reduction of at least 10% in the harmful use of alcohol by 2025;

encourages the Commission and the Member States to promote actions to reduce and prevent alcohol-related harm within the framework of a revised EU alcohol strategy\(^\text{13}\), including a European strategy of zero alcohol consumption for minors, accompanied, where appropriate, by legislative proposals, while respecting the principle of subsidiarity and existing national legislations on age limits on alcohol consumption;

supports the provision of better information to consumers by improving the labelling of alcohol beverages to include health warning labels and introducing the mandatory indication of the list of ingredients and nutritional information, and in addition, by introducing digital labelling;

asks the Commission to take specific actions targeting heavy and risky drinking\(^\text{1a}\);

considers it important to protect minors from commercial communication on alcohol consumption, as well as product placement and sponsorship of alcohol brands, including in the digital environment, as advertising shall not be aimed specifically at minors and shall not encourage consumption of alcohol;

calls for the prohibition of alcohol advertising at sport events when those
alcohol consumption, as well as product placement and sponsorship of alcohol brands, especially in the digital environment;
calls for the strong monitoring of the implementation of the revised Audiovisual Media Service Directive\textsuperscript{14};

encourages the allocation of public funds for national and European awareness campaigns; supports the planned review of EU legislation on the taxation of alcohol and on cross-border purchases of alcohol by private individuals and a review of alcohol pricing policies, \textit{including increasing taxes on alcoholic beverages};

\textit{events are mainly attended by minors} and calls for the prohibition of alcohol sponsorship of sport;
calls for the strong monitoring of the implementation of the revised Audiovisual Media Service Directive\textsuperscript{14};
\textit{calls for the upcoming proposal for Digital Services Act to strengthen the ability of Member States to uphold and enforce legislation seeking to protect minors and other vulnerable populations from commercial communication for alcoholic beverages};

encourages the allocation of public funds for national and European awareness campaigns; supports the planned review of EU legislation on the taxation of alcohol and on cross-border purchases of alcohol by private individuals and a review of alcohol pricing policies, \textit{including considering an increase of taxes on alcoholic beverages};

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\textsuperscript{13} Commission communication of 24 October 2006 on a EU strategy to support Member States in reducing alcohol-related harm (COM(2006)0625).


\textsuperscript{1a} \url{https://www.thelancet.com/journals/lancet/article/PIIS01406736(21)00279-5/fulltext}


Compromise amendment on Paragraph 13
Replacing amendments 360-362, 367-388
13. Emphasises the role of a healthy diet in cancer prevention and that individual cancer risks can be reduced by an appropriate intake of fruits and vegetables, and therefore welcomes the upcoming revision of the ‘EU school fruit, vegetables and milk scheme’;

asks the Commission and the Member States to help consumers to make informed, healthy and sustainable choices about food products via the adoption of harmonised, mandatory front-of-pack nutrition labelling, such as the Nutri-Score;

welcomes the focus on healthy nutrition in the EU Child Guarantee and calls for a new EU Action Plan on Childhood Obesity;

supports fiscal measures to make fresh foods (such as pulses, grains and vegetables) more affordable and accessible at national level, especially for people with low incomes;

encourages Member States to use pricing policies, such as value added tax differentiation, and marketing controls to influence demand for, access to and the affordability of food and drink low in saturated fats, trans-fats, salt and sugar;

supports Member States in restricting the advertising of ultra-processed food products and sugary and sweetened beverages, including on social media;

welcomes the focus on healthy nutrition in the EU Child Guarantee and calls for a new EU Action Plan on Childhood Obesity;

supports fiscal measures to make fresh foods (such as fruits and vegetables, pulses, legumes and wholegrains) more affordable and accessible at national level, especially for people with low incomes;

encourages Member States to use pricing policies, such as value added tax differentiation, and marketing controls to influence demand for, access to and the affordability of food and drink low in saturated fats, trans-fats, salt and sugar;

supports Member States in revising the relevant provisions to restrict the advertising of sweetened beverages and processed food products high in fats, salt and sugar, including advertising on social media; and calls on the Commission to come forward with a proposal for a

Compromise amendment on Paragraph 14
Replacing amendments 392-398

Motion for a resolution
14. Calls on Member States, regional and local governments, and civil society representatives to promote and facilitate the practice of sports activities, which is known to limit both the incidence and the recurrence of cancer, as well as mental health problems, and favour social inclusion;

Draft compromise Amendment
14. Calls on Member States, regional and local governments, civil society representatives and employers to promote and facilitate throughout life the practice of physical activities and sports, which are known to limit both the incidence and the recurrence of cancer, as well as to reduce mental health problems, and to favour social inclusion;

highlights the importance of making the practice of physical activities and sports accessible and inclusive from a young age, in particular for vulnerable groups, via financing public infrastructures, equipment and programs;

Compromise amendment on Paragraph 15
Replacing amendments 400, 401, 405

Motion for a resolution
15. Welcomes the launch of the EU’s ‘HealthLifestyle4all’ campaign involving the promotion of sports, physical activity and healthy diets, in addition to other key sectors;

Draft compromise amendment
15. Welcomes the launch of the EU’s ‘HealthLifestyle4all’ campaign involving the promotion of sports, physical activity and healthy diets, in addition to other key sectors;

recommends for schools to have health education included in their curricula, to ensure that minors and adolescents learn how to lead a healthy lifestyle and are made aware of the ECAC, and calls for health education to be an integral part of social assistance educational policies;
Motion for a resolution

16. Points out that radiation from the sun contains invisible ultraviolet (UV) radiation which can lead to skin cancer; supports the strengthening of protection against exposure to UV radiation at EU level, especially in the framework of occupational health and safety legislation for outdoor workers;

Draft compromise amendment

16. Points out that radiation from the sun contains invisible ultraviolet (UV) radiation which can lead to skin cancer; supports the strengthening of protection against exposure to UV radiation at EU level, especially in the framework of occupational health and safety legislation for outdoor workers;

welcomes the Commission’s commitment to explore measures on exposure to ultraviolet radiation, including from artificial tanning devices (sunbeds);

calls for stricter legislation on the use of sunbeds for cosmetic purposes and a ban on the use of it by minors;

calls therefore on the Commission to revise Directive 2006/25/EC on the exposure of workers to risks from physical agents (artificial optical radiation) and to include solar radiation into the scope;

points out the importance of information campaigns to make people aware of the risks associated to excessive sun exposure and to teach them how to recognise possible warning signs;

calls for specific measures to reduce exposure to UV radiations of minors and adolescents;

calls on Member States to include reporting of melanoma skin cancer in national cancer registries;


Compromise amendment on Paragraph 17
Replacing amendments 414-422
17. Acknowledges that around 2 % of the European cancer burden can be attributed to ionizing radiation and that indoor exposure to radon and its decay products is the second leading cause of lung cancer in Europe;

looks forward to the results of the Euratom Research and Training Programme\textsuperscript{17}, which will improve knowledge on exposure to radon, and the proposed countermeasures to reduce its accumulation in dwellings;

encourages Member States to regularly update their national plans to reduce exposure to radon, as requested in the Directive on Exposure to Radioactive Sources\textsuperscript{18};

calls on the Commission to introduce measures to protect workers exposed to ionising radiation such as airline crews, nuclear power plant workers and health professionals working in the radiology, radiotherapy or nuclear medicine sectors;

calls on the Commission to assess the implementation and effectiveness of current measures to protect workers exposed to ionising radiation such as airline crews, nuclear power plant workers, workers in relevant industrial settings, researchers and health professionals working in the radiology, radiotherapy or nuclear medicine sectors and review them where necessary, in order to set proportionate measures;

\textsuperscript{17} Council Regulation (Euratom) 2021/765 of 10 May 2021 establishing the Research and Training Programme of the European Atomic Energy Community for the period 2021-2025 complementing Horizon Europe – the Framework Programme for Research and Innovation, OJ L

\textsuperscript{18} Council Regulation (Euratom) 2021/765 of 10 May 2021 establishing the Research and Training Programme of the European Atomic Energy Community for the period 2021-2025 complementing Horizon Europe – the Framework Programme for Research and Innovation, OJ L
Compromise amendment on Paragraph 17a new
Replacing amendments 425 and 426

**Motion for a resolution**

17a. Calls on the Commission to promote multidisciplinary scientific research on the existence of links between electromagnetic fields (EMFs), including 5G, and cancer in order to gather scientific evidence on the long-term effects of EMFs and to inform the public in a timely manner of the outcome of those studies; calls for the promotion of research into the development of technology that reduces radio frequency exposure;

**Draft compromise amendment**

17a. Calls on the Commission to promote multidisciplinary scientific research on the existence of links between electromagnetic fields (EMFs), including 5G, and cancer in order to gather scientific evidence on the long-term effects of EMFs and to inform the public in a timely manner of the outcome of those studies; calls for the promotion of research into the development of technology that reduces radio frequency exposure;

Compromise amendment on Paragraph 18
Replacing amendments 428-446

**Motion for a resolution**

18. Sees the European Green Deal as a contributing factor in cancer prevention in Europe, via the reduction of air, food, water and soil pollution and of chemical exposure;

calls for an evaluation of the impact of policies on cancer incidence to be integrated into the Farm to Fork Strategy and the Chemical, Zero Pollution and Non-Toxic Environment Strategies;

welcomes the upcoming revision of the EU’s air quality standards to align them with WHO guidelines;

**Draft compromise amendment**

18. Sees the European Green Deal as a **significant** contributing factor in cancer prevention in Europe, via the reduction of air, food, water and soil pollution and of chemical exposure;

calls for an evaluation of the impact of policies on cancer incidence to be integrated into the Farm to Fork Strategy, the Chemicals **Strategy for Sustainability**, the Zero Pollution and the Non-Toxic Environment Strategies;

welcomes the upcoming revision of the EU’s air quality standards and **calls on the Commission** to align them with WHO guidelines **as referred to in Parliament’s resolution of 25 March 2021 on the**
calls on the Commission to ensure that the common agricultural policy reduces the intake of pesticide residues;

encourages the use and development of medicines that are safer for the environment;

implementation of the Ambient Air Quality Directives1;

calls on the Commission to ensure that the common agricultural policy accompanies farmers to reduce the use of pesticides;

encourages the research into, use and development of medicines that are safer for the environment, as well as implementing efficient waste removal mechanisms that avoid polluting the environment, in line with the objectives of the Pharmaceutical Strategy for Europe;

Compromise amendment on Paragraph 19
Replacing amendments 447-451

Motion for a resolution

19. Looks forward to the implementation of the revised Drinking Water Directive19 and the implementation and enforcement of the Water Framework Directive20, which will reduce the concentrations in surface and ground waters of certain pollutants that could contribute to cancer incidence;

Draft compromise amendment

19. Stresses the need for full implementation of the revised Drinking Water Directive19 and the implementation and enforcement of the Water Framework Directive20, which will reduce the concentrations in surface and ground waters of certain pollutants, that could contribute to cancer incidence;


Compromise amendment on Paragraph 20
Replacing amendments 452-462
Motion for a resolution

20. Calls for the registration, evaluation, authorisation and restriction of chemicals under the REACH Regulation to be conducted in association with the IARC assessments;

calls on the Commission to adopt effective guidance and legislation to reduce citizens’ exposure to carcinogenic substances;

Draft compromise amendment

20. Calls in particular for the strengthening of the information requirements on carcinogenicity under REACH to enable identification of all carcinogenic substances manufactured or imported, irrespective of the volume, in line with the Chemicals Strategy for Sustainability, and for the registration, evaluation, authorisation and restriction of chemicals including endocrine disrupting chemicals under the REACH Regulation to be conducted in association with the IARC and the WHO assessments;

welcomes the commitment of the Chemicals Strategy for Sustainability to extend the generic approach to risk management to ensure that consumer products do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative toxic;

calls on the Commission to swiftly implement the measures planned in the Chemicals Strategy for Sustainability to reduce citizens’ exposure to carcinogenic and endocrine disrupting substances through all exposure pathways;

calls on the Commission to give particular attention to segments of the population that are particularly vulnerable to hazardous chemicals and to better take into account those vulnerable populations in the risk assessments of chemicals;

stresses that information to consumers on exposure pathways in their everyday life is key to strengthen prevention, and welcomes in this regard the establishment of the 'Substances of Concern in Products' (SCIP) database;

calls on the European Environmental Agency to produce a report, together with the European Chemicals Agency, on chemicals in the environment in Europe; requests that the report assesses the systemic nature of carcinogenic and endocrine disrupting chemicals within...
Europe’s production and consumption systems, their use in products, occurrence in Europe’s environment, and the harm caused to human health, especially concerning cancer;

Compromise amendment on Paragraph 21
Replacing amendments 439, 463-472

Motion for a resolution

21. Considers that the next review of the European Code Against Cancer (ECAC) will have to take into account the latest knowledge on environmental carcinogens;
calls for the regulation on food contact materials\textsuperscript{22} to be reviewed in order to reduce exposure to carcinogens and endocrine disruptors;

Draft compromise amendment

21. Considers that the next edition of the European Code Against Cancer (ECAC) will have to take into account the latest knowledge on environmental carcinogens;
calls on the Commission to propose without delay a revision of Article 68(2) of REACH, the regulation on food contact materials\textsuperscript{22}, the regulation on cosmetic products\textsuperscript{1a}, the directive on toys safety\textsuperscript{2a} and other relevant consumer product legislation to ensure that consumer products do not contain chemicals that cause cancer in line with the Chemicals Strategy for Sustainability; calls, furthermore, for the regular revision of that legislation to take account of the development of new materials, trends and products;

underlines that endocrine disruptors (EDs) are present in food, food contact materials, cosmetics, consumer goods, toys, as well as drinking water, and that exposure, even at low doses, can induce adverse effects in the short and long term, including cancer\textsuperscript{3a};

highlights that given the widespread exposure of the EU population to many suspected and known EDs and the fact that combined exposure to several EDs acting on similar or different pathways can have
cumulative effects, there is a need to minimise exposure to EDs and to make EU regulation more consistent across sectors;

encourages further research in order to determine the capacity of chemicals to act as endocrine disruptors;

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Compromise amendment on Paragraph 22
Replacing amendments 475-484, 486, 487, 682, 1395

Motion for a resolution

22. Recalls that exposure at work is responsible for at least 120,000 deaths from cancer each year in the EU;

Draft compromise amendment

22. welcomes the publication of the new EU Strategic Framework on Health and Safety at Work for the 2021-2027 period notably the 'Vision Zero' approach to work-related deaths as well as the planned stocktaking occupational health and safety summit in 2023 to evaluate progress towards 'Vision Zero'; stresses the need for close and regular involvement of social partners and stakeholders in this strategy; regrets, however, the limited number of substances addressed in the strategy;

looks forward to the forthcoming new EU Strategic Framework on Health and Safety at Work for the 2021-2027 period,

encourages the constant analyses and research on new substances under suspicion of being carcinogenic, mutagenic and/or reprotoxic (CMRs), the establishment of OELs for those chemical
agents for which they do not yet exist, and periodic revisions whenever this becomes necessary in the light of more recent scientific data and technical developments; welcomes the workers survey prepared by the European Agency for Safety and Health at Work (EU-OSHA) on exposure to cancer risk factors; stresses that more systematic human biomonitoring programmes in full compliance with data protection measures, both in occupational settings and non-occupational settings, can be one of several relevant sources of information on general chemical exposure effects and health impacts;

calls therefore on the Commission to increase its ambition as a matter of urgency through ambitious and regular updates of Directive 2004/37/EC of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work\textsuperscript{23}, and the addition of further binding occupational exposure limits within that directive;

\textit{the regular update} of Directive 2004/37/EC of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work\textsuperscript{23}, and the addition of further binding occupational exposure limits within that directive;

calls therefore on the Commission to increase its ambition as a matter of urgency through ambitious and regular updates of Directive 2004/37/EC of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work\textsuperscript{23}; to do so, calls on the Commission, following consultation of the Advisory Committee on Health and Safety, to present an action plan to achieve occupational exposure limit values for at least 25 additional substances, groups of substances or process-generated substances by 2024; stresses in that regard the need for the Commission to increase the capacity for reviewing OELs and adding new ones, including through increased staffing in relevant units and authorities;

reminds, in this regard, the opportunity of the ongoing negotiations on the fourth revision of Directive 2004/37/EC, as well as to include in Annex 1 work involving exposure to Hazardous Medicinal Products meeting the criteria for classification as carcinogenic, mutagenic and/or toxic for reproduction category 1A or 1B set out in Annex 1 to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, in order to ensure the best possible general and individual
protection measures for workers handling these products; reiterates its calls for a new coherent, transparent and risk-based system to be established for setting exposure limits and to better take into account workers’ exposure to a combination of substances;

welcomes the commitment by the Commission\textsuperscript{1c} to add endocrine disruptors as a category of substances of very high concern under Regulation (EC) No 1907/2006 (REACH regulation) as well as to classify them under Regulation (EC) No 1272/2008 (CLP Regulation); stresses that workers should also be protected against exposure to endocrine disruptors;

welcomes the Commission’s commitment to presenting in 2022 a legislative proposal to further reduce workers’ exposure to asbestos, a proven carcinogen (group 1) according to the IARC which remains responsible for around half of all occupational cancers in Europe; reiterates in this regard the Parliament’s requests in its resolution of 20 October 2021 on protecting workers from asbestos, in particular its call for a European Strategy for the Removal of all Asbestos (ESRAA) and its proposals for a better evaluation of the risks linked to non-occupational exposure to asbestos;

asks Member States to facilitate recognition of and compensation for proven work-related cancers;

asks Member States to facilitate recognition of and compensation for proven work-related cancers; and to reinforce the control of work-related exposure by labour inspectorates;

\textsuperscript{23} OJ L 158, 30.4.2004, p. 50.

Compromise amendment on Paragraph 23
Replacing amendments 488-508, 571,639,640
Motion for a resolution

23. Encourages the Commission and the Member States to promote the prevention of cancers related to infectious diseases;

recalls that human papillomavirus (HPV) is a sexually transmitted infection associated with uterine, cervical and oropharyngeal cancers;

welcomes the vaccination programmes in the fight against HPV transmission;

notes and regrets major discrepancies in vaccination coverage between Member States, ranging from less than 30 % to more than 70 % (with the required level of population immunity being at 70 %);

insists that a gender-neutral HPV vaccination programme be implemented in the Member States to ensure the elimination of all HPV-related cancers;

considers it important to draw up further recommendations to better implement these programmes;

Draft compromise amendment

23. Encourages the Commission and the Member States to reach the UN SDGs targeting communicable diseases in order to promote the prevention of cancers related to infectious diseases;

welcomes the vaccination programmes in the fight against HPV transmission;

insists that a gender-neutral and publicly financed HPV vaccination programme be implemented in the Member States, to ensure the elimination of all HPV-related cancers, and calls for 90% of girls to be fully vaccinated, and for a significant increase in the vaccination of boys, with the HPV vaccine by the age of 15 by 2030;

urges that progress towards the goals of Europe's Beating Cancer Plan on HPV vaccination be reported within the Cancer Inequalities Registry;

calls on Member States to implement the Council recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases (2018/C 466/01) to reduce immunisation inequalities among vulnerable groups and improve childhood immunisation; welcomes the Commission’s intention to propose a Council recommendation on vaccine-preventable cancers; in this context, stresses the need for coordinated actions targeting carcinogenic viruses, such as HPV and HBV, in order to prevent their transmission;

calls for more harmonisation of HPV and the
hepatitis B vaccination within Member States’ national programmes, while ensuring the provision of information about and equal access to vaccination; vaccination against HPV and HBV within Member States’ national programmes, while ensuring the provision of information about vaccination and promoting equal access for vulnerable and at-risk adult groups; encourages the regular monitoring of current HPV and HBV vaccination at EU level, using a tracking system similar to the COVID-19 vaccine tracker developed by the European Centre for Disease Control and Prevention, that will also encourage Member States to adopt best practice and maintain momentum; calls on the Member States for data harmonisation, interoperability and enhanced development of national immunisation data systems; underlines that the European Centre for Disease Prevention and Control will play a key role in tracking Member States’ progress; supports further research for vaccine development against other viruses such as HCV and HIV; considers that in the meantime therapeutic solutions ought to be used massively to reach the WHO’s goal of eradicating hepatitis C by 2030, and calls on the Commission to use the financial resources under the Recovery and Resilience Fund to reach these targets by funding the screening efforts; supports further research into the most effective vaccination schedules against other carcinogenic viruses such as hepatitis C; supports further research into the most effective vaccination schedules against other carcinogenic viruses such as hepatitis C; calls for collaboration with Member States and international organisations to combat the impact of misinformation on vaccination and address vaccine hesitancy; calls for collaboration with Member States and international organisations to combat the impact of misinformation on vaccination and address vaccine hesitancy; calls for the utilisation of EU4Health and other EU funding streams for this purpose, including for support to awareness-raising efforts with citizens, education providers and healthcare professionals as well as for support to behavioural research under the Horizon Europe programme; recommends a strengthened application of the EU's Code of Practice on Disinformation particularly with regard to vaccine misinformation;
Motion for a resolution

25. Points out that genetic predisposition to cancer linked to mutations of specific genes has been demonstrated;

highlights that methods to detect these mutations are available, especially for breast and colorectal cancers, and may help to prevent or detect early-stage cancer;

Draft compromise amendment

25. Points out that genetic predisposition to cancer linked to mutations of specific genes has been demonstrated;

highlights that methods to detect these mutations are available, either at birth for early detection of certain paediatric cancers or over the course of a lifetime, especially for breast, ovarian and colorectal cancers, and that the detection of these mutations may help to prevent or detect early-stage cancer and guide treatment choices;

recommends therefore that Member States support increased access for patients in all age groups for genetic testing coupled with medical counselling and advanced sequencing diagnostics by earmarking financing and creating clear pathways for fast and efficient reimbursement, and raise awareness about to what extent citizens can access such services in the Union;

recommends boosting investment in infrastructure and skills in genetic sequencing platforms and the training of specialised genetic counsellors in specific units that already exist in some centres;

calls on the Commission to support research in genetics, to find genotypes with higher susceptibility to develop certain cancers, including childhood cancers, as a disease with short exposure to external agents;

Compromise amendment on Paragraph 25a (new)
Replacing amendment 532
Motion for a resolution

Draft compromise amendment

25a. Highlights that techniques such as molecular epidemiology can provide new insights into the gene-environment interactions in cancer compared to regular epidemiology; points out that these insights, together with further studies in epigenetics, can be used to improve the understanding of risk factors contributing to cancer causes and increase early detection;

Compromise amendment on Paragraph 26
Replacing amendments 533-538

Motion for a resolution

26. Strongly supports the planned revision of the ECAC and the launch of an EU mobile app for cancer prevention and care, as announced in Europe’s Beating Cancer Plan, in order to develop, share and implement best practices in cancer prevention and care programmes, with a focus on disadvantaged groups;

stresses that the ECAC should be systematically evaluated and that the evaluation work should be coordinated by the IARC;

Draft compromise Amendment

26. Strongly supports the planned revision of the ECAC in order to develop, share and implement best practices in cancer prevention programmes, with a dedicated focus on disadvantaged groups, and the launch of a user-friendly EU mobile app which accompanies people from cancer prevention and education to care, as announced in Europe’s Beating Cancer Plan;

highlights that in addition to the mobile apps, all up-to-date information should also be available in non-digital format to ensure inclusiveness;

stresses that the ECAC should be systematically evaluated by IARC and that the evaluation work should continue to be coordinated by the Commission;

Compromise amendment on Paragraph 27
Replacing amendments 539-544, 696
Motion for a resolution

27. Encourages the Commission and the Member States to promote health literacy as regards cancer risks and determinants, to develop educational tools for prevention and to support the creation of e-learning platforms and applications;

calls for particular attention be paid to disadvantaged, vulnerable, socially excluded, and marginalized people, and underlines that specific awareness-raising campaigns for groups with particular health literacy needs are essential;

notes the importance of increasing health literacy as regards carcinogenic substances at work, and calls on the Commission and Member States to ensure that employers provide the appropriate training;

underlines that primary healthcare providers have an important role in health promotion for various population groups since they can adapt their health promotion actions to the needs of patients with a varying degree of, or without, digital skills;

considers cancer prevention to be a first step towards a European public health education policy;

Compromise amendment on Paragraph 28
Replacing amendments 546-553

Motion for a resolution

28. Calls for the creation of a virtual European Cancer Institute, which would be in charge of establishing a European roadmap to devise and coordinate large-scale prevention campaigns and effective communication campaigns on health promotion in educational programmes (harmless behaviours, healthy nutrition, physical activity etc.) with a special focus

Draft compromise amendment

28. Calls for the continuous strengthening of the Knowledge Centre on Cancer, which would be tasked with establishing a European roadmap to devise and coordinate large-scale prevention campaigns, in synergies with national programmes, and effective communication campaigns on health promotion in educational programmes (harmless
on young people and disadvantaged groups;

behaviours, healthy nutrition, physical activity, *transmission routes of carcinogenic viruses and vaccination and treatment opportunities for such infections*, etc.), with a special focus on young people and disadvantaged groups;

notes the importance of cooperating with national and local civil society organisations when developing the messaging of such campaigns;

Compromise amendment on Paragraph 29
Replacing amendments 554-570

Motion for a resolution

29. Underlines that tobacco and alcohol consumption, poor nutrition, a high body mass index and a sedentary lifestyle are risk factors common to other chronic diseases;

believes, therefore, that cancer prevention *has* to be implemented in the context of an integrated chronic disease prevention programme, in close cooperation with the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases;

Draft compromise amendment

29. Underlines that tobacco, and alcohol consumption, poor nutrition, a high body mass index, a sedentary lifestyle *and environmental pollution* are risk factors common to other chronic diseases;

believes, therefore, that cancer prevention *and risk reduction measures have* to be implemented in the context of an integrated chronic disease prevention programme, in close cooperation with the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases;

calls for a stocktaking prevention summit focussing on commercial determinants of cancer and other chronic diseases, gathering the EU institutions, Member States, patient associations and civil society organisations active in the field of health;

Compromise amendment on Paragraph 30
Replacing amendments 572-577, 718
30. Calls for the implementation of prevention programmes to be inclusive, by involving citizens, civil society and patient associations, especially through the Conference on the Future of Europe;

30. Calls for the implementation of prevention programmes to be inclusive, by involving regions and municipalities, citizens, social partners, civil society and patient associations at all steps of decision-making process, especially through the Conference on the Future of Europe;
II. Inclusive screening and detection of cancer

Compromise amendment on Paragraph 31
Replacing amendments 578-585

Motion for a resolution

31. Deplores the frequent delays to cancer diagnosis related to a lack of information or adherence to cancer screening and detection processes;

recognises the need to pay particular attention to the continuity of screening programmes and early detection in the context of a health crisis (such as the COVID-19 crisis);

Draft compromise amendment

31. Deplores the frequent delays and shortcomings to timely diagnosis of symptomatic cancers related to a lack of information or adherence to cancer screening and detection processes;

recognises the need to pay particular attention to the continuity of screening programmes and early detection and cancer care services in the context of a health crisis (such as the COVID-19 crisis) or in situations where the capacity of the healthcare systems decreases; encourages the Commission and Member States to organise, in partnership with cancer stakeholders, public health campaigns to address any delays in screening, early detection and care that a health crisis might cause; stresses the importance of quick and up-to-date data on cancer screening programmes to enable swift reaction and follow-up in case of disruptions in regular screening capabilities with a goal of reducing the number of postponed screenings to an absolute minimum;

Compromise amendment on Paragraph 32
Replacing amendments 589-591, 713-716, 720

Motion for a resolution

32. Regrets the inequalities between Member States in access to breast cancer screening, which differs at least tenfold across the EU according to Eurostat;

[repositioned text]

Draft compromise amendment

32. Regrets the inequalities between Member States in access to cancer screening, resulting in lesser chances of survival due to late diagnosis of cancer, which represents an unacceptable discrimination for EU citizens based on their country of residence;

underlines that in the case of breast cancer screening, differences in coverage are at least tenfold across the EU according to
notes that, for instance, only 18 Member States reported that they had national or regional population-based screening programmes in place; notes that, for instance, only 18 Member States reported having national or regional population-based screening programmes for breast, cervical and colorectal cancers according to the most recent report by the IARC on the implementation of the 2003 Council Recommendations on screening;

calls on the Commission to support projects, for example via EU4Health, Horizon Europe's Cancer Mission or other relevant programmes, to explore the barriers limiting the early detection and early diagnosis of cancer in Europe;

Compromise amendment on Paragraph 33
Replacing amendments 594-601

Motion for a resolution

33. Invites Member States to work together to reduce inequalities in cancer screening and early diagnosis services, especially in cross-border regions;

Draft compromise amendment

33. Invites Member States to work together, especially in cross-border regions and isolated areas (including mountain areas and urban areas remote from screening centres), to reduce social and geographical inequalities in cancer screening and early diagnosis services;

Compromise amendment on Paragraph 34
Replacing amendments 603, 607-616, 618, 627, 699-703, 592-593

Motion for a resolution

34. Supports the launch of a new EU-supported Cancer Screening Scheme, as announced in Europe’s Beating Cancer Plan, to help Member States to ensure that 90 % of the EU population who qualify for breast, cervical and colorectal cancer screenings are offered screening by 2025;

Draft compromise amendment

34. Supports the launch of a new EU-supported Cancer Screening Scheme, as announced in Europe’s Beating Cancer Plan, to help Member States to ensure that 90 % of the EU population who qualify for breast, cervical and colorectal cancer
screenings are offered screening by 2025;
calls on the Commission to include other cancers, based on latest scientific evidence, into the Scheme with clear targets for each type of cancer; supports research on other types of cancers, which may be effectively detected by screening;
calls on the Commission to evaluate every two years the results of the Cancer Screening Scheme in terms of equal access of the targeted population, to keep track of inequalities between Member States and regions, propose appropriate new measures and correlate screening programmes with the latest cancer screening research results; if necessary, calls on the Commission to present measures for increasing the coverage of screening and prevention services in the Member States;
urges the Member States and the Commission to report and monitor the achievement of screening targets via the Cancer Inequalities Registry;

Compromise amendment on Paragraph 35
Replacing amendments 208, 215, 586, 587, 621-625, 628, 638, 697

Motion for a resolution
35. Encourages Member States to promote cancer screening for breast, cervical and colorectal cancers as part of organised population-based national and regional programmes, including in the remote and outermost regions, and provide adequate resources;

Draft compromise amendment
35. Encourages Member States to promote cancer screening for breast, cervical and colorectal cancers, as part of organised population-based national and regional programmes, including in the remote and outermost regions, and provide adequate resources; reiterates that, at the same time, there should be increased focus on screening, diagnosis and treatment initiatives for cancers that cannot be prevented, under Europe's Beating Cancer Plan;
encourages the Commission and the Member States to promote targeted screening for high-risk groups;
strongly recommends to Member States to develop a comprehensive screening policy which allows for timely screening when cancers with hereditary characteristics are detected;

recommends that Member States introduce research programmes into, and the development of, effective, accurate, non-invasive and innovative early diagnosis methods, such as biomarkers, for different types of cancer;

recommends that Member States roll out programmes for early clinical detection of oral and skin cancers;

Compromise amendment on Paragraph 36
Replacing amendments 602, 626, 629-634, 818

Motion for a resolution

36. Calls for the full implementation by Member States of the European guidelines for quality assurance in cancer screening for breast, cervical and colorectal cancers and early detection services, to minimise the delay to diagnosis for such cancers;

recommends that inequalities within Member States regarding screening be addressed, possibly by making the criteria for cancer screening, as well as the legal frameworks, governance and quality assurance structures, more stringent;

Draft compromise amendment

36. Calls on the Commission and the Member States for the full implementation of the European guidelines for quality assurance in cancer screening for breast, cervical and colorectal cancers, and early detection services to minimise the delay to diagnosis for such cancers;

recommends that inequalities within Member States regarding screening be addressed, possibly by making the criteria for cancer screening, as well as the legal frameworks, governance and quality assurance structures, more stringent and science-based;

considers that, in order to address disparities in cancer screening, common standardised screening protocols are needed at EU level, going beyond best practices guidelines, e.g. on algorithms for the organisation of screening programmes and indicators for assessing the quality of the screening programmes;

Compromise amendment on Paragraph 37
Replacing amendments 635, 636
Motion for a resolution

37. Encourages the improvement and harmonisation of cancer screening data collection to allow for an annual European report; encourages, too, the regular monitoring of current screening programmes at EU level;

Draft compromise amendment

37. Encourages the improvement and harmonisation of cancer screening data collection to allow for an annual European report; encourages, too, the regular monitoring of current screening programmes at EU level;

highlights the need to link data sets from screening programmes on cancer incidence with occupational categories, which can help to identify appropriate preventive measures; considers that stepping up public health services (including financing, infrastructure and aspects involving health professionals) is key to improving cancer prevention, screening and diagnosis; stresses the importance of screening for and collecting data on common cancer comorbidities in order to better anticipate them;

underlines that scientific advances in cancer risk prediction should allow for the development of risk-appropriate screening programmes;

Compromise amendment on Paragraph 38
Replacing amendments 642-661, 697

Motion for a resolution

38. Welcomes the upcoming update of the 2003 Council recommendation on breast, cervical and colorectal cancer screening to take into account new screening tests and the most recent data on the best screening protocols (magnetic resonance imaging, HPV testing);

Draft compromise amendment

38. Welcomes the process initiated by the Commission’s Group of Chief Scientific Advisors and the Scientific Advice Mechanism on the upcoming update of the 2003 Council recommendation on breast, cervical and colorectal cancer screening to take into account new screening tests and the most recent data on the best screening protocols (magnetic resonance imaging, HPV testing, risk stratified approaches and risk calculators);

emphasises that those programmes should be regularly evaluated by the competent...
calls for research efforts to be fostered in order to assess, in close cooperation with the IARC and the WHO, the possible inclusion of new science-based cancer screening programmes (including lung, prostate, stomach and ovarian cancers) in the recommendation;

 Calls on the Commission to develop EU guidelines for research efforts to be fostered, in order to assess, in close cooperation with the IARC, the WHO, healthcare professionals and patient organisations, the inclusion of new science-based cancer screening programmes (including lung, prostate, stomach and ovarian cancers) and the role of AI in the framework of the update of the Council recommendations in 2022;

 calls for recognising the evidence that proves the positive effect of targeted lung cancer screening on mortality; encourages the Council, based on the outcome of the above mentioned assessment, to consider including lung and prostate cancer screening in the update of the Council recommendations in 2022;

 further to the opinion of the Commission’s Chief Scientific Advisors and the 2022 update of the Council Recommendations on Cancer Screening, calls for clear and tangible targets to be set on any new cancers to be addressed by the Commission;

Compromise amendment on Paragraph 39
Replacing amendments 603-605, 667-669

Motion for a resolution

39. Advocates the launch of a platform for national screening centres to share expertise and implement best practices, discuss common challenges and encourage collaboration, based on the model of the European Network for Health Technology Assessment (EUnetHTA);

Draft compromise amendment

39. Advocates the launch by the Commission and the Member States of a European platform for national screening centres, drawing on the experience of similar platforms for exchange and cooperation such as the European Network for Health Technology Assessment.
and the Heads of Medicines Agencies (HMA);

recommends that this platform be entrusted with (i) sharing expertise and implement best practices, (ii) discussing common challenges, (iii) encouraging collaboration, training and capacity-building for improving quality in screening programmes, (iv) acting as central hub for projects and initiatives on cancer screening supported by the EU, and (v) maintaining in the long term the network of data providers to the implementation report by the IARC on cancer screening;

Compromise amendment on Paragraph 40
Replacing amendments 670-681, 683

Motion for a resolution
40. Stresses the importance of increasing the uptake of cancer screening and early detection among EU citizens through European Awareness Days, motivation surveys and better implementation of existing communication campaigns;

draft compromise amendment
40. Stresses the importance of increasing awareness about, and the uptake of, cancer screening and early detection among EU citizens, via a Union-wide awareness raising campaign through European Awareness Days, motivation surveys and better implementation of existing communication campaigns;

calls on the Commission and the Member States to support, fund and implement further actions aimed at raising awareness about cancer screening, and promoting participation in screening both among the general population and to eligible citizens via direct notifications;

encourages Member States to actively work on educational strategies in primary healthcare centres;

encourages research into behavioural adherence factors and obstacles impeding early detection and diagnosis of cancer to boost participation in screening programmes, supported by European funding such as the Horizon Europe
Compromise amendment on Paragraph 41
Replacing amendments 684-693

Motion for a resolution

41. Calls for reinforced cooperation with third countries to encourage the organisation of screening campaigns, in particular for women’s cancers and notably in low- and middle-income countries;

Draft compromise amendment

41. Calls for reinforced cooperation with third countries and especially with the broader European region, to encourage the organisation of screening campaigns and early diagnosis programmes, in particular for women’s cancers and notably in low- and middle-income countries, and with minority communities, while also taking into account the specificities of women’s cancers in those countries; stresses that this can mark an important contribution by the EU towards the achievement of international goals in cancer, such as the WHO goal for the elimination of cervical cancer as a public health problem;

III.a. Equal access to cancer care: towards best quality care

Compromise on Paragraph 42
Replacing amendments: 721, 722, 723, 724, 725, 726-727, 728, 729, 730, 731, 767

Motion for a resolution

42. Deplores the fact that EU patients still face challenges in accessing healthcare services in other Member States and that only a minority of patients are aware of their right to seek cross-border healthcare; emphasises the need for better implementation of, and an improved financial model for, the Cross-border Healthcare Directive to allow for mobility and access to highly specialised equipment and care through the reinforcement of the National Contact Points (NCPs) by providing them with more budgetary resources, and calls for an increase in the number of information campaigns on patients’ rights to cross-border healthcare;

Draft compromise Amendment

42. Deplores the fact that EU patients still face challenges in accessing healthcare services and participating in clinical trials in other Member States and that only a minority of patients, and not all healthcare professionals, are aware of the right of patients to seek cross-border healthcare under the two existing frameworks: the Cross-border Healthcare Directive 2011/24/EU and the Social Security Regulation 883/2004; calls for a reform of the Cross-border Healthcare Directive, notably to allow for mobility and access to highly specialised equipment and care...
emphasises the need to facilitate the process, through the revision of the Cross-border Healthcare Directive, for patients who travel abroad for clinical trials and face issues such as a lack of clarity on follow-up protocols after their return home and on coverage of costs related to their clinical trial participation by national insurance agencies; calls on the Commission and the Member States to work together to conduct regular evaluations of the Commission’s eHealth Strategy from 2018 to ensure interconnected electronic health records for cancer patients at regional, national and European level; through the reinforcement of the National Contact Points (NCPs) by providing them with more budgetary resources, and for the development of Commission guidelines setting acceptable and harmonised review and approval timelines to expedite time-to-treatment in the EU under the Social Security Regulation; calls for an increase in the number of information campaigns on patients’ rights to cross-border healthcare, including those aimed at health professionals, as well as the development of a one-stop-shop for information on the EU’s cross-border access pathways; emphasises the need to reduce logistic and linguistic barriers faced by patients when accessing healthcare in another EU Member State; stresses the need to provide patients with clear information on prior authorisation requirements that apply to certain Member States; emphasises the need to facilitate the process, through a holistic revision of the cross-border healthcare frameworks, giving equal consideration to the Cross-border Healthcare Directive and the Social Security Regulation, for patients who, in view of unmet needs and potential benefits, travel abroad for clinical trials and may face issues such as a lack of clarity on follow-up protocols after their return home and on coverage of costs related to their clinical trial participation by national insurance agencies; emphasizes the need for clarification regarding access to cross-border clinical trials, as the latter is not clear in the Cross-Border Healthcare Directive; underlines that all costs related to the treatment should be financed before the beginning of the treatment, to avoid the exclusion of low-income patients; calls on the Commission to consider, in the context of the next revision of existing frameworks, the setting up of a single set of authorisation and reimbursement rules for the access to cross border healthcare, including a right to second opinion; calls
on the Commission and the Member States to work together to conduct regular evaluations of the Commission’s eHealth Strategy from 2018 to ensure interconnected electronic health records, better interoperability, as well as improved data quality, privacy and security for cancer patients at regional, national and European level, while ensuring strict adherence to patients’ health data privacy and security rules; notes the potential of the Cancer Inequalities Registry as a means of reporting and measuring improvement on these concerns;

Compromise on Paragraph 43
Replacing amendments: 711, 712, 737,738, 739, 740, 741, 742

Motion for a resolution

43. Calls for consideration of mutual recognition of medical qualifications in cancer care across the EU;

Draft compromise Amendment

43. Calls for consideration of mutual recognition of health-related qualifications in cancer care across the EU and a common recognition scheme for non-EU countries, as requested in Directive 2005/36/EC, while ensuring that it is facilitative for oncology related specialties; calls for the development of upskilling programmes to enable those wishing to move into that field to do so at any point in their careers;

Compromise on Paragraph 44


44. Calls for full recognition of medical oncology as a specialist discipline, the establishment of pan-European quality standards for administering and supervising medical treatments for cancer, and the facilitation of patients’ access to cancer specialists so that they may benefit from innovations and access to early clinical trials on new promising drugs;

Draft compromise Amendment

44. Calls for full recognition of medical oncology and paediatric oncology as specialist disciplines, the establishment of pan-European quality standards for administering and supervising medical treatments for cancer, both for adults and children, and the facilitation of patients’ access to cancer specialists so that they may benefit from innovations and access to early clinical trials on new promising drugs, health technologies, and reference centres for complex treatments like cell and gene therapy; highlights the need to ensure that access to innovation in early clinical trials for relapsed or difficult-to-treat malignancies is covered by the relevant provisions;
Compromise on Paragraph 45
Replacing amendments: 519, 619, 755-756, 757, 759, 857, 858, 1034, 1035

Motion for a resolution

45. Calls for surgical skills in the EU to be strengthened via the recognition of surgical oncology as a specialist discipline, the establishment of pan-European quality standards for cancer surgery, the facilitation of patients’ access to ‘high-volume’ centres for cancer surgery and access to innovative surgical procedures;

Draft compromise Amendment

45. Calls for surgical skills in the EU to be strengthened via the recognition of surgical oncology as a specialist discipline, the establishment of pan-European quality standards for cancer surgery, the facilitation of patients’ access to ‘high-volume’ centres for cancer surgery and access to innovative surgical procedures; highlights the importance of high-quality surgery in curing cancers detected in early stages; calls for the recognition of high quality surgery; stresses the need to promote the development of a core curriculum in surgical oncology as well as an individual specialist training in surgical oncology, and calls for programmes to harmonize surgical oncology education in the EU; supports the development of clinical trials in surgical oncology as part of loco-regional treatment, and promotes greater investment of EU and national research and innovation funds in surgical oncology research; stresses the importance of standardised surgical oncology treatments to improve long-term quality of life of cancer survivors;

Compromise on Paragraph 46
Replacing amendments: 761, 762, 763, 764, 765, 766, 769

Motion for a resolution

46. Supports the improvement of high-quality radiation therapy in the EU through the recognition of medical physics and radiation therapy as dedicated disciplines, the promotion of common education and training standards, and the greater investment of EU and national research and innovation funds in radiation therapy research;

Draft compromise Amendment

46. Supports the improvement of, and an increased and equal access to, high-quality radiation therapy in the EU through the recognition of medical physics and radiation therapy as dedicated disciplines, the promotion of common education and training standards, increased EU funding for Member States to expand their radiation therapy infrastructure, and the
greater investment of EU and national research and innovation funds in radiation therapy research;

Compromise on Paragraph 46 a
Replacing amendments: 242, 1158, 1159, 1160, 1161, 1162, 1279-1280, 1309

Motion for a resolution

46 a (new). Calls for the promotion of geriatric oncology as a branch that deserves special consideration and needs to be enriched by scientific research in order to ascertain best treatment and diagnostic methods for elderly patients; recalls that in the EU over 60% of new cancer cases and over 70% of cancer deaths occur in people aged 65 and older, whereas this proportion is expected to increase, as the population in Europe ages, thus representing a crucial challenge for healthcare systems; calls on the Commission and Member States to urgently address this situation with concrete actions; asks, in particular, the Commission and Member States to act in order to facilitate clinical trials in the elderly and to facilitate the implementation of multi-disciplinary and comprehensive oncogeriatric care models in routine clinical pathways, as well as the creation of centres of excellence in geriatric oncology; calls on the Commission and Member States to foster opportunities for the training and upskilling of the oncology workforce in the principles of geriatrics;

Compromise on Paragraph 47
Replacing amendments: 769, 771, 772, 773, 774, 775, 777, 778, 779, 780, 781, 783, 784, 1330

Motion for a resolution

47. Welcomes the upcoming new action plan under the Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA)26 which will support the security of supply of radioisotopes for

Draft compromise Amendment

47. Welcomes the new action plan under the Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA) 26, which will support the security of
cancer diagnosis and care and enhance the quality and safety of radiation technology in medicine;

production capacities and supply of radioisotopes via the replacement of the current ageing fleet and implementation of existing technologies, notably reactors and particles accelerators, through existing financial instruments, avoid shortages of radioisotopes by facilitating the crossing of borders and exemptions for transportations and enhance the quality and safety of radiation technology in medicine, which is currently not equally available in all EU Member States, through the evaluation of radioisotopes in Health Technology Assessment, the harmonisation of market access, the affirmation of nuclear medicine as a fully independent medical specialty, the promotion of training standards, as well as investments in nuclear medicine research;

Compromise on Paragraph 48
Replacing amendments: 240, 241, 629, 630, 631, 745, 754, 785, 786, 787, 788, 789, 792, 793, 794, 795, 796, 797, 798, 800, 801, 802, 803, 804, 829, 1128, 1234, 1351

Motion for a resolution
48. Calls on the Commission to promote, and on Member States to strengthen, the role of general practitioners, paediatricians and primary care professionals, given their importance in patient referral to diagnostic tests and oncology specialists, as well as during cancer treatment and follow-up care; calls for the development of multidisciplinary decision-making in the framework of dedicated concertation meetings bringing together various cancer specialists;

Draft compromise Amendment
48. Calls on the Commission to promote, and on Member States to strengthen, the role of general practitioners, paediatricians, nurses, primary care professionals and specialist physicians, given their importance in patient referral to diagnostic tests and oncology specialists, as well as the role of specialised nutritionists or dieticians, psychologists and rehabilitation specialists during cancer treatment and follow-up care, in order to ensure access to the right treatment and care at the right time via an optimal care pathway; calls for the development of multidisciplinary teams (MDT) to manage
cancer patients throughout their treatment journey, and multidisciplinary decision-making in the framework of dedicated cross-discipline concertation meetings bringing together various cancer specialists and primary care professionals; underlines the importance of a constant training for health professionals to keep them updated on new cancer treatment options; calls for the role of a treatment coordinator to be made more widespread in order to ensure that patients receive appropriate coordination, to give them easy access to updated information related to cancer diagnosis and advice on how to use the health system;

Compromise on Paragraph 49
Replacing amendments: 805, 806, 807, 808, 809, 810

**Motion for a resolution**

49. Considers that the EU regulatory framework for the recognition of professional qualifications should be broadened to allow for the standardisation of cancer nursing education;

**Draft compromise Amendment**

49. Considers that the scope of Directive 2005/36/EC\(^1a\) should be revised to allow for the mutual recognition of cancer nursing education and education for other medical staff supporting the treatment process:


Compromise on Paragraph 50
Replacing amendments: 812, 813, 814, 815

**Motion for a resolution**

50. Calls on the Member States to take preventive measures against the risk of burnout among cancer care professionals;

**Draft compromise Amendment**

50. Calls on the Member States to develop, within their national cancer control plans, strategies that encompass and implement preventive measures against the risk of burnout among cancer care professionals; urges that the Commission and EU-OSHA provide attention to this concern, and be considered important
Compromise on Paragraph 51
Replacing amendments: 819, 820, 821, 822, 823, 824, 825, 826, 827, 828

Motion for a resolution

51. Encourages, where possible and safe, the use of ambulatory cancer treatments in order to preserve the quality of life of patients; calls on Member States to implement or improve e-health technologies and telemedicine services to ensure the continuity of cancer care;

Draft compromise Amendment

51. Encourages, where feasible and safe, the use of ambulatory cancer treatments in order to preserve the quality of life of patients and their families; stresses, in particular, that ambulatory treatments for children should be stimulated, provided that the relevant spaces/environments and medical devices available are designed in such a way as to cater for the needs of paediatric patients; stresses the role of pharmacists, oncologists and nurses within a multidisciplinary follow-up of patients taking oral anticancer medicines; calls on Member States to implement or improve e-health technologies, telemedicine and telecare services to ensure the continuity of inpatient and outpatient cancer care as well as in the community; urges the deployment of Horizon Europe research funding to support the use of telemedicine, and to assist the establishment of evidence-based guidelines; calls for actions to ensure equal access to telemedicine services across the Member States, and for EU4Health and Digital Europe funding to support the increase of digital literacy for patients and healthcare professionals;

Compromise on Paragraph 52
Replacing amendments: 743, 744, 811, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 1130, 1232

Motion for a resolution

52. Calls on the Member States to provide optimal relief for advanced-stage cancer patients at the end of their lives in order to ease their pain and discomfort while

Draft compromise Amendment

52. Calls on the Member States to provide integral and multidisciplinary palliative care services for cancer patients in order to ease their pain and discomfort,
preserving their dignity; supports more intensive exchanges and the implementation of best practices on hospice and palliative care at EU level; encourages Member States to assess the number of palliative units in each region and to ensure sustainable funding and sufficient and well-trained human resources; promoting comfort care and ensuring the nurses’ or carers’ presence, while preserving their dignity and taking into account the advance care planning and the autonomy of the patient; calls on the Commission to support and coordinate regular exchange of information and the implementation of best practices on hospice and home palliative care at EU level; calls for the development of child-specific palliative care, especially in Member States where those cares are not yet widely provided; encourages Member States to address palliative care in NCCPs, maximise the number of palliative units in each region in order to appropriately adjust their number to the needs of patients, as well as to minimise waiting times, and to ensure sustainable funding and sufficient and well-trained human resources; considers that the EU regulatory framework for the recognition of professional qualifications should be broadened to allow for the standardisation of palliative care education and best practices of health professionals; emphasizes the need for reference networks for palliative care and their integration with cancer pathways at all levels, specialist hospital, primary health care centres, hospice and territory-hospital integration as well as at home; urges that patients’ access to supportive and palliative care (including psycho-oncology services) across the EU be measured and reported via the Cancer Inequalities Registry; calls for deeper cooperation between healthcare systems and social assistance systems in all Member States;

Compromise on Paragraph 53
Replacing amendments: 588, 847, 849, 850, 851, 852, 853, 855

Motion for a resolution

53. Encourages the Commission and the Member States to adopt specific quality assurance criteria (including adequate organisations, infrastructures and competences, multidisciplinary practice,

Draft compromise Amendment

53. Encourages the Commission and the Member States to adopt specific quality assurance criteria and schemes (including common standards of care, adequate organisations, infrastructures and
continuing education for professionals, patient education and participation in clinical research) for accreditation standards to be applied to public and private hospitals treating cancer patients, in order to ensure the efficient, safe and equal management of cancers all over the EU; competences, multidisciplinary practice, continuing education for professionals, patient education and participation in clinical research), as well as joint clinical guidelines, for accreditation standards to be applied to public and private hospitals treating cancer patients, in order to ensure efficient, safe and equal management of cancers all over the EU; insists that these criteria adhere to the highest available standards of evidence-based science that have been published in peer-reviewed scientific journals; insists that both public and private institutions that meet the quality assurance criteria should be included in national cancer control plans as part of Europe's Beating Cancer Plan with the goal of providing the highest level of cancer treatment quality to all patients across the EU; calls on the Member States to create maps of health needs in oncology, coupling it with a realistic mapping and inventory of their existing oncological infrastructure; is of the view that this mapping exercise will allow Member States to better plan the access to existing medical infrastructure, set clear areas of action and prioritise the allocation of resources, and plan the cross-border cooperation between the oncological reference centres;

Compromise on Paragraph 54
Replacing amendments: 768, 859, 860, 861, 862, 864, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 1237, 1278

Motion for a resolution

54. Welcomes the planned establishment, as announced in Europe's Beating Cancer Plan, of an EU network linking recognised National Comprehensive Cancer Centres (reference centres) in every Member State to facilitate the uptake of quality-assured diagnosis and treatments, including training, research and promotion of clinical trials across the EU; calls on the Commission to identify such existing centres within the EU, to promote the

Draft compromise Amendment

54. Welcomes the planned establishment, as announced in Europe’s Beating Cancer Plan, of an EU network linking recognised National Comprehensive Cancer Centres (reference centres) in every Member State to facilitate the uptake of quality-assured diagnosis and treatments, including training, research and promotion of clinical trials across the EU; calls on the Member States and the Commission to support the establishment of such
establishment of at least one comprehensive cancer centre in each Member State and to support the coordination of the network of these centres via a European Cancer Institute; reference centres for rare cancers and cancers with complex treatments; calls on the Commission to identify such existing centres within the EU, to promote the establishment of at least one comprehensive cancer centre in each Member State and to support the coordination of the network of these centres; stresses that these objectives should include the reduction of inequalities and the strengthening of translational, clinical and outcomes research; highlights that promotion and development of translational research should be considered as an important core objective of the EU Network of National Comprehensive Cancer Centres; notes that, when developing this EU network, the Commission should consider the need to invest in state-of-the-art equipment and well-trained physicians and other healthcare specialists in various specialties, and recommends that a diversity of well-trained cancer specialties and medical disciplines be involved from the start in the work of the envisioned EU Network of National Comprehensive Cancer Centres to reinforce multi-disciplinary collaboration, therefore improving outcomes for patients; calls on the Commission and the Member States to support the sustainability of pre-existing cross-border collaborations, such as in the paediatric cancer sector, and the European Reference Networks; calls on the Commission to support Member States by earmarking some of the budget in the cohesion and regional funds to support the establishment of these centres to ensure full coverage of the population;

Compromise on Paragraph 55
Replacing amendments: 875, 876, 877, 878, 879, 880, 881, 882, 885, 886

Motion for a resolution

55. Calls for the identification, reinforcement or creation in each Member State of a National Cancer Control Programme (NCCP), consisting of a unique structure, possibly a National Cancer

Draft compromise Amendment

55. Calls for the identification, reinforcement or creation in each Member State of a National Cancer Control Programme (NCCP), in coherence with
Institute, in charge of the implementation and follow-up of the respective NCCPs, with adequate objectives and resources; recommends that the NCCPs are set up in coherence with the European Guide for Quality National Cancer Control Programmes initiated by the European Partnership for Action Against Cancer (EPAAC); welcomes the setting up of a network of these organisations coordinated by the European Cancer Institute;

**WHO guidance on NCCPs.** consisting of a unique structure, possibly a National Cancer Institute, in charge of the implementation and follow-up of the respective NCCPs, with adequate objectives and resources; calls for the NCCPs’ contents to be aligned as closely as possible with Europe's Beating Cancer Plan in order to facilitate the latter’s successful implementation; recommends that the NCCPs are set up in coherence with the European Guide for Quality National Cancer Control Programmes initiated by the European Partnership for Action Against Cancer (EPAAC) and calls for the inclusion of a dedicated paediatric cancer and rare cancers component in all NCCPs to ensure that appropriate resources and implementation programmes are allocated to the specific needs of these patients; welcomes the setting up of a network of these organisations; stresses that a NCCP should include provisions on adequate staff capacities so as to guarantee sufficient number of oncology-workers in each Member State, commensurate with the overall population number;
III.b. Equal access to cancer care: towards a European Medicines Market

Compromise amendment on Subheading III.b
Replacing amendments: 888, 889, 890, 891

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Compromise on Paragraph 56
Replacing amendments: 753, 883, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 992, 1333

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<td>56. Calls on the Commission to strengthen the European medicines market in order to guarantee equal access to treatment, reduce medicine shortages, overcome the problem of high prices for innovative treatments, and improve cancer treatments for adults and children;</td>
<td>56. Calls on the Commission to strengthen the European medicines market in order to improve equal access to treatment, including innovations and personalised medicine, reduce medicine shortages, overcome the problem of high prices for innovative technologies and treatments, encourage the use of generic and biosimilar medicines and improve cancer treatments for adults and children; calls on the Commission and national competition authorities to assess the European medicines market keeping the attention on the acquisition of SMEs by large pharmaceutical companies that undermine fair competition; encourages a multi-stakeholder dialogue on access to medicines and innovation based on models such as ACCELERATE in the paediatric cancer sector and involving all relevant actors including academia, industry, health professionals and patient representatives;</td>
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Compromise on Paragraph 58
Replacing amendments: 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 931

Motion for a resolution

58. Notes that cancer patients are frequently affected by medicine shortages; calls on the Commission to present a specific strategy for managing shortages of all medicines and medical products in Europe and of cancer medicines in particular; supports the development of a common basket of the cancer drugs of which there may be shortages to ensure that patients have continuous access to appropriate treatment;

Draft compromise Amendment

58. Notes that cancer patients are frequently affected by medicine shortages and that severe disruptions in the supply of cancer treatments are highly detrimental for cancer patients, carers and families; calls on the Commission and the Member States to work together to prevent and manage shortages of all medicines and medical products and of cancer medicines in particular, including shortages of inexpensive essential cancer medicines; supports the development of a common basket of cancer drugs of which there may be shortages to ensure that patients have continuous access to appropriate treatment, based on transparently and appropriately defined patient needs;

Compromise on Paragraph 59
Replacing amendments: 921, 922, 923, 924, 925, 926, 927, 928, 929, 930

Motion for a resolution

59. Calls for the reinforcement and diversification of the supply chain, in particular that of cancer drugs, within the EU, close monitoring of medicine tensions and shortages, and the creation of a strategic stockpile of such medicines;

Draft compromise Amendment

59. Calls for the reinforcement, diversification of the supply chain, in particular that of cancer drugs, within the EU, close monitoring of supply tensions and shortages, and the creation of a strategic stockpile of such critical medicines, active ingredients or raw materials, particularly where the number of suppliers is limited: calls for the EU pharmaceutical legislation to introduce a legal obligation for pharmaceutical companies to report information to the EMA on adequate safety stocks of essential cancer medicines, stresses the importance of the role of sustainable procurement practices in preventing medicine shortages; urges the Commission, in the context of the EU
Public Procurement Directive 2014/24/EU, to develop guidelines to support public procurement practices in the pharmaceutical field for cancer drugs, in particular with regard to the implementation of the criteria of the most economically advantageous tender (MEAT), aimed at ensuring long-term sustainability, competition and security of supply and stimulating investment in manufacturing;

Compromise on Paragraph 60
Replacing amendments: 932, 933, 934, 935, 936, 937, 938, 939

Motion for a resolution

60. Points out that generic and biosimilar medicines enable efficient and safe cancer care, increased competition and savings for healthcare systems, thus helping to improve access to medicines for patients; stresses that their market entry should not be hampered or delayed;

Draft compromise Amendment

60. Points out that generic and biosimilar medicines enable efficient and safe cancer care, increased competition, innovation and savings for healthcare systems, thus helping to improve access to medicines; calls for the introduction of a strategic objective in the Europe's Beating Cancer Plan as well as in the national cancer strategies to actively promote the use of off-patent medicines, where appropriate and beneficial for patients; stresses that their market entry should not be hampered or delayed and their development process should be promoted and funded; calls on the Commission to ensure healthy competition at the expiry of intellectual property (IP) exclusivities as a matter of urgency by ensuring accessibility to biosimilar medicines from day one and by removing all barriers to access to competition, for example through patent linkage, by banning IP ever greening practices that unduly delay access to medicines and by allowing single global development;
Compromise on Paragraph 61
Replacing amendments: 782, 920, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 963, 976

Motion for a resolution

61. Considers that Member States should converge on the evaluation of medical technologies; welcomes, therefore, the provisional agreement on the Health Technology Assessment (HTA) Regulation reached by the European Parliament and the Council on 22 June 2021\(^2\)\(^8\) to support harmonised access to innovative cancer diagnosis and treatments;

Draft compromise Amendment

61. Considers that Member States should converge on the evaluation of medical technologies; welcomes, therefore, the provisional agreement on the Health Technology Assessment (HTA) Regulation reached by the European Parliament and the Council on 22 June 2021 to support harmonised assessment of and faster access to innovative cancer diagnosis and treatments and considers that a more efficient decision making process could, among other measures, play a role in facilitating it; welcomes that cancer medicines is one of the first medicinal product groups to be jointly assessed under the Health Technology Assessment (HTA) regulation; calls on the Commission and Member States to take further measures aimed at encouraging the uptake and use of Joint Clinical Assessments that are to be carried out under the regulation; highlights the existence of tools being used by the World Health Organisation (WHO) to incorporate cancer medicines on the WHO Model List of Essential Medicines;

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Compromise on Paragraph 62
Replacing amendments: 952, 953, 954, 955, 956, 958, 959, 960, 961, 962

Motion for a resolution

62. Insists on the need to ensure equal access to affordable drugs, in particular cancer drugs, within the EU; calls for collective negotiation on the price of medicines with pharmaceutical industries, as per the Beneluxa Initiative on

Draft compromise Amendment

62. Recalls that all patients have the right to optimal treatment, regardless of their financial means, gender, age or nationality; notes with concern that there is a great disparity in the availability of and access to different cancer therapies, with
Pharmaceutical Policy and the Valetta Declaration; *considers that* pharmaceutical companies *should respect* conditionalities on charging an affordable price for medicines developed in the framework of publicly funded research; unaffordability being one of the main reasons; *insists therefore* on the need to ensure equal access to safe, effective and affordable drugs, in particular cancer drugs, within the EU; *calls on Member States to consider joint price* negotiation with pharmaceutical companies, as per the Beneluxa Initiative on Pharmaceutical Policy and the Valletta Declaration; *calls on the Commission to make fair pricing and affordability of new treatments a core element of the Europe’s Beating Cancer Plan and the Pharmaceutical Strategy for Europe, notably by attaching conditionalities to European public funding (e.g., Horizon Europe, Innovative Medicines Initiative - IMI) and ensure that public investment in R&D is accounted for and that medicines resulting from publicly funded research, are available for a fair and affordable price; underlines that this should also be the case for medicines benefitting from specific regulatory or market protection such as medicines developed to treat rare or paediatric cancers; *calls for more transparency throughout the pharmaceutical system, especially regarding pricing components, reimbursement criteria and the actual (net) prices of medicines in different European countries to ensure fairer prices and bring public accountability in the pharmaceutical sector;*

**Compromise on Paragraph 63**
Replacing amendments: 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975

**Motion for a resolution**

63. **Strongly advocates the extension of joint procurement procedures for cancer medicines to improve affordability and access to cancer treatments at EU level;**

**Draft compromise Amendment**

63. **Strongly advocates the extension of joint procurement procedures, especially for (ultra)rare, paediatric and novel cancer medicines and treatments, diagnostic procedures and companion diagnostic tests, as well as cancer preventing vaccines like HPV and hepatitis B vaccines, to counter shortages and improve affordability and access to cancer treatments at EU level; notes that the joint**
Compromise on Paragraph 65
Replacing amendments: 983, 984, 985, 986, 987, 988, 989, 990

Motion for a resolution

65. Calls on the Commission to submit a proposal for the revision of Directive 89/105/EEC on the transparency of measures regulating the prices of medicinal products in order to ensure effective controls and full transparency of the procedures used to determine the price and reimbursement of the cost of medicines, in particular cancer medicines, in Member States; calls for pharmaceutical companies to provide information on financing with public resources, as well as on the tax benefits and subsidies they have received; requests that the calculation of drug costs should take into account the use of public funds; calls on the European Medicines Agency (EMA) to increase the number of audits in order to assess pharmaceutical companies’ compliance with the requirements on transparency;

Amendment

65. Calls on the Commission to submit a proposal for the revision of Directive 89/105/EEC on the transparency of measures regulating the prices of medicinal products in order to ensure effective controls and full transparency of the procedures used to determine the price and reimbursement of the cost of medicines, in particular cancer medicines, in Member States; encourages competent authorities to request pharmaceutical companies to provide information on research and development costs, including the financing with public resources, prior to market authorisation, as well as on the tax benefits and subsidies they have received; requests that the calculation of drug costs should take into account the use of public funds; calls on the European Medicines Agency (EMA) to increase the number of audits in order to assess pharmaceutical companies’ compliance with the requirements on transparency;

Compromise on Paragraph 66
Replacing amendments: 993, 994, 995, 996, 997, 998, 999, 1000, 1001, 1002, 1281

Motion for a resolution

66. Notes that huge advances in biology have revealed that cancer is an umbrella term for more than 200 diseases, and that precision or personalised medicine can be made available through the drug targeting of various mutations; considers that precision or personalised medicine, consisting of a treatment choice based on individual tumour biomarkers, is a promising way to improve cancer treatment; encourages Member States, therefore, to promote the implementation of regional molecular genetics platforms and facilitate equal and rapid access to personalised treatment for patients;

Draft compromise Amendment

66. Notes that huge advances in biology have revealed that cancer is an umbrella term for more than 200 diseases, and that precision or personalised medicine can be made available through the drug targeting of various mutations; considers that precision or personalised medicine, consisting of a treatment choice based on individual tumour biomarkers reflecting genotypes/phenotypes, is a promising way to improve cancer treatment; encourages Member States, therefore, to develop personalised medicine across the EU through cooperation among them and to promote the implementation of regional molecular genetics platforms and facilitate equal and rapid access to advanced diagnostics and personalised treatment for patients, in full respect of data privacy and ensuring that patients are informed and consent to the use of their health data for research; notes that the fragmentation and classification of cancers, based on specific genotypes, should not lead to the definition of "artificial rare diseases", aiming to increase financial compensation;

Compromise on Paragraph 67
Replacing amendments: 1003, 1004, 1005, 1006, 1007, 1008, 1009, 1010, 1352

Motion for a resolution

67. Calls for the full and rapid application of Regulation (EU) No 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use; considers that the application of the regulation would facilitate the launch of large clinical trials carried out in a harmonised, efficient and coordinated manner at European level in order to facilitate research into cancer drugs and

Draft compromise Amendment

67. Calls for the full and rapid application of Regulation (EU) No 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use; considers that the application of the regulation would facilitate the launch of large clinical trials across Europe carried out in a harmonised, efficient and coordinated manner at European level in
improve cancer patients’ and their families’ quality of life; order to facilitate research into cancer drugs and improve cancer patients’ and their families’ quality of life; considers, furthermore, that the regulation should be applied in a consistent manner in all EU Member States with the aim of rationalising procedures for carrying out clinical research; urges for a fresh review of opportunities to reduce the administrative burden associated to clinical trials; calls for long-term learning from the COVID-19 pandemic on future forms of international trial cooperation and information-sharing;

Compromise on Paragraph 68
Replacing amendments: 1013, 1014, 1015, 1017, 1016, 1018, 1021

Motion for a resolution

68. Calls for a more sustainable environment for conducting research into the repurposing of medicines for cancer treatment and for the creation of an additional project that uses high-performance computing to rapidly test existing molecules and new drug combinations, starting with treatment for cancers with a poor prognosis and rare cancers;

Draft compromise Amendment

68. Calls for a more sustainable environment, including financial support, for conducting research and analysing existing research into the repurposing of medicines for cancer treatment, especially performed by third parties with no commercial intent, and for the creation of an additional project that uses high-performance computing to rapidly test existing molecules and new drug combinations, starting with high unmet needs, such as treatment for cancers with a poor prognosis, metastatic cancers and rare cancers;

Compromise on Paragraph 69
Replacing amendments: 1022, 1023, 1024, 1025, 1026, 1027, 1028, 1029, 1030, 1031, 1032, 1033

Motion for a resolution

69. Supports the development of clinical trials on the use of new cancer drugs in adults and children;

Draft compromise Amendment

69. Reiterates the importance of generating and reporting strong evidence on the efficacy and safety profiles of medicines, both in clinical trials and in
post-market entry follow-up studies; supports the development of clinical trials on the use of new and affordable cancer drugs in adults and children; supports the development of multi-centred clinical trials across Europe for the discovery of improved forms of treatment and care for patients, including children and older patients; underlines that authorities must ensure transparency, compliance with study conduct requirements and early communication of relevant data to the EMA and the general public;

Compromise on Paragraph 70
Replacing amendments: 1020, 1036, 1037, 1038, 1039, 1040, 1041, 1042, 1043, 1045, 1019

Motion for a resolution

70. Welcomes the Commission’s intention to adopt a legislative proposal to establish a Health Emergency Preparedness and Response Authority (HERA) in order to anticipate, incentivise, co-develop and facilitate rapid, equal and sustainable access to cancer innovations for cancer patients; calls for a large consortium of public authorities, private companies and NGOs, including patient associations, to work together to guarantee the accessibility and affordability of cancer treatment options requiring complex technologies, for instance, cellular therapy (CAR T cells), adoptive immunotherapy through the use of tumour genome extracts (messenger RNA) and nanotechnologies;

Draft compromise Amendment

70. Takes note of the Commission’s legislative proposal to establish a Health Emergency Preparedness and Response Authority (HERA); takes note that by 2023 and every 2 years thereafter the Commission shall carry out an in-depth review of the implementation of the operations of HERA, including its structure, governance, funding and human resources and that those reviews shall address in particular any need to modify HERA’s structure, including but not limited to the possibility of upgrading HERA to a stand-alone agency, the mandate of HERA and the financial implications of any such modification; takes note that the Commission shall report to the European Parliament and the Council on the findings of the reviews and that those findings shall be made public; takes note that the reviews shall be accompanied, where appropriate, by a legislative proposal to address these issues in full respect of the role of the European Parliament as co-legislator; considers that if HERA is upgraded as a stand-alone agency, the authority could, at the latter
stage, be able to anticipate, incentivise, co-develop and facilitate rapid, equal and sustainable access to cancer innovations for cancer patients, including diagnostic procedures as well as companion diagnostic tests; stresses the need to promote the innovation of life-saving cancer treatments; calls therefore on the Commission to create a pharmaceutical legislation framework for oncological medicines and therapies which promotes real breakthrough innovations and not the so-called ‘me too’ pharmaceuticals which are just another substance for the same indication without major benefits or highly expensive pharmaceuticals that offer only minor improvements for patients; calls for a large consortium of public authorities, private companies and NGOs, including patient and survivors associations and academia, to work together to guarantee the accessibility and affordability of cancer treatment options requiring complex technologies, for instance complex treatments like cell therapy (CAR T cells), gene therapy, adoptive immunotherapy through the use of tumour genome extracts (messenger RNA) and nanotechnologies; considers that HERA could, in the long-term, closely collaborate with public and private entities to plan, coordinate and build an ecosystem of private and public capabilities which can provide suitable emergency frameworks for EU access to key raw materials in case of global supply shocks; stresses that, to facilitate wider utilisation of innovative therapies, the EU and Member States must not only do their best to finance currently available therapies but also support the development of more cost-efficient modalities; believes that lowering the costs of the most innovative and effective therapies will increase their wider availability for the benefit of patients in the EU and beyond; calls for securing equal access to innovative therapies, both in the densely
populated urban regions and smaller, rural or remote areas;
III.c Equal access to cancer care: towards a better response to the impact of health crises on cancer patients

Compromise on Subheading III.c
Replacing amendments: 1048, 1049

Motion for a resolution

III.c Equal access to cancer care: towards a better response to the impact of health crises on cancer patients

Draft compromise Amendment

III.c Equal access to multidisciplinary and quality cancer care: towards a better response to the impact of health crises on cancer patients

Compromise on Paragraph 71
Replacing amendments: 707, 708, 709, 710, 1050, 1051, 1052, 1053, 1054, 1055, 1056, 1057, 1058, 1059

Motion for a resolution

71. Underlines that the COVID-19 crisis has had, and is still having, a significant impact on cancer patients’ survival and quality of life at all stages of the disease, due to delays in screening, referral and surgical procedures, treatment postponement, shortages in the supply of medicines and other medical supplies, specialised workforce shortages and reduced communication with health professionals;

Draft compromise Amendment

71. Underlines that the COVID-19 crisis has had, and is still having, a significant impact on cancer patients’ survival and quality of life at all stages of the disease, due to delays in prevention activities such as vaccination and postponements of prevention schemes, clinical trials, screenings, referral, diagnosis, surgical procedures, treatment, shortages in the supply of medicines and other medical supplies, specialised workforce shortages and reduced communication with health professionals and patients’ fear of infection; highlights evidence suggesting that clinicians across Europe saw 1.5 million fewer cancer patients in the first year of the pandemic, an estimated 100 million cancer screening tests were not performed in Europe as a result of the pandemic, and consequently, 1 million citizens in the EU may presently be undiagnosed with cancer as a consequence of the COVID-19 pandemic;123
Compromise on Paragraph 72
Replacing amendments: 951, 1061-1064, 1079, 1102, 1103, 1104

Motion for a resolution

72. Considers that the COVID-19 pandemic was a real stress test for the EU’s health systems; underlines that the main lesson learned should be the need to build an emergency strategy to allow Member States to react accordingly in times of any future health crises; stresses that specific measures under this emergency strategy should be aimed at the protection of vulnerable groups, including cancer patients;

Draft compromise Amendment

72. Considers that the COVID-19 pandemic was a real stress test for the EU’s health systems; underlines that the main lesson learned should be the need to build an emergency strategy to allow Member States to react in a coordinated manner against any future health crises; stresses that vulnerable groups, including cancer patients, are particularly exposed during a health crisis; stresses that specific measures under this emergency strategy should support the development, production and stockpiling of products to protect those vulnerable groups;

Compromise on Paragraph 73
Replacing amendments: 816, 1060, 1069, 1070, 1071, 1072, 1073, 1074, 1075, 1076, 1077, 1078

Motion for a resolution

73. Notes with concern that the COVID-19 pandemic has exacerbated pre-existing health workforce shortages; acknowledges the urgency of ensuring a sufficient number of specialised health professionals in cancer care; reiterates that specific measures under the emergency strategy should be aimed at addressing workforce shortages through the recruitment of health professionals;

Draft compromise Amendment

73. Notes with concern that the COVID-19 pandemic has exacerbated pre-existing health workforce shortages; acknowledges the urgency of ensuring a sufficient number of specialised health professionals in cancer care; reiterates that specific measures under the emergency strategy should be aimed at addressing workforce shortages through the recruitment of health professionals, in both primary and specialized care, and their retraining should they be specialists in other fields; suggests that the Cancer Inequalities Registry may serve as a tool in
measuring and reporting on pre-existing workforce shortages; underlines that new approaches for human-centered healthcare are required in order to ensure access to diagnostics, therapeutics and quality public health services for all; stresses the need for work on a skill mix in order to optimise the response to staffing needs in the health sector; supports the exchange of good practices between Member States in this regard; calls on the Commission and the Member States to create online training platforms for healthcare professionals such as carers, as well as therapeutic care programmes granting qualifications and recognising their competences;

Compromise on Paragraph 73a
Replacing amendments: 1067, 1068, 1146, 1157

Motion for a resolution

73a. Recognises that the pandemic has exacerbated the crucial role of informal carers, who provide most of the daily care for cancer patients and who face a clear lack of practical and policy support (may it be in terms of social rights, training, psychological help, information, recognition); points to the high percentage of informal carers among the European population and to the disparities regarding the way they are supported and how their rights are recognised between Member States; calls on Member States and relevant authorities to recognise the pivotal role of informal carers, to integrate them within the health and care team and empower them with the possibility of making informed choice regarding
available supportive measures with the support of healthcare professionals; calls on the Commission to consider the formalization of an informal caregiver status, ensuring the recognition of a certain minimum standard of rights, especially for those who are providing long-term care;

Compromise on Paragraph 74
Replacing amendments: 1080, 1081, 1082, 1083, 1085, 1086, 1087, 1088

Motion for a resolution
74. Advocates the development of a digital health system to monitor symptoms and ensure cancer treatment and care at home; calls for permanent access to medical consultations and psychosocial services to be guaranteed through the use of telemedicine or in health threat-free environments in hospitals;

Draft compromise Amendment
74. Advocates the development of a digital health communication channel to monitor symptoms remotely and ensure continued cancer treatment in out-of-hospital care; calls for permanent access to medical consultations and psychosocial services, as well as contact between patient and health professionals and between the attending health professional and the patient's family, to be guaranteed through the use and integration of telemedicine and telecare within healthcare systems or in health threat-free environments in hospitals or, when possible and safe, pharmacies; calls for the stimulation of the development of therapeutics that can support a transition to home care;

Compromise on Paragraph 75
Replacing amendments: 1089, 1090, 1091, 1092, 1093, 1094, 1095, 1096

Motion for a resolution
75. Asks for enhanced communication between health professionals, patients and public authorities regarding the effectiveness and safety of health interventions, in particular cancer screening, diagnosis and treatment, and for

Draft compromise Amendment
75. Asks for enhanced communication between health professionals, patients, survivors, caregivers, parents and public authorities regarding the effectiveness and safety of health interventions, in particular cancer screening, diagnosis and treatment,
increased awareness campaigns in times of crises; and for increased awareness campaigns for prevention in times of crises;

**Compromise on Paragraph 76**
Replacing amendments: 1097, 1098, 1099, 1100, 1101

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<tr>
<td>76. Calls on the Commission and the Member States to adopt European prevention and management plans to address cancer drug shortages in times of health crises;</td>
<td>76. Calls on the Commission and the Member States to adopt European prevention and management plans <strong>as part of a coherent and holistic contingency strategy to prevent and address shortages of medicines, devices, products and staff</strong> in times of health crises; <strong>underlines the responsibilities of market authorisation holders (MAHs) and wholesale distributors with respect to relevant EU legislation</strong>;</td>
</tr>
</tbody>
</table>
IV. Strong support to cancer patients, survivors and caregivers

Compromise on Paragraph 78
Replacing amendments: 856, 1112, 1113, 1114, 1115, 1116, 1117, 1118, 1119, 1120, 1121, 1122, 1125, 1129, 1137, 1148, 1149, 1170, 1171, 1205, 1206, 1207, 1208, 1499

Motion for a resolution
78. Emphasises the importance of specific EU recommendations to improve the quality of life of patients, including via supportive care (pain relief, psychological services, adapted physical activity, nutritional support, social assistance, access to reproductive health and restoration of aesthetic integrity); asks Member States for recognition of sequelae (physical or mental disabilities), as well as social discrimination;

Draft compromise Amendment
78. *Notes that there is a need to focus on the quality of life for a rising number of chronic cancer patients whose illness cannot be cured but which may be stabilised for a number of years; emphasises the importance of specific EU recommendations to improve the quality of life of patients and survivors, including via comprehensive supportive care integrated into cancer care from the diagnosis and throughout the disease process* (pain relief, psychological services, adapted physical activity, *scientific evidence-based complementary therapies, access to education, nutritional support, social assistance encompassing all day-to-day tasks such as household help or child care, access to reproductive health and restoration of aesthetic integrity*) *and access to specialised supportive centres; asks Member States for recognition of sequelae (physical or mental disabilities), as well as social discrimination, including in the workplaces; asks the Commission to propose guidelines for Member States to address the importance of establishing comprehensive coverage systems that guarantee these needs; recognises that cancer is a financially burdensome disease, even beyond cancer treatments; calls on the Commission to set up a platform for the exchange of best practices in palliative care and support research in palliative care;*
Compromise on Paragraph 78a (new)
Replacing amendments: 790, 830, 887, 1361

Motion for a resolution

Draft compromise Amendment

78a. Highlights the fact that scientifically recognised integrative medicine approved by public health authorities can bring benefits to patients in relation to the parallel effects of several diseases, such as cancer, and their treatment; stresses the importance of developing a holistic, integrative and patient-centric approach and encouraging, where appropriate, the complementary use of these therapies under the supervision of healthcare professionals;

Compromise on Paragraph 78b (new)
Replacing amendments: 829, 1044, 1123, 1126, 1127, 1134, 1135, 1136

Motion for a resolution

Draft compromise Amendment

78b. Underlines that the results of cancer treatment can be hampered by malnutrition, therefore optimal nutritional care is essential for cancer care; calls on Member States to develop recommendations for incorporating clinical nutrition into all aspects of cancer, including treatment, support and research; considers that, wherever indicated, cancer patients must be provided with clinical nutritional support by a dietitian specialist to be included into the multidisciplinary team (MDT); welcomes, therefore, the planned inter-speciality training on nutrition support and calls on the Commission and Member States to develop minimum standards for continuous training on nutritional care for the multidisciplinary workforce; recommends that nutrition management be an integral ethical part of all clinical research involving cancer patients; recommends, furthermore, that proper nutritional support be included into the cancer patients' Charter of Rights;
Compromise on Paragraph 79
Replacing amendments: 1140, 1141, 1142, 1143, 1144, 1145, 1146, 1147

Motion for a resolution

79. Encourages Member States to take into account the frequent exhaustion of the families and relatives of cancer patients and to provide them with psychological assistance and rest periods in the workplace;

Draft compromise Amendment

79. Encourages Member States to take into account the frequent exhaustion of the families and relatives of cancer patients and to provide them with psychological and socio-economic assistance, especially for the most vulnerable ones, and rest periods in the workplace, along all the disease path, as well as bereavement support; encourages, furthermore, the development of integrated, adequate and accessible support schemes for cancer patients and their families, taking into account health, community and social services;

Compromise on Paragraph 80
Replacing amendments: 1138, 1150, 1151, 1152, 1153, 1154, 1155, 1156

Motion for a resolution

80. Recalls that patient empowerment is crucial for the European cancer strategy and that patient-centeredness and participatory decision-making must be at the heart of treatment and care development processes; encourages the therapeutic education of caregivers and patients and their empowerment in the care programmes;

Draft compromise Amendment

80. Recalls that patient empowerment and health literacy is crucial for the European cancer strategy and that patient-centeredness and participatory decision-making must be at the heart of treatment and care development processes; encourages the promotion of active and expert patients and calls for therapeutic education of caregivers and patients and their empowerment in the care programmes; considers that a specifically tailored methodology should be used for the training and empowerment process of paediatric patients, given their specific characteristics and needs; calls for participatory decision-making with personalised and understandable evidence-based information to be provided to patients as an integral part of the National Cancer Control Programmes (NCCPs), supported by the EBCP; calls for supporting such initiatives and actions to empower cancer patients through EU
funding, namely the EU4Health programme;

Compromise on Paragraph 81
Replacing amendments: 1163, 1164, 1165, 1166, 1167, 1168

81. Acknowledges the positive role of patients’ associations in relation to patient advocacy and accompaniment; calls on the Commission and the Member States to take into account their requests and recommendations when formulating cancer-related policies and legislation and to provide them with public support in order to guarantee their independence from private funding;

Motion for a resolution

Draft compromise Amendment

81. Acknowledges the central role of independent patients’ and carers’ associations in relation to patient advocacy and accompaniment, services provided to cancer patients and caregivers, dissemination of health literacy, awareness raising and ongoing support both at EU and national level; calls on the Commission and the Member States to take into account the formal participation of those associations, as well as their requests and recommendations, when formulating cancer-related policies and legislation, and to provide them with public support in form of both operating grants and project-related grants in order to guarantee their independence from private funding; calls on the Commission to set clear criteria according to which public financial support can be awarded; considers that paediatric patients should play a role, both individually and collectively, in improving healthcare and research procedures for all patients by contributing with their specific experiences; takes the view, therefore, that adequate learning and educational tools should be developed and properly financed to plan and ensure the involvement of children;
Compromise on Paragraph 82  
Replacing amendments: 545, 736, 791, 1111, 1131, 1132, 1172, 1173, 1174, 1175, 1176, 1177, 1178, 1179, 1180, 1181

Motion for a resolution

82. Calls on the Member States to improve the reintegration of cancer survivors into the labour market and to facilitate the return to school of paediatric cancer survivors; advocates specific EU recommendations for measures for cancer survivors to prevent the recurrence of primary cancer and the development of new cancers and for their rehabilitation;

Draft compromise Amendment

82. Calls on the Member States to improve the reintegration of cancer survivors into the social activities and the labour market, also helping them in the transition to a new professional role in case of sequelae preventing their continuity in the same job, and to facilitate the return to school, or higher education, of paediatric cancer survivors; notes the general underestimation of aftercare compared to the equally important cancer prevention; recalls the recommendations and tools developed by the CHRODIS+ Joint Action to foster patients’ retention at work, return to work and reintegration into the labour market and encourages the Commission to support the implementation of those recommendations and tools across the Member States; advocates specific EU recommendations for measures for cancer survivors to prevent the recurrence of primary cancer and the development of new cancers and for their rehabilitation, including specific provisions for long-term follow-up care for childhood cancer survivors as they transition into adulthood; stresses the need for medical and psychological aftercare for cancer survivors;

Compromise amendment on Paragraph 84  
Replacing amendments 1187, 1188, 1189

Motion for a resolution

84. Supports the upcoming roll-out of a Cancer Survivor Smart Card, as announced in Europe’s Beating Cancer Plan, to all European cancer survivors, especially survivors of childhood and adolescent cancers, which will summarise their clinical history, including patients’ own experience,

Draft compromise Amendment

84. Supports the upcoming roll-out of a Cancer Survivor Smart Card, as announced in Europe’s Beating Cancer Plan, for all European cancer survivors, especially survivors of childhood and adolescent cancers, for whom the Survivorship
Passport model exists as a basis, which will summarise their clinical history, including patients’ own experience, and facilitate and monitor follow-up care; stresses the sensitive nature of individual health data and hence the need for the Smart Card to be fully protected under the EU’s GDPR;

Compromise amendment on Paragraph 85
Replacing amendments 1190, 1191, 1192, 1193, 1194

Motion for a resolution

85. Considers that insurers and banks should not take into account the medical history of people who have been affected by cancer; calls for national legislation to ensure that cancer survivors are not discriminated against compared to other consumers; notes the Commission’s intention to engage with businesses to develop a code of conduct to ensure that developments in cancer treatments and their improved effectiveness are reflected in the business practices of financial service providers; supports, in parallel, the promotion of advances made in France, Belgium, Luxembourg and the Netherlands, where cancer survivors enjoy the ‘Right to be Forgotten’; requests that by 2025, at the latest, all Member States should guarantee the Right to be Forgotten to all European patients ten years after the end of their treatment, and five years after the end of treatment for patients whose diagnosis was made before the age of 18; calls for the introduction of common standards for the Right to be Forgotten under the relevant provisions on consumer protection policy of the Treaty on the Functioning of the European Union, in order to remedy the fragmented national practices in the area of creditworthiness assessment and ensure equal access to credit for cancer survivors;

draft compromise Amendment

85. Considers that insurers and banks should not take into account the medical history of people who have been affected by cancer; calls for national legislation to ensure that cancer survivors are not discriminated against compared to other consumers; notes the Commission’s intention to engage with businesses to develop a code of conduct to ensure that developments in cancer treatments and their improved effectiveness are reflected in the business practices of financial service providers; supports, in parallel, the promotion of advances made in France, Belgium, Luxembourg and the Netherlands, where cancer survivors enjoy the ‘Right to be Forgotten’; requests that by 2025, at the latest, all Member States should guarantee the Right to be Forgotten to all European patients ten years after the end of their treatment, and up to five years after the end of treatment for patients whose diagnosis was made before the age of 18; calls for the introduction of common standards for the Right to be Forgotten under the relevant provisions on consumer protection policy of the Treaty on the Functioning of the European Union, in order to remedy the fragmented national practices in the area of creditworthiness assessment and ensure equal access to credit for cancer survivors; calls for embedding into relevant EU legislation the Right to be Forgotten for
Motions for a resolution

Draft compromise amendment

86. Calls on the Commission to support the European Code of Cancer Care launched by the European Cancer Organisation (ECO), which is an empowering and informative tool to ensure that the best available care is provided to European citizens and patients;

87. Sees an urgent need for a European charter of the rights of cancer patients; calls for this charter to define the rights of cancer patients at every stage of their care pathway, i.e. access to prevention, initial diagnosis and throughout their treatment, and for it to apply equally to all EU citizens, regardless of the country or region in which they live;
V. Challenges in cancer among children, adolescents, and young adults

Compromise amendment on Paragraph 88
Replacing amendments 1212-1213, 1214, 1215, 1216, 1217, 1218, 1220, 1221, 1222, 1224, 1418

Motion for a resolution

88. Calls for clear policy requirements on paediatric cancer research needs; calls on Member States and the Commission to redress the unequal allocation of investment to paediatric cancers; considers that a clear and specific EU funding stream should be dedicated to paediatric cancer research and budget allocations earmarked across all relevant EU programmes;

Draft compromise Amendment

88. **Welcomes the childhood cancer spotlight initiatives announced by the Commission;** calls for clear policy requirements on paediatric cancer research needs; calls on Member States and the Commission to redress the unequal allocation of investment to paediatric cancers; considers that a clear and specific EU funding stream should be dedicated to paediatric cancer research and treatment and budget allocations earmarked across all relevant EU programmes; **highlights the importance of supporting international academic research platforms in paediatric cancers, informed by research performed by other relevant actors;**

Compromise amendment on Paragraph 89
Replacing amendments 1225, 1226, 1227, 1258, 1262

Motion for a resolution

89. Calls on the Commission and the Member States to focus on ensuring equal access to the best specialist diagnostics and multi-disciplinary treatment for children with cancer, and to improve cancer treatment outcomes in all Member States; considers that the professional figure of the paediatric oncologist should be recognised in all Member States;

Draft compromise Amendment

89. Calls on the Commission and the Member States to focus on ensuring equal and geographically balanced access to the best specialist diagnostics and multi-disciplinary treatment for children with cancer, and to improve cancer treatment outcomes in all Member States; considers that the academic specialty and the professional figure of the paediatric oncologist should be recognised in all Member States; **believes that every patient who has experienced cancer as a child or adolescent should receive ongoing medical care and monitoring even after reaching adulthood, and therefore calls for measures to make cooperation between paediatric and adult health professionals more flexible; encourages the exchange of**
knowledge on the course of cancers among children and adolescents;

Compromise amendment on Paragraph 89 a (new)
Replacing amendments 1228, 1229, 1233, 1260, 1261

Motion for a resolution

89a. Stresses the need for comprehensive population-based childhood cancer registries based on internationally agreed childhood cancer classification systems, ensuring high-quality comparable data across Europe; reinforces the need for publishing at least annually the number of cancer cases in children and adolescents in Europe and in each Member State;

Compromise amendment on Paragraph 91
Replacing amendments 1230, 1231, 1238, 1239, 1242, 1243, 1244

Motion for a resolution

91. Stresses the need to strengthen the right to cross-border care for children and AYA cancer patients when the best treatment is not available in their country of residence;

Draft compromise Amendment

91. Stresses the need to strengthen the right to cross-border care for children and AYA cancer patients when the best treatment is not available in their country of residence, and ensure that access to innovation in clinical trials for relapsed or difficult-to-treat malignancies is covered by the relevant provisions, by enhancing the sustainability of existing cross-border collaborations including the European Reference Networks, in particular the ERN PaedCan; emphasises the need for clarification regarding access to cross-border clinical trials, which is not clearly specified in the Cross-Border Healthcare Directive;
92. Calls for an ambitious revision of the regulations on paediatric and orphan medicinal products in order to ensure access to innovative cancer drugs, identify the most important drugs to meet the needs of children with poor prognostic cancers, reduce delays so that children can have faster access to paediatric drugs, and address limited access to certain essential medicines due to drug shortages and the high price of innovative medicines; recommends an increase of 20 % in the available new paediatric cancer drugs by 2027;

92. Notes that both regulations on paediatric and orphan medicinal products have fostered the development and availability of medicines for patients with rare diseases and for children, redirecting private and public investments towards previously neglected areas; calls for an ambitious revision of the regulations on paediatric and orphan medicinal products in order to ensure the development of and an affordable access to innovative cancer drugs, identify the most important drugs to meet the needs of children with poor prognostic cancers, support academic research and SME involvement, reduce delays so that children can have faster access to paediatric drugs and gene and cell therapies, stimulate competition by adapting the regulatory framework and encouraging investments in off-patent orphan and paediatric medicines, and address limited access to certain essential medicines due to drug shortages and the high price of innovative medicines; recommends an increase of 20 % in the available new paediatric cancer drugs by 2027, as well as an increase in the accessibility of personalised medicine; considers, consequently, that a clear obligation to include paediatric research should be considered as a condition for application; calls on the Commission, where appropriate in dialogue with the Member States, to work on a system that favours access to real breakthrough innovation for paediatric cancer patients; calls on the Commission to facilitate the repurposing of medicines failing in adults when there is scientific and preclinical rationale, as well as to provide more effective and tailored incentives to foster the development of medicines for cancer in children and the First-in-Child
development of new paediatric anticancer medicines, encourage timely paediatric development and reduce delays, such as by means of early proportionate rewards allocated incrementally and not exclusively at the end of the Supplementary Protection Certificate (SPC); calls on the Commission to remove Article 11b of the Paediatric Regulation in the upcoming review to allow paediatric cancer medicine development to be driven by science and the medicine’s mechanism of action;

Compromise amendment on Paragraph 96
Replacing amendments 1266, 1267, 1268, 1269, 1270

Motion for a resolution
96. Supports the recommendation of the Joint Action on Rare Cancers for the roll-out of a European unique patient identifier, in order to ensure the monitoring of long-term outcomes in childhood cancer survivors in a cross-border setting;

Draft compromise Amendment
96. Supports the recommendation of the Joint Action on Rare Cancers for the roll-out of a European unique patient identifier, the Survivorship Passport and guidelines on long-term surveillance and transition from paediatric to adult care in order to ensure the monitoring of long-term outcomes in childhood cancer survivors in a cross-border setting; stresses the need for the ‘Right to be Forgotten’ to be fit for purpose for this population;
VI. Challenges of rare adult cancers

Compromise adding a new section VI on Challenges of rare adult cancers

Compromise amendment on Paragraph 96 a (new)
Replacing amendments 817, 1219, 1271, 1283, 1284, 1285, 1286, 1287, 1288, 1289, 1290, 1291, 1292, 1293, 1294, 1295, 1296, 1297, 1298, 1299, 1454, 1455, 1456, 1457, 1497

Motion for a resolution  Draft compromise Amendment

96 a. 1. Acknowledges that rare adult cancers are a public health challenge; recalls that patients affected by rare adult cancers share the challenges linked to the rarity and uncommon nature of their disease: long delays to diagnosis, and sometimes misdiagnosis, difficult access to timely and adequate care and treatments; notes that patients often feel alone, isolated and suffer greatly reduced quality of life, whereas their carers are also significantly and negatively impacted; calls for the Cancer Inequalities Registry to integrate information on rare cancers which amount to about 24% of new cancers cases occurring from birth up to elderly age groups;

2. Supports the introduction of a dedicated flagship initiative on rare adult cancers within the Europe’s Beating Cancer Plan to tackle the specific challenges faced by this patient community and make the best use of the recommendations set out in the Rare Cancer Agenda 2030 to foster research and improve care in each step of the rare cancer patient journey; urges for ensuring that rare adult cancers are included in all initiatives across the four pillars of the Europe’s Beating Cancer Plan;

3. Calls for dedicated funding for rare adult cancer research projects under Horizon Europe, including under the Mission on Cancer (for instance under UNCAN.eu – the European Initiative to Understand Cancer) to develop targeted therapies, and support the development of
databases, registries and biobanks relevant to rare adult cancers;

4. Stresses the difficulty in diagnosing rare adult cancers more timely, and therefore recommends easier and timely access to molecular testing that can help patients receive an accurate diagnosis and targeted therapy, and even access relevant clinical trials where appropriate; stresses, further, that research on biomarkers is critical in that area;

5. Calls for increasing awareness of rare adult cancers amongst primary and secondary healthcare professionals and implementing adequate referrals to specialised multidisciplinary expert centres at both national and European level;

6. Encourages Member States to establish national networks for rare adult cancers to optimise the referral of patients to specialised centres in a timely fashion and facilitate interaction with ERNs to maximise the exchanges of multidisciplinary knowledge and high-quality care as well as to foster clinical research;

7. Calls for improving access to clinical trials and compassionate use for rare adult cancer patients; regrets that it continues to be very difficult for rare adult cancer patients from many countries to access EAPs and trials abroad; calls for a better implementation of EU schemes for rare adult cancer patients to access healthcare abroad, whereas national healthcare systems should facilitate access to trials and EAPs for patients with rare adult cancers who have few treatment options;

8. Encourages novel regulatory approaches to enable rare adult cancer patients to access new innovative therapies under safe monitoring, while facilitating the collection of real-world data in addition to data collected in clinical trials;

9. Emphasises the need to include rare
adult cancers in the “inter-specialty cancer training programme” including specialised nursing training, in conjunction with ERNs for rare adult cancers; additionally, emphasises the need to support educational programmes targeting rare adult cancer patients, carers and patient representatives in conjunction with ERNs, to increase levels of health literacy and ultimately help patients and their families to make informed choices about treatment options and follow-up care;

10. Acknowledges the specificities of rare adult cancers in programmes dedicated to improving the quality of life of cancer patients, survivors and carers; calls on the Commission and Member States to implement specific training for professionals, other than healthcare providers (e.g. social workers, case managers), taking care of rare adult cancer patients; stresses that rare adult cancer patients need to receive adequate psychological support, rehabilitation and monitoring of long-term side effects of treatments by professionals who understand their rare disease and the specificities linked to it; recommends that all patients with rare adult cancers also be provided with a survivorship care plan; considers that carers for rare adult cancer patients (often family members) also need access to specific psychosocial support to cope with the severity and complexity of the disease, and the significant burden of care which they take on;

11. Calls on Member States to include a specific section on the management of rare adult cancers in their National Cancer Control Programme (NCCP) (along with a distinct section on cancers in children) as recommended in the Rare Cancer Agenda 2030; considers that the specificities should be acknowledged in specific distinct sections in all the NCCPs, with relevant synergies with rare disease national plans, to foster research as well as improve care management and care pathways for these patients, from primary care up to highly
specialised multi-disciplinary healthcare centres, notably belonging to, or in close contact with a relevant ERN; notes that, to date, rare cancers in adults and paediatric cancers are hardly included in many NCCPs of Member States;

12. Urges relevant national authorities to involve rare adult cancer patient organisations as partners in NCCPs to voice rare adult cancer patients’ needs and expectations, as well as actively participate in the implementation of dedicated measures for rare adult cancers;

B. Tools for action

I. Holistic research

Compromise amendment on Subheading I
Replacing amendments 1300-1301

Motion for a resolution
I. Holistic research

Draft compromise Amendment
I. Holistic research and its implications

Compromise amendment on Paragraph 97
Replacing amendments 1302, 1303, 1304, 1305, 1306, 1307

Motion for a resolution
97. Stresses that Europe’s Beating Cancer Plan should be implemented in close cooperation with the Cancer Mission under Horizon Europe and its objectives of promoting EU investment in cancer research and innovation;

Draft compromise Amendment
97. Stresses that Europe’s Beating Cancer Plan should be implemented in close cooperation with the Cancer Mission under Horizon Europe and its objectives of promoting EU investment in cancer research and public production and innovation; welcomes that Horizon Europe will fund research infrastructures, cloud computing and European Innovation Council actions; calls on the Commission to consider paediatric cancer as a topic for
a European Partnership under the next Strategic Programme of Horizon Europe; recommends that appropriate funding be given to projects under Horizon Europe dedicated to new paediatric cancer medicines in order to fill the existing gap in paediatric medicines;

Compromise amendment on Paragraph 98
Replacing amendments 1308, 1311, 1312, 1313, 1314, 1315, 1316, 1317, 1318, 1537

Motion for a resolution

98. Recalls that cancer research, and its translation into everyday clinical practice, is fundamental to ensuring continuous improvements in cancer prevention, diagnosis, treatment and follow-up care for survivors; welcomes, therefore, the launch of Horizon Europe partnerships to translate scientific knowledge into innovations;

Draft compromise Amendment

98. Recalls that multidisciplinary cancer research and its translation into everyday clinical practice is fundamental to ensuring continuous improvements in cancer prevention, diagnosis, treatment and follow-up care for survivors; welcomes, therefore, the launch of Horizon Europe partnerships to translate scientific knowledge into innovations that reach patients; asks the Commission to follow closely the Horizon Europe partnerships activity and the translation of research into real added value for current medical practice;

Compromise amendment on Paragraph 99
Replacing amendments 1310, 1322, 1323, 1324, 1325, 1326, 1327, 1328, 1329, 1330, 1331, 1332, 1334, 1402

Motion for a resolution

99. Reiterates its call for sustainable and adequate funding for competitive European research on cancer; calls for at least a 20 % increase in the mobilisation of public and private research on therapeutic and diagnostic cancer innovations;

Draft compromise Amendment

99. Reiterates its call for sustainable and adequate funding for competitive European research on cancer; stresses that such research should aim to address areas of highly unmet needs and be conducted across all parts of the cancer care continuum, including for all treatment modalities; calls on Member States to increase by 20 % at least the mobilisation of public research on therapeutic, diagnostic and screening cancer
innovations, covering all patient populations concerned; calls, furthermore, for the EU Framework Programme and national research programmes to support research into paediatric and orphan medicines through innovation prize funds; considers that conditions for access to public funding should be revised, ensuring transparency of the contracts stipulated between public and private entities as well as conditionalities as regards the accessibility and affordability of new innovations when projects are successful;

Compromise amendment on Paragraph 100
Replacing amendments 1340, 1341, 1342, 1343, 1344, 1345, 1346, 1347, 1348, 1350

Motion for a resolution

100. Stresses the need for independent and multidisciplinary research on cancer ‘from bench to bedside’, that is from the laboratory to applied studies in patients; urges the establishment of measures to limit misinformation, especially on social media;

Draft compromise Amendment

100. Stresses the need for independent and multidisciplinary research on cancer ‘from bench to bedside’, that is from the laboratory to applied studies in patients but also for the regular re-evaluation of the effectiveness of medicines already on the market; stresses the need for the results of this research to be made public in a transparent and simple way; urges for the establishment of measures to limit the health risks posed by disinformation and misinformation, especially on social media, with special attention to measures protecting children and young people, and to support science dissemination initiatives;
102. Considers the significant potential impact of the use of artificial intelligence and modern technologies in diagnosis and decision-making for cancers in the coming years; encourages the Commission and the Member States to promote the knowledge of cancer biology through the implementation of genomics and informatics infrastructures; underlines that the combination of real-world data, mathematical modelling, artificial intelligence and digital tools will significantly help to develop innovative treatments in a more cost-efficient way, and potentially reduce the required number of patients to be involved in clinical trials and the use of animals in research; encourages the Commission and the Member States to promote the knowledge of cancer biology through the implementation of genomics and informatics infrastructures; urges all implementation partners to be ever mindful of the principles of data privacy and security, trust, transparency, patient centricity and patient involvement at all times;

106. Welcomes the planned Partnership for Personalised Medicine, announced in Europe’s Beating Cancer Plan and to be funded under Horizon Europe, which will identify priorities for research and education in personalised medicine, support research projects on cancer prevention, diagnosis and treatment, and make recommendations for the roll-out of personalised medicine approaches in daily medical practice; supports the establishment of a supportive and enabling regulatory framework and funding mechanisms; stresses the need to
of a roadmap for personalised prevention allowing for the identification of gaps in research and innovation and for the mapping of all known biological anomalies leading to cancer susceptibility, including hereditary factors; establish a well-defined, globally consistent terminology for 'personalised medicines' that would streamline investment in research and benefit patients’ health literacy; supports the establishment of a roadmap for personalised prevention allowing for the identification of gaps in research and innovation and for the mapping of all known biological anomalies leading to cancer susceptibility, including hereditary and environmental factors and paediatric issues; calls for consideration to make these solutions accessible through public healthcare systems;

Compromise amendment on Paragraph 107
Replacing amendments from 1380 to 1388

Motion for a resolution

107. Encourages research on non-profit clinical trials to improve treatment strategies, with a focus on the elderly;

Draft compromise Amendment

107. Calls for enhanced capacity building, infrastructure, collaboration and funding of research on non-profit clinical trials to improve treatment strategies, with a focus on the elderly as well as on vulnerable and under-represented patient populations, including women and children; urges for EU support for the health system and treatment optimisation agenda;

Compromise amendment on Paragraph 108
Replacing amendments from 1389 to 1394

Motion for a resolution

108. Calls on the Commission and the Member States to promote studies dedicated to human and social sciences, in particular those addressing health inequalities at the different stages of cancer diseases;

Draft compromise Amendment

108. Calls on the Commission and the Member States to promote studies dedicated to human and social sciences, in particular those addressing health inequalities at the different stages of cancer diseases, as well as research on optimising the organisation of cancer treatment, the financing of healthcare services and providers and the organisation of their delivery and the
functioning of management institutions; calls for the studies to include attention to those inequalities in cancer care which are related to factors such as gender, age and socio-economic status, with particular attention to marginalised and vulnerable groups in society;

Compromise amendment on Paragraph 109
Replacing amendments 1362, 1396 - 1401

Motion for a resolution

109. Considers that the Commission and the Member States should support the development of European multicentre clinical trials;

Draft compromise Amendment

109. Calls on the Commission and the Member States to support the development of European multicentre clinical trials, especially in the case of low incidence cancers and/or cancers with reduced treatment options, and to strengthen multinational cooperation and the conduct of cross-border clinical trials, building on existing structures where appropriate, such as the European Clinical Research Council in the paediatric cancer sector, and encourage the engagement of smaller countries; highlights, furthermore, the need for all EU cancer policy initiatives to be coordinated towards defined and shared aims;

Compromise amendment on Paragraph 111
Replacing amendments 1403 - 1407

Motion for a resolution

111. Strongly believes that patient associations should be involved in defining research endpoints for clinical trials, in order to ensure that the trials address the unmet needs of European patients; considers that the final results of the trials should be communicated to the participating patients and to the public;

Draft compromise Amendment

111. Strongly believes that patients and independent patient associations, as well as parents and carers, should be involved in defining research priorities and endpoints for clinical trials, in order to ensure that the trials address the unmet needs of European patients, including quality of life as primary endpoint; considers that the final results of the trials should be communicated to the participating patients and to the
calls for paediatric patients to be involved in the definition of unmet needs to provide input in the design of the clinical trials protocol, improve communication with the target population and enhance methods for dissemination of findings; stresses that the extent to which transparency provisions within the Clinical Trials Regulation 536/2014 are being met, should be kept under surveillance, and therefore regularly reported on;

Compromise amendment on Paragraph 112
Replacing amendments 1365, 1408 - 1414

Motion for a resolution

112. Advocates more transparency in the process of research into and the development of cancer treatments, including the establishment of a portal to allow patients access to information on the available clinical trials in Europe;

Draft compromise Amendment

112. Advocates more robust scrutiny of clinical trials and more transparency in research and development of cancer treatments, including the establishment of a portal to allow patients access to information on the available clinical trials in Europe; calls for transparency on access to, and the use of, data of clinical trials at Union level, including those that have been discarded; underlines that this should also include information tailored to children and young patients;

Compromise amendment on Paragraph 112 a
Replacing amendments 1415, 1416, 1417

Motion for a resolution

112a. Recommends that research be a parameter of the Cancer Inequalities Registry in order to measure and monitor inequalities in respect to access to clinical trials as well as to better understand and respond to regional and national disparities in trial activity, and to track improvement from initiatives to be taken up via Europe’s Beating Cancer Plan, such as the EU Network of Comprehensive Cancer Centres;
Compromise amendment on Paragraph 113
Replacing amendments 719, 1364, 1421-1426, 1498

Motion for a resolution

113. Considers that the sharing of expertise, data, training programmes and communication tools is needed to improve the knowledge of cancer among both health professionals and patients; stresses the sensitive nature of health data and calls for full compliance with Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)36.

Draft compromise Amendment

113. Considers that the sharing of expertise, data, training programmes and communication tools is needed to improve the knowledge of cancer among both health professionals, researchers and patients; calls for cross-sector and cross-country collaboration and knowledge sharing that will be crucial for further enhancing the quality of cancer care in the EU; notes that data sharing is key to applying artificial intelligence and machine learning tools to research provided there is human oversight, and to enabling the digital transformation of healthcare, to tackle disparities in cancer prevention, diagnosis, and treatment around Europe and to optimise the use of healthcare systems resources, increasing efficiency and thus allowing for wider availability of oncological care data, also in less urbanised and remote areas; stresses the sensitive nature of health data; calls for full compliance with Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)36 to avoid unnecessary restrictions for cross-border healthcare; stresses the need for harmonised interpretation and implementation of the GDPR, especially by Data Protection Authorities, including its Recitals 33 and 157, and its interaction with the Clinical Trials Regulation once applicable, including Recital 29 and Article 28 (2) of that Regulation, across the EU to facilitate scientific research; requests the European Data Protection
Board to ensure that its guidelines concerning health research are updated with the aim of fostering research, and calls on the Commission to make concrete proposals by the end of 2022

Compromise amendment on Paragraph 114
Replacing amendments 1428-1433

Motion for a resolution

114. Asks the Commission to assess the functioning of the European Reference Networks (ERNs), especially their role in gathering and sharing expertise and best practices, thus rationalising patient referral in the management of rare cancers, which affect an estimated 5.1 million patients across Europe and require cooperation on a large scale;

Draft compromise Amendment

114. Asks the Commission to assess the functioning of the European Reference Networks (ERNs), especially their role in gathering and sharing expertise and best practices, thus rationalising patient referral in the management of rare cancers, which affect an estimated 5.1 million patients across Europe and require cooperation on a large scale; emphasizes the importance of the ERNs with regard to overcoming health inequalities and ensuring safer and high-quality treatment across EU borders;

Compromise amendment on Paragraph 115
Replacing amendments 1437-1444, 1458

Motion for a resolution

115. Emphasises the need to secure sustained long-term funding for the ERNs; supports the expansion of the ERNs to specific types of cancer (rare, complex, poorly curable) and paediatric cancers;

Draft compromise Amendment

115. Calls on the Commission and the Member States to secure appropriate and sustained long-term funding for the ERNs, as well as their integration into national health systems; calls for the funding to cover, inter alia, compensation of virtual consultations, support for twinning and education programmes, and effective reimbursement of patient travel in line with the Cross-Border Healthcare Directive when this is required, in order to foster improved standards of care and equal access to the best possible interventions to all patients who require them across Europe; calls also for support to the roll-out, upgrade and the smooth functioning of digital infrastructure that simplifies and facilitates access to the ERNs, as well as to the creation of a EU health data strategy to improve current
rare disease registries in a common and uniform data space; stresses the need to guarantee funding through the EU4Health Programme, Horizon Europe, the European Semester programme, Structural Funds, and through Article 195 of the Financial Regulation; supports the expansion to rare, complex, poorly curable cancers and paediatric cancers of the four existing ERNs (PaedCan on paediatric cancers, EURACAN on rare adult solid cancer, EuroBloodNet on rare haematological diseases including rare haematological malignancies and GENTURIS on genetic tumour risk syndromes), as this could facilitate equal access of patients, including children and AYA, to the best available care across Europe and would improve the functionality of the ERNs and health outcomes in rare disease patient populations;

Compromise amendment on Paragraph 116
Replacing amendments 760, 1445 - 1450

Motion for a resolution
116. Believes that the revamping of ERNs will necessarily involve the participation of all Member States in existing ERNs, with each Member State having at least one ‘full’ or ‘affiliate’ member in each ERN, the facilitation of the individual patient journey through the effective collaboration of national contact points with ERNs, the evaluation of the functioning of the ERNs by sharing data on their performance and networking in the field of rare cancers, the deployment of telemedicine tools allowing for the sharing of case records and imaging results, and the allocation of adequate and long-term funding, both at Union (EU4Health) and national level;

Draft compromise Amendment
116. Believes that the further development and optimisation of ERNs will necessarily involve the participation of all Member States in existing ERNs, with each Member State having at least one ‘full’ or ‘affiliate’ member in each ERN and in each sub-clinical domain/thematic network of ERNs, the facilitation of the individual patient journey through the effective collaboration of national contact points with ERNs, the evaluation of the functioning of the ERNs by sharing data on their performance and networking in the field of rare cancers, the deployment of efficient telemedicine tools allowing for the sharing of case records and imaging results in a secured fashion to discuss complex rare cancer cases, and the allocation of adequate and long-term funding, both at Union (EU4Health) and national level;

Compromise amendment on Paragraph 117
Replacing amendments 1434, 1452, 1453
117. Encourages Member States to support a dedicated and tailored approach to rare cancers in adults and paediatric cancers, taking stock of EU initiatives, and to fully integrate ERNs into their national healthcare systems;

Draft compromise Amendment

117. Encourages Member States to support a dedicated and tailored approach to rare cancers in adults and paediatric cancers, taking stock of EU initiatives and to fully integrate ERNs into their national healthcare systems; calls for the creation of common and consistent protocols governing the collection of data, and for the creation of a single set of definitions explaining the data collected; calls for the rare cancer patient organisations to be associated to the ERNs and the European reference centre;

Compromise amendment on Paragraph 119
Replacing amendments 1336, 1462, 1463, 1500 - 1525 and deleting original paragraph 124

Motion for a resolution

119. Welcomes the launch of a Knowledge Centre on Cancer in 2021, announced in Europe’s Beating Cancer Plan, in order to contribute to the exchanges and coordination of scientific and technical initiatives related to cancer at EU level; believes that this knowledge centre should be based on data screening, ERN reports and cancer registries, and be part of a European Cancer Institute;

Draft compromise Amendment

119. Welcomes the launch of a Knowledge Centre on Cancer in 2021 in order to contribute to the exchanges and coordination of scientific and technical initiatives related to cancer at EU level; considers that the knowledge centre should involve all stakeholders (representatives of each NCCP, patients’ and caregivers’ associations, learned societies, relevant EU bodies and agencies, representatives of economic operators, etc.); believes that this knowledge centre should be based on data screening, ERN reports and cancer registries;

considers that its mission should be clearly defined and include:

a) coordinating the network of all NCCPs;

b) producing a European roadmap to trigger large-scale prevention campaigns and educational programmes on health promotion;

c) coordinating the establishment of common quality criteria to guide the national accreditation of screening programmes, cancer registries and cancer
d) developing, on the basis of latest scientific evidence, clinical practice guidelines and quality assurance schemes to improve the entire care pathway for all cancer types, in particular for rare and paediatric cancers; drafting annual reports and establishing frameworks to improve data collection from screening programmes, cancer registries and ERNs at EU level;

e) presenting studies on the impact of prevention and diagnosis, including estimates concerning the reduction of economic costs generated through increased investment in prevention and diagnosis;

f) coordinating the exchange of best practices and results between the ERNs and the Comprehensive Cancer Centres;

g) generating a comprehensive model based on Europe’s Beating Cancer Plan and Horizon Europe, as well as with the input from patients and carers, in order to identify research priorities and possibly enable the development of a coordinated and efficient cancer research force in Europe;

h) facilitating the sharing of anonymised data, collected in a European Cancer Cloud, for clinicians and researchers, as well as for entities developing health services and modern technological solutions for cancer patients;

i) supporting common training programmes for health professionals, patients and caregivers;

j) delivering updated, certified and transparent information to citizens and professionals on cancer causes, treatments and EU legislation;

k) monitoring the level of implementation of relevant recommendations in the Member States’ NCCPs, and regularly making available the results of this monitoring;

l) proposing measurable and reproducible indicators for the main outcomes outlined in Europe’s Beating
Cancer Plan;

*recalls that researchers have to work together to find the best possible treatment especially for patients suffering from rare cancer, but that they are facing serious obstacles;* calls therefore on the Commission to systematically look, via its Scientific Advice Mechanism or through the appointment of a cross border cancer research special envoy, at all the obstacles in cross-border cancer research and cooperation, including regulation, in order to promote cross-border cancer research;

Compromise amendment on Paragraph 120
Replacing amendments 1464 -1474, 1479

**Motion for a resolution**

120. Recommends the creation of at least one cancer registry in each EU region, including remote and outermost regions; supports the strengthening of the capacity of national cancer registries to collect data (including lifestyle and socio-economic information) to better identify the causes of inequalities in cancer incidence, prevalence and survival; asks Member States to ensure the comparability of data sources and the interoperability of regional and national cancer registries;

**Draft compromise Amendment**

120. Recommends the creation of at least one cancer registry in each EU region, including remote and outermost regions; considers it pivotal to ensure the smooth functioning of the cancer registries; supports the strengthening of the capacity of national cancer registries to collect standardised patient-reported outcomes, to better map EU citizens’ lifestyle, socio-economic conditions and occupational information, environmental factors, and data to identify the causes of inequalities in cancer incidence, prevalence and survival; stresses the essential need to collect data collaboratively across all Member States; calls for the comparability of data sources and the interoperability of regional and national cancer registries via the harmonisation of the scope and quality of data collection, and for secure access to such data; calls for mandating national cancer registries to analyse disparities in morbidity and to make recommendations to national cancer councils and the Joint Research Centre on the need for interventions; calls for the use of modern
Compromise amendment on Paragraph 121
Replacing amendments 1475 - 1482

Motion for a resolution

121. Strongly supports the creation of a Cancer Inequalities Registry at European level, announced in Europe’s Beating Cancer Plan, in order to identify trends, disparities, inequalities and inequities between and within Member States; believes that this registry will help to identify challenges and specific areas of action so as to guide investment and intervention at EU, national and regional level;

Draft compromise Amendment

121. Strongly supports the creation of a Cancer Inequalities Registry at European level, announced in Europe’s Beating Cancer Plan, in order to identify trends, disparities, inequalities and inequities between and within Member States; believes that this registry will help to identify challenges and specific areas of action so as to guide investment and intervention, and facilitate research into inequalities, at EU, national and regional level; calls for making the Registry accessible to the public; stresses the need for the Registry to also cover social inequalities such as those related to socio-economic status, occupation and gender;

Compromise amendment on Paragraph 122
Replacing amendments 1483, 1485 - 1492

Motion for a resolution

122. Supports the Commission’s intention to enable cancer patients to securely access and share electronic health records across borders; considers that the Commission could lay the foundation for the European Health Data Space, in association with Digital Health Europe, by collecting and analysing anonymised medical data (from cancer registries, hospitals, academic clinical trials and cohorts) and biological data (from blood and tumour samples) in a European Cancer

Draft compromise Amendment

122. Supports the Commission’s intention to enable cancer patients to securely access and share electronic health records across borders; considers that the Commission could lay the foundation for the European Health Data Space, in association with Digital Health Europe, by collecting, analysing and exchanging anonymised medical data (from cancer registries, hospitals, academic clinical trials and cohorts) and biological data (from blood and tumour samples) in a European
Cloud hosted by a European Cancer Institute; encourages the use of health data for non-commercial purposes (‘data altruism’); welcomes the planned creation of a virtual European Cancer Patient Digital Centre under Horizon Europe’s Mission on Cancer in order to support a standardised approach to the participation of willing patients in the deposit and exchange of their health data; recommends the inclusion of patients in any actions related to the storage and use of health data for policy-making and research purposes; welcomes the planned expansion of the European Cancer Information System before 2022;

Cancer Cloud; underlines that a harmonised interpretation of the General Data Protection Regulation (GDPR) in all EU Member States is the foundation for new data-sharing initiatives such as the European Health Data Space; encourages the use of health data for research purposes (‘data altruism’); welcomes the planned creation of a virtual European Cancer Patient Digital Centre under Horizon Europe’s Mission on Cancer in order to support a standardised approach to the participation of willing patients in the deposit and exchange of their standardised and uniformly defined health data; recommends the inclusion of patients in any actions related to the storage and use of health data for policy-making and research purposes; welcomes the planned expansion of the European Cancer Information System before 2022;

Compromise amendment on Paragraph 123
Replacing amendments 1493 - 1496

Motion for a resolution

123. Calls for improved standards in the education and training of health professionals; encourages common and multidisciplinary training programmes for health professionals in close collaboration with European learned societies; welcomes the launch of an inter-specialty cancer training programme, which will involve cooperation between Member States via a European Cancer Institute;

Draft compromise Amendment

123. Calls for improved standards in the education and training of health professionals; encourages common and multidisciplinary training programmes for health professionals in close collaboration with European learned societies; welcomes the launch of an inter-specialty cancer training programme at every stage of the treatment and care pathway through diagnosis, treatment, complications and co-morbidities, survivorship and end-of-life care;
IV. Financing Europe’s Beating Cancer Plan

Compromise amendment on Paragraph 125
Replacing amendments 1526 - 1529

Motion for a resolution

125. Emphasises that Europe’s Beating Cancer Plan should not only be seen as a political commitment to driving change but as a set of concrete and ambitious initiatives that will support, coordinate and complement Member States’ efforts to reduce the suffering caused by cancer; stresses that, in order for the initiatives outlined in the Plan to be translated into concrete actions, these initiatives have to be adequately funded; underlines, however, the differing capacity of Member States to absorb the funds dedicated to healthcare programmes thus far;

Draft compromise Amendment

125. Emphasises that Europe’s Beating Cancer Plan should not only be seen as a political commitment to driving change but as a set of concrete and ambitious initiatives that will support, coordinate and complement Member States’ efforts to reduce the physical and mental suffering caused by cancer; encourages the Commission to optimise the coherent implementation of the initiatives outlined in the Plan, with clear guidance to Member States regarding concrete actions against unequal access to cancer diagnosis and treatment, as well as adequate funding, especially in order to address that unequal access;

underlines, however, the differing capacity of Member States to absorb the funds dedicated to healthcare programmes thus far; calls on the Commission to provide Member States with guidance and a clear overview of the dedicated EU resources, the specifically defined pathways that link the actions outlined in the Plan with the EU funding mechanisms identified in it, as well as the possible synergies and complementarities between the EU4Health programme and others -such as Digital Europe, Horizon Europe, NextGenerationEU / Recovery and Resilience Facility, Structural and Cohesion Funds- to enhance equitable access to quality diagnosis and care; adequate investments in cancer prevention and innovation and improved resilience of health systems; emphasises the importance of Cohesion Funds for achieving equality of access to healthcare especially in less
developed parts of the EU, including rural regions, by investing into health infrastructure and workforce;

Compromise amendment on Paragraph 127
Replacing amendments 1530, 1535, 1536

Motion for a resolution

127. Welcomes the funding plan of EUR 4 billion and notes the complementarity of the sources of funding as set out in the Plan itself; recalls that the Plan will benefit from different sources of funding, such as the EU4Health, Horizon Europe and Digital Europe programmes, cohesion policy funds, and the Recovery and Resilience Facility; highlights the need to include the fight against cancer across all funding sources in a coherent and transparent manner; stresses, in particular, the importance of enhancing cancer research and cancer prevention and the need to dedicate more funds to them;

Draft compromise Amendment

127. Welcomes the funding plan of EUR 4 billion and notes the complementarity of the sources of funding as set out in the Plan itself; notes that the proposed budget should be seen as a first step towards the realisation of all actions under the Europe’s Beating Cancer Plan; recalls that the Plan will benefit from different sources of funding, such as the EU4Health, Horizon Europe and Digital Europe programmes, cohesion policy funds, and the Recovery and Resilience Facility; highlights the need to include the fight against cancer across all funding sources in a coherent and transparent manner; stresses, in particular, the importance of enhancing cancer research and innovation and cancer prevention and the need to dedicate more funds to them; stresses the need for regular revision of the proposed budget allocation for the Europe’s Beating Cancer Plan, with a view to potentially increasing it when possible; stresses the need for the mobilisation of these funds by the Member States to be in line with the needs identified by each country, and geared towards benefitting the public interest and public health services;
Compromise amendment on Recital A
Replacing amendments 38-46,

Motion for a resolution

A. whereas Europe’s Beating Cancer Plan should effectively respond to the call for progress by the families and doctors of the 1.3 million people who die from cancer each year in Europe, including 6 000 children, the crucial needs of patients who are currently in need of efficient and innovative treatments, the rightful expectations of more than 12 million cancer survivors facing the difficult return back to a ‘normal life’, the clear will of future generations to be protected against health threats, and the concern of governments facing a growing economic burden from cancer and its related treatments;

Draft compromise amendment

A. whereas Europe’s Beating Cancer Plan should effectively respond to the call for progress by the families and health professionals of the 1.3 million people who die from cancer each year in Europe, including 6 000 children and young people, the crucial needs of patients who are currently in need of timely diagnosis, as well as effective, innovative, accessible and affordable treatments and care for cancer and cancer-related complications and comorbidities, the rightful expectations of more than 12 million cancer survivors and their families facing the difficult return back to a ‘normal life’, the clear will of future generations to be protected against health threats and risk factors, and the concern of governments facing a growing economic and social burden from cancer and its related treatments; whereas Union actions in the fight against cancer should aim to increase the five-year survival rate of cancer patients;

Compromise amendment on Recital B
Replacing amendments 47, 58, 60-64

Motion for a resolution

B. whereas Europe represents less than 10 % of the world’s population, but accounts for a quarter of all cancer cases, and whereas cancer is the second leading cause of death in Europe after cardiovascular diseases; whereas although there has been a slight decrease in mortality rates thanks to screening campaigns and therapeutic innovation, the number of cases diagnosed is nevertheless increasing, notably due to longer life expectancies, which results in ageing populations; whereas almost three quarters of all cancer diagnoses in the EU occur in

Draft compromise amendment

B. whereas Europe represents less than 10 % of the world’s population, but accounts for a quarter of all cancer cases, and whereas cancer is the second leading cause of death in Europe after cardiovascular diseases and the first cause of death by disease in children older than one year of age; whereas the specific needs of children and adolescents with cancer require continued attention and support globally, and paediatric oncology should be differentiated from adult cancer; whereas although there has been a slight decrease in mortality rates thanks to
people aged 60 or above;

screening campaigns, improved diagnostics and therapeutic innovation, the number of cases diagnosed is nevertheless increasing, notably due to longer life expectancies, which results in ageing populations; whereas almost three quarters of all cancer diagnoses in the EU occur in people aged 60 or above;

Compromise amendment on Recital C
Replacing amendments 71-81, 161

Motion for a resolution
C. whereas cancer illustrates social injustice in healthcare, as differences in cancer survival rates across the EU Member States exceed 25%; whereas EU citizens are unequal in terms of prevention, unequally protected against risk factors, unequally educated in terms of healthy behaviours and unequally equipped against misinformation; whereas EU citizens are unequal in terms of timely access to quality care from Member State to Member State and from region to region in any given country; whereas after recovery or when in remission, EU citizens are unequal in their ability to return to work, to be financially independent and to return to a harmonious familial, social and emotional life;

Draft compromise amendment
C. whereas cancer illustrates social injustice and inequity in healthcare, as differences in cancer survival rates across the EU Member States exceed 25%; whereas EU citizens are facing inequities in terms of prevention, unequally protected against risk factors, unequally educated in terms of healthy behaviours and unequally equipped against misinformation; whereas EU citizens are unequal in terms of timely access to affordable and quality treatment and care from Member State to Member State and from region to region in any given country; whereas access to fully multidisciplinary and multi-professional medical teams varies widely across Europe; whereas after recovery or when in remission, EU citizens are unequal in their ability to return to work, to be financially independent and to return to a harmonious familial, social and emotional life; whereas class and gender are important measures and drivers of inequalities and inequities at all stages of the disease;

Compromise amendment on Recital D
Replacing amendments 85-88

Motion for a resolution
D. whereas specific national or regional cancer policies have been set up in

Draft compromise amendment
D. whereas specific national or regional cancer policies have been set up in most
most Member States, whose missions and budgets are heterogeneous; Member States, whose missions, capacities and budgets are heterogeneous; whereas some regions have become hubs in the fight against cancer, with an expertise that should be shared all over the Union;

Compromise amendment on Recital E
Replacing amendments 90-94

Motion for a resolution

E. whereas the goal of Europe’s Beating Cancer Plan should not only be to fight against a crucial public health issue and to help patients live longer and better lives, but should also be to initiate a reduction in health inequalities and inequities and lower the social and economic burden of the disease; whereas the Commission should promote a patient-centred and citizens’ rights-based approach by integrating considerations of justice, sustainability, equity, solidarity, innovation and collaboration at the very core of Europe’s Beating Cancer Plan;

Draft compromise amendment

E. whereas the goal of Europe’s Beating Cancer Plan should not only be to fight against a crucial public health issue and to help patients live longer and better lives, but should also be to initiate a reduction in health inequalities and inequities and lower the social and economic burden of the disease; whereas the Commission should promote a patient-centred and citizens’ rights-based approach by integrating considerations of justice, sustainability, equity, solidarity, innovation and collaboration at the very core of Europe’s Beating Cancer Plan, including its 'Helping Children with Cancer Initiative';

Compromise amendment on Recital Ea (new)
Replacing amendments 48-53

Motion for a resolution

Ea. Whereas the COVID-19 pandemic has caused, and is still causing, severe disruptions to cancer screening programmes, treatment, research, and survivorship and follow-up services, with the resulting impact on cancer patients, families and health care professionals; whereas the pandemic has created an urgent need to build back cancer services in all European countries and to address highly concerning backlogs in prevention actions, as well as in early detection and diagnosis;

Draft compromise amendment

Ea. Whereas the COVID-19 pandemic has caused, and is still causing, severe disruptions to cancer screening programmes, treatment, research, and survivorship and follow-up services, with the resulting impact on cancer patients, families and health care professionals; whereas the pandemic has created an urgent need to build back cancer services in all European countries and to address highly concerning backlogs in prevention actions, as well as in early detection and diagnosis;

whereas an estimated 100 million screening tests were not performed in
Europe during the pandemic and 1 million cancer cases are undiagnosed; whereas 1 in 5 cancer patients did not receive the surgical or chemotherapy treatment they needed on time\(^1\); whereas healthcare professionals have supported the burden of a pandemic and a very stressful working environment;

\(^1\) [https://www.europeancancer.org/resources/201:time-to-act.html](https://www.europeancancer.org/resources/201:time-to-act.html)


**Compromise amendment on Recital Eb new**
Replacing amendments 56, 57, 66, 68, 177

**Motion for a resolution**

**Draft compromise amendment**

*Eb. whereas about 40% of cancer cases in the EU are preventable; whereas prevention is more effective than any cure, as well as the most cost-effective long-term cancer control strategy; whereas Europe’s Beating Cancer Plan should address all key risk factors and social determinants of cancer; whereas the EU level is crucial in cancer prevention as it has strong competences that impact most risk factors for cancer.*

**Compromise amendment on Recital F**
Replacing amendments 103-113

**Motion for a resolution**

**Draft compromise amendment**

*F. whereas health literacy includes the acquisition of knowledge and skills, awareness of rights and the confidence to take action to improve personal and community health; whereas actions to promote health literacy under the Plan should focus on empowering patients and citizens; whereas all efforts to increase health literacy should take into account people with learning disabilities, as well as ensure that the necessary information is available to those who have disabilities through state-of-the-art communication tools, also by seeking the expertise of, and collaborating with, patient organisations and other NGOs.*
available in common non-EU languages in order to reach migrants and new arrivals;

which have been working on disseminating and spreading health literacy for years; whereas patient empowerment requires assisting patients in understanding their rights; whereas all efforts to increase health literacy, including digital literacy, should take into account people who are experiencing exclusion and the needs of people with learning disabilities; whereas inequalities in knowledge, access and use of IT technologies, as well as regional and national, social and economic differences should be taken into account; whereas the necessary information should be available in common non-EU languages in order to reach migrants, new arrivals and other vulnerable groups and minority communities; whereas efforts to improve health literacy should also include an onus to assist citizens to identify misinformation, noting the harmful impacts this can have across all areas of cancer care including prevention, vaccination and treatment;

Compromise amendment on Recital Fa (new)
Replacing amendments 171-176, 178-180, 490-493, 507

Motion for a resolution

Draft compromise amendment

Fa. Whereas the Commission communication on strengthened cooperation against vaccine preventable diseases recommends to develop EU guidance for establishing at national level comprehensive electronic immunisation information systems for effective monitoring of immunisation programmes; whereas this should be done in full compliance with data protection rules;

whereas human papillomavirus (HPV) is a sexually transmitted infection associated with almost 5% of all cancers in women and men worldwide: cervical and oropharyngeal, but also anal, penile, vaginal and vulval cancers;

whereas both reaching HPV vaccination coverage targets for girls and calling up high-quality organised cervical cancer
screening is necessary in order to reach the 2030 WHO goals regarding the elimination of cervical cancer as a public health problem;

whereas HPV vaccination rates are worryingly low across the Member States;

whereas, regretfully, there are major discrepancies in vaccination coverage between Member States, ranging from less than 30 % to more than 70 % (with the required level of population immunity being at 70 %);

whereas Helicobacter Pylori is the most important infectious cause of cancer worldwide, mainly for non-cardia gastric adenocarcinoma;

Compromise amendment on Recital Fb (new)
Replacing amendments 361, 369-371, 373, 375-378, 381

Motion for a resolution

Draft compromise amendment

Fb. whereas the Mediterranean diet is known as a healthy, balanced diet, that plays a protective role in the primary and secondary prevention of the main chronic degenerative diseases;

Compromise amendment on Recital Fc (new)
Replacing amendments 82, 83, 84, 138, 475, 477-480, 482

Motion for a resolution

Draft compromise amendment

Fc. whereas exposure to dangerous substances at work is responsible for about 120 000 work-related cancer cases each year, leading to approximately 80 000 fatalities annually, which represents 8% of all cancer deaths (12% of cancer deaths among men, and 7% of cancer deaths among women); whereas it can however be difficult to establish causal relationships due to long latency periods;

whereas 50 priority carcinogens have been identified by IARC/WHO and that workers are widely exposed to them in Europe;
whereas the vast majority of cancers induced by occupational carcinogens at work appears preventable if regulated accordingly but, under Directive 2004/37/EC, binding Occupational Exposure Limit (OEL) Values exist to date for only 27 of them;

whereas further action is necessary to prevent, detect and better recognise occupational cancers related to night shift work as well as UV radiation (for outdoor workers);

Compromise amendment on Recital Fd (new)
Replacing amendment 427

Motion for a resolution

Draft compromise amendment

Fd. Whereas radon is a radioactive gas that has no colour or odour, and as radon decays in the air, it releases radiation that can damage the DNA of cells inside the body; points out that radon levels vary widely in different regions or even residential areas and can be present in both outdoor and indoor air;

Compromise amendment on Recital Fe (new)
Replacing amendment 127, 423

Motion for a resolution

Draft compromise amendment

Fe. Whereas in 2011 the WHO's International Agency for Research (IARC) on Cancer classified radiofrequency electromagnetic fields as possibly carcinogenic to humans, based on an increased risk of glioma, associated with mobile phone use; whereas there are studies, published in 2015 and 2018, showing a significant increase (more than doubling) in Glioblastoma tumours over twenty years (1995-2015) in all age groups, and others showing the increased risk of
Glioblastoma associated with mobile and cordless phone use in people aged 18-80; whereas more studies are needed to establish these associated risks;

Compromise amendment on Recital Ff (new)
Replacing amendments 67, 133, 134, 135

Motion for a resolution

Draft compromise amendment

Ff. Whereas 24% of all new cancer diagnoses, including all paediatric cancers, across Europe each year are rare forms of cancer and represent a public health challenge altogether; whereas patients with rare cancers face challenges linked to a late or incorrect diagnosis, lack of access to appropriate therapies and expertise, lack of understanding of underlying science, lack of commercial feasibility in developing new therapies, difficulties in conducting well-powered clinical studies, feelings of isolation, and few available tissue banks;

Compromise amendment on Recital G
Replacing amendments 115-125

Motion for a resolution

Amendment

G. whereas the Plan should be implemented in close association with the recommendations and actions of the International Agency for Research on Cancer (IARC), the UN SDGs for global health, and the recommendations and guidelines of the World Health Organization (WHO), and should acknowledge as a priority the EU’s solidarity and partnership with low- and middle-income countries;
Compromise amendment on Recital Ga (new)
Replacing amendment 694

Motion for a resolution

Ga. Whereas Europe’s Beating Cancer Plan gives remarkable attention to a range of policy needs in respect of cancer screening, less initiative is offered for early detection of cancers not covered by screening programmes; whereas targeted action is necessary to foster better awareness of cancer warning signs among citizens and healthcare professionals;

Draft compromise amendment

Compromise amendment on Recital H
Replacing amendments 128-132

Motion for a resolution

H. whereas addressing cancer could be used as a model for other non-communicable diseases, and whereas patients with other chronic diseases should therefore also benefit from the achievements of Europe’s Beating Cancer Plan;

Amendment

H. whereas addressing cancer in a comprehensive strategy such as the Beating Cancer Plan presented by the Commission could be used as a model for other non-communicable diseases, and whereas patients with other chronic diseases should therefore also benefit from the achievements and principles of the Plan and going forward to build similar plans for other pathologies with high mortality rates;

Compromise amendment on Recital I
Replacing amendments 54, 55, 100, 136, 137, 139 -142

Motion for a resolution

I. whereas a common policy driven at European level is absolutely essential for progress in the area of cancer; whereas the primary responsibility for health protection and healthcare systems lies with the Member States;

Amendment

I. whereas coordination between European countries, a common policy driven at European level and cross-border knowledge-sharing are absolutely essential for progress in the area of cancer, whereas the primary responsibility for health protection and healthcare systems lies with the Member States;
Compromise amendment on Recital J
Replacing amendments 89, 101, 143-152, 160, 169, 170, 181, 183

Motion for a resolution
J. whereas a comprehensive, multidisciplinary and coordinated approach to addressing social, individual, environmental and commercial health determinants is needed at regional, national and European level in order to support actions targeting all aspects of cancer (prevention, detection, treatment, palliative care and reintegration) through the effective mobilisation of key tools such as research and knowledge sharing; whereas new technologies and artificial intelligence have high potential for improvements in the field of cancer research;

Amendment
J. whereas a comprehensive, multidisciplinary and coordinated approach to addressing behaviour-related, biological, environmental, work-related, socio-economic and commercial health determinants is needed at regional, national and European level in order to support actions targeting all aspects of cancer (prevention, detection, treatment, palliative care, follow-up care for survivors and reintegration) through the effective mobilisation of key tools such as adequate resources and funding, legislation, research and knowledge sharing; whereas patient-centric approaches to treatment have shown to improve the quality of life and overall survivorship of patients; whereas new technologies and artificial intelligence have high potential for improvements in the field of cancer research, treatment process and care;

Compromise amendment on Recital M
Replacing amendments 162-168, 182

Motion for a resolution
M. whereas Europe’s Beating Cancer Plan could therefore represent the first step towards a real European Health Union;

Amendment
M. whereas Europe’s Beating Cancer Plan could therefore represent an important step towards a real European Health Union and a public demonstration to citizens of the success that EU health cooperation can achieve;

Compromise amendment on Recital Ma (new)
Replacing amendments 315, 316

Motion for a resolution

Draft compromise amendment
Ma. Whereas the Act of Accession of Austria, Finland and Sweden grants an exemption to Sweden from the EU-wide
prohibition of the sale of certain types of tobacco for oral use;
3. Alternative compromise Amendments

Alternative compromise amendments, co-signed by EPP and ECR

Paragraph 18

18. Sees the European Green Deal as a significant contributing factor in cancer prevention in Europe, via the reduction of air, food, water and soil pollution and of chemical exposure;
calls for an evaluation of the impact of policies on cancer incidence to be integrated into the Farm to Fork Strategy, the Chemicals Strategy for Sustainability, the Zero Pollution and the Non-Toxic Environment Strategies;
welcomes the upcoming revision of the EU’s air quality standards and calls on the Commission to align them with the WHO guidelines following the conclusion of a comprehensive impact assessment on health, environmental, societal, and economic aspects; guidelines as referred to in Parliament’s resolution of 25 March 2021 on the implementation of the Ambient Air Quality Directives;
calls on the Commission to ensure that the common agricultural policy accompanies farmers to reduce the use of pesticides;
encourages the research into, use and development of medicines that are safer for the environment, as well as implementing efficient waste removal mechanisms that avoid polluting the environment, in line with the objectives of the Pharmaceutical Strategy for Europe;

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Paragraph 20

20. Calls in particular for the strengthening of the information requirements on carcinogenicity under REACH to enable identification of all carcinogenic substances manufactured or imported, irrespective of the volume, in line with the Chemicals Strategy for Sustainability, and for the registration, evaluation, authorisation and restriction of chemicals including endocrine disrupting chemicals under the REACH Regulation to give careful consideration to be conducted in association with the IARC and the WHO assessments;

welcomes the commitment of the Chemicals Strategy for Sustainability to extend the generic approach to risk management to ensure that consumer products do not contain chemicals which, if the product is used incorrectly, can cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative toxic;
calls on the Commission to swiftly implement the measures planned in the Chemicals Strategy for Sustainability to reduce citizens’ exposure to carcinogenic and endocrine disrupting substances through all exposure pathways;

calls on the Commission to give particular attention to segments of the population that are particularly vulnerable to hazardous chemicals and to better take into account those vulnerable populations in the risk assessments of chemicals;

stresses that information to consumers on exposure pathways in their everyday life is key to strengthen prevention, and welcomes in this regard the establishment of the 'Substances of Concern in Products' (SCIP) database;

calls on the European Environmental Agency to produce a report, together with the European Chemicals Agency, on chemicals in the environment in Europe; requests that the report assesses the systemic nature of carcinogenic and endocrine disrupting chemicals within Europe’s production and consumption systems, their use in products, occurrence in Europe's environment, and the harm caused to human health, especially concerning cancer;


Paragraph 21

21. Considers that the next edition of the European Code Against Cancer (ECAC) will have to take into account the latest knowledge on environmental carcinogens;

calls on the Commission to propose without delay a revision of Article 68(2) of REACH, the regulation on food contact materials, the regulation on cosmetic products and other relevant consumer product legislation to ensure that consumer products do not contain chemicals that cause cancer unless they are not harmful to the health of users in the intended use of the products in line with the Chemicals Strategy for Sustainability; calls, furthermore, for the regular revision of that legislation to take account of the development of new materials, trends and products;

underlines that endocrine disruptors (EDs) are present in food, food contact materials, cosmetics, consumer goods, toys, as well as drinking water, and that exposure, even at low doses, can induce adverse effects in the short and long term, including cancer;

highlights that given the widespread exposure of the EU population to many suspected and known EDs and the fact that combined exposure to several EDs acting on similar or different pathways can have cumulative effects, there is a need to minimise exposure to EDs and to make EU regulation more consistent across sectors;
encourages further research in order to determine the capacity of chemicals to act as endocrine disruptors;

Paragraph 113

13. Considers that the sharing of expertise, data, training programmes and communication tools is needed to improve the knowledge of cancer among both health professionals and patients;

notes the sensitive nature of health data;

notes that data sharing is key to applying artificial intelligence and machine learning tools to research, and to enabling the digital transformation of healthcare, to tackle disparities in cancer prevention, diagnosis, and treatment around Europe;

calls for a prudent implementation of Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) to avoid unnecessary restrictions for cross-border healthcare;

calls therefore on the Commission to make concrete proposals by the end of the year to address this problem through appropriate guidelines or other non-legislative measures, and should these fail to be effective, to propose a revision of the GDPR;
VIII. Final Report adopted by the BECA Committee on 9 December 2021
REPORT

on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy (2020/2267(INI))

Special Committee on Beating Cancer

Rapporteur: Véronique Trillet-Lenoir
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The European Parliament,

– having regard to its decision of 18 June 2020 on setting up a special committee on beating cancer, and defining its responsibilities, numerical strength and term of office¹,

– having regard to the working document of its Special Committee on Beating Cancer of 27 October 2020 entitled ‘Inputs of the Special Committee on Beating Cancer (BECA) to influence the future Europe’s Beating Cancer Plan’²,

– having regard to the Commission communication of 3 February 2021 on Europe’s Beating Cancer Plan (COM(2021)0044),

– having regard to the EU’s Framework Programme for Research and Innovation 2021-2027 (Horizon Europe)³ and the dedicated Horizon Europe Mission on Cancer⁴,

– having regard to the Commission communication of 11 December 2019 on the European Green Deal (COM(2019)0640),

– having regard to the Council conclusions of 15 June 2021 on access to medicines and medical devices for a stronger and resilient EU⁵,

– having regard to the guides developed by the Joint Actions on cancer (EPAAC, CANCON, iPAAC) and the Rare Cancer Agenda 2030 established under the Joint Action on Rare Cancers (JARC),

– having regard to the Commission communication of 30 September 2020 on a new ERA for Research and Innovation (COM(2020)0628),

– having regard to Council Recommendation 2003/878/EC of 2 December 2003 on cancer screening⁶,

– having regard to the report of the International Agency for Research on Cancer (IARC) of May 2017 on the implementation of the Council Recommendation on cancer

¹ OJ C 362, 8.9.2021, p. 182.
⁴ Interim report of the Mission Board for Cancer entitled ‘Conquering cancer: Mission possible’.
⁵ OJ C 269I, 7.7.2021, p. 3.
screening\textsuperscript{7},

– having regard to the European guidelines for quality assurance in breast, cervical and colorectal cancer screening and diagnosis,

– having regard to the Commission communication of 20 May 2020 entitled ‘A Farm to Fork Strategy for a fair, healthy and environmentally friendly food system’ (COM(2020)0381),

– having regard to the Commission communication of 28 June 2021 on the EU strategic framework on health and safety at work 2021-2027 (COM(2021)0323),


– having regard to Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (the Carcinogens and Mutagens Directive – CMD)\textsuperscript{8}, including its three amending directives and the proposal by the Commission for the fourth amending directive (COM(2020)0571),

– having regard to Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work\textsuperscript{9},

– having regard to the public consultation synopsis report of its Special Committee on Beating Cancer of 19 April 2021 entitled ‘The impact of the COVID-19 pandemic on cancer prevention, health services, cancer patients and research: lessons from a public health crisis’,


\textsuperscript{7} https://ec.europa.eu/health/sites/default/files/major_chronic_diseases/docs/2017_cancerscreening_2ndreportimplementation_en.pdf

\textsuperscript{8} OJ L 158, 30.4.2004, p. 50.

\textsuperscript{9} OJ L 131, 5.5.1998, p. 11.
having regard to Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027\(^\text{10}\),


– having regard to Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use (the Clinical Trials Regulation)\(^\text{11}\) and to the Clinical Trials Information System set up in accordance with that regulation,


– having regard to Report No 21/2019 of the European Environment Agency (EEA) entitled ‘Healthy environment, healthy lives: how the environment influences health and well-being in Europe’\(^\text{13}\),

– having regard to the opinion of the European Economic and Social Committee of 9 June 2021 on Europe’s Beating Cancer Plan\(^\text{14}\),

– having regard to the conclusions and recommendations of the study prepared for its Panel for the Future of Science and Technology (STOA) in July 2021 on ‘The health impact of 5G’\(^\text{15}\),

– having regard to the UN Sustainable Development Goals (SDGs), in particular SDG 3 on good health and well-being,

– having regard to the fourth edition of the European Code Against Cancer\(^\text{16}\),

– having regard to the European Code of Cancer Practice\(^\text{17}\),

– having regard to the Commission communication of 24 March 2021 entitled ‘EU strategy on the rights of the child’ (COM(2021)0142),


\(^{10}\) OJ L 107, 26.3.2021, p. 1.

\(^{11}\) OJ L158, 27.5.2014, p. 1.


\(^{13}\) https://www.eea.europa.eu/publications/healthy-environment-healthy-lives

\(^{14}\) OJ C 341, 24.8.2021, p. 76.


\(^{17}\) https://www.europeancancer.org/2-standard/66-european-code-of-cancer-practice
having regard to the report of the World Health Organization (WHO) of 2020, entitled ‘Alcohol and cancer in the WHO European Region: An appeal for better prevention’,

having regard to the activity and conclusions of the all-party interest group MEPs Against Cancer (MAC),

having regard to its resolution of 15 January 2020 on the European Green Deal,

having regard to its resolution of 2 March 2017 on EU options for improving access to medicines,

having regard to its resolution of 10 July 2020 on the Chemicals Strategy for Sustainability,

having regard to its resolution of 12 February 2019 on the implementation of the Cross-Border Healthcare Directive,

having regard to its resolution of 16 January 2019 on the Union’s authorisation procedure for pesticides,

having regard to its resolution of 10 July 2020 on the EU’s public health strategy post-COVID-19,

having regard to its resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem,

having regard to its resolution of 15 December 2016 on the regulation on paediatric medicines and the Commission’s inception impact assessment concerning the revision of the EU legislation on medicines for children and rare diseases,

having regard to Rule 54 of its Rules of Procedure,

having regard to the report of its Special Committee on Beating Cancer (A9-0001/2022),

whereas Europe’s Beating Cancer Plan (‘the Plan’) should effectively respond to the call for progress by the families and health professionals of the 1.3 million people who die from cancer each year in Europe, including 6 000 children and young people, the crucial needs of patients who are currently in need of timely diagnosis and effective, innovative, accessible and affordable treatments and care for cancer and cancer-related complications and comorbidities, the rightful expectations of more than 12 million cancer survivors and their families facing the difficult return back to a ‘normal life’, the

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23 OJ C 411, 27.11.2020, p. 48.
clear will of future generations to be protected against health threats and risk factors, and the concern of governments facing a growing economic and social burden from cancer and its related treatments; whereas Union actions in the fight against cancer should aim to increase the five-year survival rate of cancer patients;

B. whereas Europe represents less than 10% of the world’s population, but accounts for a quarter of all cancer cases, and whereas cancer is the second leading cause of death in Europe after cardiovascular diseases and the first cause of death by disease in children older than one year; whereas the specific needs of children and adolescents with cancer require continued attention and support globally, and paediatric oncology should be differentiated from adult cancer management; whereas although there has been a slight decrease in mortality rates thanks to screening campaigns, improved diagnostics and therapeutic innovation, the number of cases diagnosed is nevertheless increasing, notably due to longer life expectancies, which result in ageing populations; whereas almost three quarters of all cancer diagnoses in the EU occur in people aged 60 or above;

C. whereas cancer illustrates social injustice and inequity in healthcare, as differences in cancer survival rates across the EU Member States exceed 25%; whereas EU citizens are facing inequities in terms of prevention, and are unequally protected against risk factors, unequally educated in terms of healthy behaviours and unequally equipped against misinformation; whereas EU citizens are unequal in terms of timely access to affordable and quality treatment and care from Member State to Member State and from region to region in any given country; whereas access to fully multidisciplinary and multiprofessional medical teams varies widely across Europe; whereas after recovery or when in remission, EU citizens are unequal in their ability to return to work, to be financially independent and to return to a harmonious familial, social and emotional life; whereas class and gender are important measures and drivers of inequalities and inequities at all stages of the disease;

D. whereas specific national or regional cancer policies have been set up in most Member States, whose missions, capacities and budgets are heterogeneous; whereas some regions have become hubs in the fight against cancer, with an expertise that should be shared all over the Union;

E. whereas the goal of the Plan should not only be to fight against a crucial public health issue and to help patients live longer and better lives, but should also be to initiate a reduction in health inequalities and inequities and lower the social and economic burden of the disease; whereas the Commission should promote a patient-centred and citizens’ rights-based approach by integrating considerations of justice, sustainability, equity, solidarity, innovation and collaboration at the very core of the Plan, including its ‘Helping Children with Cancer Initiative’;

F. whereas the COVID-19 pandemic has caused, and is still causing, severe disruptions to cancer screening programmes, treatment, research, and survivorship and follow-up services, with the resulting impact on cancer patients, families and healthcare professionals; whereas the pandemic has created an urgent need to build back cancer services in all European countries and to address highly concerning backlogs in prevention actions, as well as in early detection and diagnosis; whereas an estimated 100 million screening tests were not performed in Europe during the pandemic and 1 million cancer cases are undiagnosed; whereas 1 in 5 cancer patients did not receive the surgical
or chemotherapy treatment they needed on time27; whereas healthcare professionals have taken on the burden of a pandemic and have had to cope in a very stressful working environment;

G. whereas health literacy includes the acquisition of knowledge and skills, awareness of rights and the confidence to take action to improve personal and community health; whereas actions to promote health literacy under the Plan should focus on empowering patients and citizens through state-of-the-art communication tools, and also by seeking the expertise of, and collaborating with, patient organisations and other NGOs which have been working on disseminating and spreading health literacy for years; whereas patient empowerment requires assisting patients in understanding their rights; whereas all efforts to increase health literacy, including digital literacy, should take into account people who are experiencing exclusion and the needs of people with learning disabilities; whereas inequalities in knowledge of, access to and use of IT technologies, as well as regional, national, social and economic differences, should be taken into account; whereas the necessary information should be available in common non-EU languages in order to reach migrants, new arrivals and other vulnerable groups and minority communities; whereas in efforts to improve health literacy, the onus should also be on assisting citizens in identifying misinformation, noting the harmful impacts this can have across all areas of cancer care, including prevention, vaccination and treatment;

H. whereas about 40 % of cancer cases in the EU are preventable; whereas prevention is more effective than any cure, as well as the most cost-effective long-term cancer control strategy; whereas the Plan should address all key risk factors and social determinants of cancer; whereas the EU level is crucial in cancer prevention as it has significant competences that have an impact on most risk factors for cancer;

I. whereas according to Report No 21/2019 of the EEA, cancer is the top non-communicable disease attributable to the environment, with more than 250 000 cancer deaths attributed to the environment in 2016 in 32 high-income European countries; whereas the EEA identified ambient air pollution, chemicals, indoor fuel combustion and radiation as environmental risk factors for cancer;

J. whereas air pollution is a main driver of mortality, with pollutants from a wide range of sources, including energy, transport, agriculture and industry, contributing to 400 000 premature deaths per year, including from lung cancer, heart disease and strokes;

K. whereas the Commission communication on strengthened cooperation against vaccine-preventable diseases (COM(2018)0245) recommends developing EU guidance to establish comprehensive electronic immunisation information systems at national level for effective monitoring of immunisation programmes; whereas this should be done in full compliance with data protection rules; whereas human papillomavirus (HPV) is a sexually transmitted infection associated with almost 5 % of all cancers in women and men worldwide, namely cervical and oropharyngeal, but also anal, penile, vaginal and vulval cancers; whereas both reaching HPV vaccination coverage targets for girls and setting up high-quality organised cervical cancer screening is necessary in order to reach the 2030 WHO goals regarding the elimination of cervical cancer as a public health

27 https://www.europeancancer.org/resources/201:time-to-act.html
https://www.europeancancer.org/timetoact/impact/data-intelligence
problem; whereas HPV vaccination rates are worryingly low across the Member States; whereas, regretfully, there are major discrepancies in vaccination coverage between Member States, ranging from less than 30% to more than 70% (with the required level of population immunity being at 70%); whereas Helicobacter pylori is the principal infectious cause of cancer worldwide, mainly for non-cardia gastric adenocarcinoma;

L. whereas certain endocrine cancers (such as thyroid, breast and testicular cancer) are on the rise; whereas endocrine treatments for hormone-dependent cancers can have endocrine side effects; whereas cancer treatments can have long-term effects such as endocrine comorbidities in cancer survivors; whereas obesity is a known risk factor for many cancers, including endocrine cancers; whereas exposure to endocrine-disrupting chemicals (EDCs) is known to have an effect on the development of obesity and cancer; whereas EDCs cost the Member States between EUR 157 and 270 billion annually (up to 2% of EU GDP)\(^{28}\) in healthcare expenses and lost earning potential, largely due to neurodevelopmental and metabolic disorders and cancer;

M. whereas exposure to dangerous substances at work is responsible for about 120 000 work-related cancer cases each year, leading to approximately 80 000 fatalities annually, which represents 8% of all cancer deaths (12% of cancer deaths among men, and 7% of cancer deaths among women); whereas it can be difficult to establish causal relationships, however, due to long latency periods; whereas the WHO’s IARC has identified 50 priority carcinogens and shown that workers are widely exposed to them in Europe; whereas the vast majority of cancers induced by occupational carcinogens at work appear to be preventable if the carcinogens are regulated accordingly but, under Directive 2004/37/EC, binding occupational exposure limit (OEL) values exist to date for only 27 of them; whereas further action is necessary to prevent, detect and better recognise occupational cancers related to night-shift work as well as UV radiation (for outdoor workers);

N. whereas a changing labour market with demographic developments, new technologies and new types of jobs has potential impacts on occupational health and safety; whereas more workers are moving into platform work, non-traditional work or atypical employment; whereas factors such as radiation, stress, work organisation and working conditions have all been linked to work-related cancer\(^{29}\); whereas there is currently a lack of reliable and comparable EU-level data on workplace exposure to cancer risk factors\(^{30}\);

O. whereas contrary to workplace accidents, where injuries can be more easily assessed and compensation awarded, it can take years or decades before work-related cancers are diagnosed and the cause is properly identified; whereas the Commission Recommendation on occupational diseases\(^{31}\) recommends that Member States introduce, as soon as possible, into their national laws, regulations or administrative provisions concerning occupational diseases liable for compensation the European schedule set out in Annex I to the aforementioned recommendation; whereas the


existing disparities between Member States with regard to the recognition rate of occupational diseases mean that many workers never have their occupational disease recognised;

P. whereas radon is a radioactive gas that has no colour or odour, and as radon decays in the air, it releases radiation that can damage the DNA of cells inside the body; whereas radon levels vary widely in different regions or even residential areas and can be present in both outdoor and indoor air;

Q. whereas in 2011 the IARC classified radiofrequency electromagnetic fields as possibly carcinogenic to humans, based on an increased risk of glioma associated with mobile phone use; whereas there are studies, published in 2015 and 2018, showing a significant increase (more than doubling) in glioblastoma tumours over 20 years (1995-2015) in all age groups, and others showing the increased risk of glioblastoma associated with mobile and cordless phone use in people aged 18-80; whereas more studies are needed to establish these associated risks;

R. whereas 24 % of all new cancer diagnoses, including all paediatric cancers, across Europe each year are rare forms of cancer and represent a public health challenge in themselves; whereas patients with rare cancers face challenges linked to late or incorrect diagnosis, lack of access to appropriate therapies and expertise, lack of understanding of underlying science, lack of commercial feasibility in developing new therapies, few available tissue banks, difficulties in conducting well-powered clinical studies, and also feelings of isolation;

S. whereas the Plan should be implemented in close association with the recommendations and actions of the IARC, the UN SDGs for global health, including the objective of achieving universal health coverage, the recommendations and guidelines of the WHO, international health agreements including the WHO Framework Convention on Tobacco Control and the WHO Global Initiative for Childhood Cancer, the EU Joint Actions on Cancer, and recommendations and guidelines by experts and patients’ associations; whereas the Plan should acknowledge as a priority the EU’s solidarity and partnership with low- and middle-income countries, including those in the wider WHO Europe region;

T. whereas the Act concerning the conditions of accession of Austria, Finland and Sweden grants an exemption to Sweden from the EU-wide prohibition of the sale of certain types of tobacco for oral use;

U. whereas the Mediterranean diet is known as a healthy, balanced diet that plays a protective role in the primary and secondary prevention of the main chronic degenerative diseases;

V. whereas while the Plan gives remarkable attention to a range of policy needs in respect of cancer screening, less initiative is offered for early detection of cancers not covered by screening programmes; whereas targeted action is therefore necessary to foster better awareness of cancer warning signs among citizens and healthcare professionals;

W. whereas the increase in the prices of cancer medicines has exceeded the increase of total cancer spending, and new cancer medicines coming onto the market at a high price were identified as an important driver of the increase in cancer care expenditure; whereas the
WHO Technical Report of 2018 on the pricing of cancer medicines and its impacts\textsuperscript{32} recognised that prices of cancer medicines were higher than for other indications and their costs were growing at a faster rate, resulting in lack of access to treatment for many patients worldwide and hampering the capacity of governments to provide affordable access for all;

X. whereas addressing cancer in a comprehensive strategy such as the Beating Cancer Plan presented by the Commission could be used as a model for other non-communicable diseases, and whereas patients with other chronic diseases should therefore also benefit from the achievements and principles of the Plan, and similar plans should be developed for other pathologies with high mortality rates;

Y. whereas coordination between European countries, a common policy driven at European level and cross-border knowledge-sharing are absolutely essential for progress in the area of cancer; whereas the primary responsibility for health protection and healthcare systems lies with the Member States;

Z. whereas a comprehensive, multidisciplinary and coordinated approach to addressing behaviour-related, biological, environmental, work-related, socio-economic and commercial health determinants is needed at regional, national and European level in order to support actions targeting all aspects of cancer (prevention, detection, treatment, palliative care, follow-up care for survivors and reintegration) through the effective mobilisation of key tools such as adequate resources and funding, legislation, research and knowledge-sharing; whereas patient-centred approaches to treatment have been shown to improve the quality of life and overall survivorship of patients; whereas new technologies and artificial intelligence have high potential for improvements in the field of cancer research, treatment processes and care;

AA. whereas research and innovation are our only hope of definitely beating cancer one day; whereas sustained and effective funding is needed to support ambitious projects and good and stable working conditions for researchers working in the cancer field; whereas pharmaceutical companies, including SMEs, are key stakeholders for innovation in the cancer field;

AB. whereas the ‘Health in All Policies’ and ‘One Health’ approaches should be promoted further, and efforts to fight cancer should be integrated into all EU policies;

AC. whereas the EU and its Member States should mobilise their forces and provide adequate incentives and sustainable budgets so as to achieve the ambitious objective of conquering the cancer burden and the fatality of cancer in Europe;

AD. whereas the Plan could therefore represent an important step towards a real European Health Union and a public demonstration to citizens of the success that EU health cooperation can achieve;

1. Welcomes the Plan and calls on the Commission to seek new synergies between the Plan and the EU4Health Programme, the Pharmaceutical Strategy for Europe, the Chemicals Strategy and the updated European Industrial Strategy; considers that such a comprehensive cancer framework would contribute to the prevention, early detection

\textsuperscript{32} https://www.who.int/publications/m/item/technical-report-on-pricing-of-cancer-medicines-and-its-impacts
and curing cancer; calls on the Commission to work towards developing a common cancer policy which includes, where necessary, proposals for draft legislation;

**A. Areas of action**

**I. Cancer prevention in all European policies**

2. Strongly believes that comprehensive preventive actions against cancer, through measures supporting the elimination or reduction of harm caused by modifiable risk factors, should be implemented across all European policies and funding programmes; calls on the Commission and the Member States to integrate public awareness-raising campaigns about cancer prevention into all relevant policies; calls on the Commission to streamline the objectives of the Plan into all relevant sectoral policies; strongly believes that preventive actions should be evidence-based; therefore, calls on the Commission and Member States to increase the funding for scientific research into the causes of cancer and the efficiency and implementation of preventive measures;

3. Calls on the Commission and Member States to design and implement effective prevention measures at national and EU level which are based on independent scientific expertise, best practices and lessons learned, and clinical guidance; in this regard calls, in particular, for the implementation of the European Code Against Cancer (ECAC) to reduce cancer risks on the basis of the latest scientific evidence, and for regular updates to the ECAC through a cycle that is based on continuous monitoring and evaluation;

4. Acknowledges that more than 40% of all cancers are preventable through coordinated actions targeting behaviour-related, biological, environmental, work-related, socio-economic and commercial health determinants; calls for more attention to be dedicated to maintaining a healthy lifestyle in order to prevent cancer and reduce recurrence of certain cancers;

5. Supports Horizon Europe Mission on Cancer’s aim of averting more than 3 million additional premature deaths over the 2021-2030 period, by accelerating progress in cancer prevention and control programmes, which strive for equal opportunities in access to these programmes; calls on the Commission to allocate adequate funding to the Horizon Europe Mission on Cancer and other relevant programmes (such as ‘Science and Policy for a Healthy Future’ - HBM4EU) in order to achieve this objective;

6. Deplores the significant health inequalities and inequities in the EU in cancer prevention; insists on the need to identify, as well as to pay special attention to, vulnerable, marginalised, socially excluded populations and people living in remote areas (such as in rural, isolated or outermost regions far from medical centres), in order to ensure their access to cancer prevention services; considers in this regard that cancer prevention also needs to be framed in the context of social justice, entailing the need for systemic changes through population-wide public policies beyond changes in individual behaviour;

7. Acknowledges that tobacco use is by far the largest preventable cause of cancer in the EU, as the cause of 15-20% of European cancer cases and the main risk factor for cancer death in Europe (27% of cancer fatalities equalling 700,000 cancer deaths annually in the EU); recalls that major differences exist across the EU since the
proportion of smokers varies more than fivefold from one country to another;

8. Strongly supports the goal of a ‘tobacco-free generation’, as set out in the Plan, whose aim is for less than 5% of the population to use tobacco by 2040, compared to around 25% today; urges the Commission to establish interim goals that are constantly monitored and promoted, including at national level, and are reported within the Cancer Inequalities Registry in order to best direct efforts to achieve the overall target; calls on the Commission to fund programmes that promote smoking cessation; calls on the Commission to back cooperation between Member States in exchanging the best and most effective practices for reducing smoking;

9. Welcomes the Commission’s intention to review the Tobacco Products Directive\(^{33}\), the Tobacco Products Tax Directive\(^{34}\) and the legal framework on cross-border purchases of tobacco by private individuals, and urges the Commission to take appropriate measures and to bring forward legislative proposals, in order to introduce the following:
   a) an increase and an upward convergence in minimum excise duties for all tobacco products and their final market price, which would improve prevention by reducing tobacco uptake and use, notably among current smokers, and prevent young people from starting smoking;
   b) a requirement for standardised plain packaging and the obligation to include health warnings on 80% of the front and back of tobacco product packaging, including pictorial warnings; and
   c) the strict enforcement of the ban on characterising flavours in tobacco products to reduce the appeal of these products to smokers, non-smokers, and young people;

10. Calls for the evaluation and review of currently used measurement methods for tar, nicotine and carbon monoxide in tobacco and related products, based on independent and recent scientific research;

11. Calls for the full implementation by Member States of the obligations under the Single Use Plastics Directive 2019/904\(^{35}\) as regards filters in tobacco products containing plastics to address environmental and health concerns related to these filters;

12. Calls on the Commission to follow up on the scientific evaluations of the health risks related to electronic cigarettes, heated tobacco products and novel tobacco products, including the assessment of the risks of using these products compared to consuming other tobacco products, and the establishment at European level of a list of substances contained in, and emitted by, these products; considers that electronic cigarettes could allow some smokers to progressively quit smoking; considers at the same time that e-cigarettes should not be attractive to minors and non-smokers; calls on the Commission, therefore, to evaluate, in the framework of the Tobacco Products Directive, which

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flavours in e-cigarettes are in particular attractive to minors and non-smokers, and to propose a ban on these, and furthermore, to propose a ban on all characteristic flavours in heated tobacco products and novel tobacco products;

13. Calls for the rapid and complete implementation of the WHO Framework Convention on Tobacco Control (FCTC)\(^{36}\) and the WHO Protocol to Eliminate Illicit Trade in Tobacco Products\(^{37}\), paying specific attention to the FCTC Article 5.3 and its guidelines on protection of public health policies from the vested interests of the tobacco industry; urges the Commission to implement specific rules of conduct for all of its officials and other servants when interacting with the tobacco industry, in line with the European Ombudsman’s decision in case 852/2014/LP\(^{38}\);

14. Supports the Commission’s proposal to update the Council recommendation of 30 November 2009 on smoke-free environments\(^{39}\) to extend its coverage to emerging products, such as e-cigarettes and heated tobacco products, and to extend smoke-free environments to include outdoor spaces;

15. Recalls that ethanol and acetaldehyde from the metabolism of ethanol in alcoholic beverages are classified as carcinogenic to humans by the IARC, and that in Europe an estimated 10% of all cancer cases in men and 3% of all cancer cases in women are attributable to alcohol consumption;\(^{40}\) underlines that the lower the amount of alcohol consumed, the lower the risk of developing cancer is; recalls that alcohol consumption is a risk factor for many different cancers, such as oral cavity, pharynx, larynx, oesophagus, liver, colorectal and female breast cancer; recalls the study referred to by WHO\(^{41}\) which recognises that there is no safe level of alcohol consumption when it comes to cancer prevention, and stresses the need to take this into account when devising and implementing cancer prevention policy\(^{42}\);

16. Welcomes the Commission’s target of achieving a reduction of at least 10% in the harmful use of alcohol by 2025; encourages the Commission and the Member States to promote actions to reduce and prevent alcohol-related harm within the framework of a revised EU alcohol strategy\(^{43}\), including a European zero alcohol consumption strategy for minors, accompanied, where appropriate, by legislative proposals, while respecting the principle of subsidiarity and current national legislation on age limits on alcohol consumption; supports the provision of better information to consumers by improving the labelling of alcoholic beverages to include health warning labels and introducing the mandatory indication of the list of ingredients and nutritional information, and in addition, by introducing digital labelling; asks the Commission to take specific actions targeting heavy and risky drinking\(^{44}\), considers it important to protect minors from

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\(^{36}\) [https://fctc.who.int/who-fctc/overview](https://fctc.who.int/who-fctc/overview)

\(^{37}\) [https://fctc.who.int/protocol/overview](https://fctc.who.int/protocol/overview)


\(^{42}\) [https://www.thelancet.com/action/showPdf?pii=S0140-6736%2818%2931310-2](https://www.thelancet.com/action/showPdf?pii=S0140-6736%2818%2931310-2)

\(^{43}\) Commission communication of 24 October 2006 on a EU strategy to support Member States in reducing alcohol-related harm (COM(2006)0625).

\(^{44}\) [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(21)00279-5/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(21)00279-5/fulltext)
commercial communication on alcohol consumption, as well as product placement and sponsorship of alcohol brands, including in the digital environment, as advertising must not be aimed specifically at minors and not encourage alcohol consumption; calls for the prohibition of alcohol advertising at sport events when those events are mainly attended by minors, and calls for the prohibition of alcohol sponsorship of sport; calls for the close monitoring of the implementation of the revised Audiovisual Media Service Directive\(^45\); calls for the proposed Digital Services Act to strengthen the ability of Member States to uphold and enforce legislation seeking to protect minors and other vulnerable populations from commercial communication for alcoholic beverages; encourages the allocation of public funds for national and European awareness campaigns; supports the planned review of EU legislation on the taxation of alcohol and on cross-border purchases of alcohol by private individuals and a review of alcohol pricing policies, including considering an increase of taxes on alcoholic beverages;

17. Underlines that food has a significant influence on the health of individuals, and that scientific evidence shows that the consumption of inappropriately-sized food portions has negative impacts on health and may increase the risk of developing cancer; calls for the development of comprehensive nutrition campaigns, aligned with the European Union’s Farm to Fork Strategy;

18. Encourages Member States to consider making nutrition counselling available in primary healthcare;

19. Emphasises the role of a healthy diet in preventing and limiting the incidence and the recurrence of cancer, and stresses that individual cancer risks can be reduced by an increased consumption of sustainably-produced plants and plant-based foods, such as fresh fruits and vegetables, whole grains and legumes; emphasises, furthermore, the need to address the overconsumption of meat and ultra-processed products, and products high in sugars, salt and fats; welcomes, therefore, the upcoming revision of the EU school fruit, vegetables and milk scheme and of the EU’s policy on the promotion of agricultural products; asks the Commission and the Member States to encourage and help consumers to make informed, healthy and sustainable choices about food products by means of the adoption of a mandatory and harmonised EU front-of-pack nutritional label that is developed based on robust and independent scientific evidence; welcomes the focus on healthy nutrition in the EU Child Guarantee\(^46\) and calls for a new EU Action Plan on Childhood Obesity; supports fiscal measures to make fresh foods (such as fruits and vegetables, pulses, legumes and wholegrains) more affordable and accessible at national level, especially for people on low incomes; encourages Member States to use pricing policies, such as value added tax differentiation, and marketing controls to influence demand for, access to, and the affordability of food and drink low in saturated fats, trans-fats, salt and sugar; supports Member States in revising the relevant provisions to restrict the advertising of sweetened beverages and processed food products high in fats, salt and sugar, including advertising on social media, and calls on the Commission to come forward with a proposal for a comprehensive EU-wide


regulation to prohibit such advertising to minors;

20. Acknowledges that obesity is considered as a risk factor for many types of cancer, such as colorectal, kidney or breast cancers, among others; calls on the Member States to actively fight against obesity by making available healthy dietary choices and the practice of sports, not only by educating and encouraging citizens to make the right choices, but also by including integral programmes in primary healthcare that help patients suffering from obesity to lose weight in a healthy way; calls on the Commission and Member States to support research and innovation related to obesity aiming to describe the influence of genetic factors, the human microbiota or psychological status, among others, on body weight, and to explore the most effective interventions;

21. Welcomes the Commission’s intention to tackle the presence of carcinogenic contaminants in food; recalls to the Commission Parliament’s resolution of 8 October 2020\(^{47}\) calling for setting strict legal limits for the presence of acrylamide in food to adequately protect consumers, especially the most vulnerable such as infants and children; urges the Commission to swiftly come forward with regulatory proposals;

22. Calls on the Commission to heed Parliament’s various calls in its resolution of 16 January 2019 to improve the Union’s authorisation procedure for pesticides;

23. Calls on Member States, regional and local governments, civil society representatives and employers to promote and facilitate the practice of physical activities and sports throughout life, as they are known to limit both the incidence and the recurrence of cancer, as well as to reduce mental health problems and to favour social inclusion; highlights the importance of making the practice of physical activity and sports accessible and inclusive from a young age, in particular for vulnerable groups, by financing public infrastructures, equipment and programmes; calls on the Member States to facilitate access to physical activity for hospitalised patients if clinically recommended;

24. Welcomes the launch of the EU’s ‘HealthLifestyle4all’ campaign involving the promotion of sports, physical activity and healthy diets, in addition to other key sectors; recommends that schools include health education in their curricula to ensure that minors and adolescents learn how to lead a healthy lifestyle and are made aware of the ECAC, and calls for health education to be an integral part of social assistance educational policies;

25. Points out that radiation from the sun contains invisible ultraviolet (UV) radiation which can lead to skin cancer; calls therefore on the Commission to revise Directive 2006/25/EC on the exposure of workers to risks from physical agents (artificial optical radiation)\(^{48}\) and to include solar radiation in its scope; supports the strengthening of protection against exposure to UV radiation at EU level, especially through occupational health and safety legislation for outdoor workers; welcomes the Commission’s commitment to explore measures on exposure to UV radiation, including

\(^{47}\) Texts adopted, P9_TA(2020)0256.
\(^{48}\) OJ L 114, 27.4.2006, p. 38.
from artificial tanning devices (sunbeds)\(^{49}\); points out the importance of information campaigns to make people aware of the risks associated to excessive sun exposure and to teach them how to recognise possible warning signs; calls for specific measures to reduce the exposure to UV radiation of minors and adolescents; calls for stricter legislation on the use of sunbeds for cosmetic purposes and a ban on the use of it by minors; calls on Member States to include the reporting of melanoma skin cancer in national cancer registries;

26. Acknowledges that around 2 % of the European cancer burden can be attributed to ionising radiation and that indoor exposure to radon and its decay products is the second leading cause of lung cancer in Europe; looks forward to the results of the Euratom Research and Training Programme\(^ {50}\), which will improve knowledge on exposure to radon, and the proposed countermeasures to reduce its accumulation in dwellings; recalls that ionising radiation could also be present in private households; encourages the Commission and Member States to map current and potential critical areas in order to effectively react to this threat; calls on the Commission to allocate funds to the creation of such a forecast map and to promote information campaigns for the public in order to raise awareness on this matter; encourages Member States to regularly update their national plans to reduce exposure to radon, as requested in the Directive on Exposure to Radioactive Sources\(^ {51}\) and to update guidelines on radon mitigation for new constructions; calls on the Commission to assess the implementation and effectiveness of current measures to protect workers exposed to ionising radiation such as airline crews, nuclear power plant workers, workers in relevant industrial settings and researchers and health professionals working in the radiology, radiotherapy or nuclear medicine sectors, and to review these measures where necessary and proportionate;

27. Calls on the Commission to promote multidisciplinary scientific research on the existence of links between electromagnetic fields (EMFs), including 5G, and cancer in order to gather scientific evidence on the long-term effects of EMFs, and to inform the public in a timely manner of the outcome of those studies; calls for the promotion of research into the development of technology that reduces radio frequency exposure;

28. Sees the European Green Deal as a significant contributing factor to cancer prevention in Europe, by means of reducing air, food, water and soil pollution and chemical exposure; calls for an evaluation of the impact of policies on cancer incidence to be integrated into the Farm to Fork Strategy, the Chemicals Strategy for Sustainability, the Zero Pollution and the Non-Toxic Environment Strategies; welcomes the upcoming revision of the EU’s air quality standards and calls on the Commission to align them with WHO guidelines as referred to in Parliament’s resolution of 25 March 2021 on the implementation of the Ambient Air Quality Directives\(^ {52}\); calls on the Commission to ensure that the common agricultural policy helps farmers to reduce the use of pesticides; encourages the research into, the use and the development of medicines that are safer


\(^{52}\) Texts adopted, P9_TA(2021)0107.
for the environment, and encourages the implementation of efficient waste removal mechanisms that avoid polluting the environment, in line with the objectives of the Pharmaceutical Strategy for Europe;

29. Stresses the need for full implementation of the revised Drinking Water Directive\(^{53}\) and the implementation and enforcement of the Water Framework Directive\(^{54}\), which will reduce the concentrations in surface and ground waters of certain pollutants that could contribute to cancer incidence;

30. Calls in particular for the strengthening of the information requirements on carcinogenicity under the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH)\(^{55}\) in order to enable the identification of all carcinogenic substances manufactured or imported, irrespective of their volume, in line with the Chemicals Strategy for Sustainability, and calls also for the registration, evaluation, authorisation and restriction of chemicals, including EDCs, under the REACH Regulation to be conducted in association with the IARC and the WHO assessments; welcomes the commitment in the Chemicals Strategy for Sustainability to extend the generic approach to risk management to ensure that consumer products do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistently or bioaccumulatively toxic; calls on the Commission to swiftly implement the measures planned in the Chemicals Strategy for Sustainability to reduce citizens’ exposure to carcinogenic and endocrine-disrupting substances through all exposure pathways; calls on the Commission to devote particular attention to segments of the population that are particularly vulnerable to hazardous chemicals and to better take into account these vulnerable populations in the risk assessments of chemicals; stresses that information to consumers on exposure pathways in their everyday life is key to strengthening prevention, and welcomes in this regard the establishment of the Substances of Concern in Products database; calls on the EEA to produce a report together with the European Chemicals Agency on chemicals in the environment in Europe; calls for the report to assess the systemic nature of carcinogenic and EDCs within Europe’s production and consumption systems, their use in products, their occurrence in Europe’s environment, and the harm caused to human health, especially concerning cancer;

31. Considers that the next edition of the ECAC will have to take into account the latest knowledge on environmental carcinogens; calls on the Commission to propose without delay a revision of Article 68(2) of REACH, the Regulation on Food Contact Materials\(^{56}\), the Regulation on Cosmetic Products\(^{57}\), the Directive on Toy Safety\(^{58}\) and other relevant consumer product legislation to ensure that consumer products do not


contain chemicals that cause cancer, in line with the Chemicals Strategy for Sustainability; calls, furthermore, for the regular revision of this legislation to take account of the development of new materials, trends and products; underlines that endocrine disruptors (EDs) are present in food, food contact materials, cosmetics, consumer goods, toys, as well as drinking water, and that exposure, even at low doses, can induce adverse effects in the short and long term, including cancer; highlights that given the widespread exposure of the EU population to many suspected and known EDs and the fact that combined exposure to several EDs acting on similar or different pathways can have cumulative effects, there is a need to minimise exposure to EDs and to make EU regulation more consistent across sectors; encourages further research in order to determine the capacity of chemicals to act as endocrine disruptors;

32. Fully supports the Commission’s commitment under the Chemicals Strategy for Sustainability to amend the Regulation on the classification, labelling and packaging of chemicals (Regulation (EC) No 1272/200860) to introduce new hazard classes on, inter alia, EDs, including suspected EDs, and to update the information requirements in all relevant legislation to allow their identification;

33. Calls on the Commission to integrate the ‘benign by design’ approach into the regulatory requirements related to the production of chemicals and pharmaceuticals, in order to take a true precautionary approach to mitigating risks for our health, society and the environment;

34. Welcomes the publication of the new EU strategic framework on health and safety at work for the 2021-2027 period notably the ‘Vision Zero’ approach to work-related deaths, as well as the planned stock-taking occupational health and safety summit in 2023 to evaluate progress towards ‘Vision Zero’; stresses the need for the close and regular involvement of social partners and stakeholders in this strategy; regrets, however, the limited number of substances addressed in the strategy; encourages the constant analyses and research on new substances suspected of being carcinogenic, mutagenic and/or reprotoxic, the establishment of OELs for chemical agents for which they do not yet exist, and periodic revisions whenever this becomes necessary in the light of further recent scientific data and technical developments; welcomes the workers survey prepared by the European Agency for Safety and Health at Work (EU-OSHA) on exposure to cancer risk factors; stresses that more systematic human biomonitoring programmes in full compliance with data protection measures, both in occupational settings and non-occupational settings, can be one of several relevant sources of information on general chemical exposure effects and health impacts; calls therefore on the Commission to increase its ambition as a matter of urgency through ambitious and regular updates of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work; to do so, calls on the Commission, following consultation of the Advisory Committee on Health and Safety, to present an action plan to achieve OEL values for at least 25 additional substances, groups of substances or process-generated substances by 2024; stresses, in this regard, the need for the Commission to increase the capacity for reviewing OELs and adding new ones, including through increased staffing in relevant units and authorities; recalls, in this context, that ongoing negotiations on the fourth revision of Directive 2004/37/EC

are an opportunity to also include in Annex 1 work involving exposure to hazardous medicinal products meeting the criteria for classification as carcinogenic, mutagenic and/or toxic for reproduction category 1A or 1B set out in Annex I to Regulation 1272/2008, in order to ensure the best possible general and individual protection measures for workers handling these products; reiterates its calls for a new coherent, transparent and risk-based system to be established for setting exposure limits and to better take into account workers’ exposure to a combination of substances; welcomes the commitment by the Commission to add EDs as a category of substances of very high concern under Regulation 1907/2006 (REACH Regulation) and to classify them under Regulation 1272/2008; stresses that workers should also be protected from exposure to EDs; welcomes the Commission’s commitment to presenting in 2022 a legislative proposal to further reduce workers’ exposure to asbestos, a proven carcinogen (group 1) according to the IARC, which remains responsible for around half of all occupational cancers in Europe; reiterates in this regard Parliament’s requests in its resolution of 20 October 2021 on protecting workers from asbestos, in particular its call for a European strategy for the removal of all asbestos and its proposals for a better evaluation of the risks linked to non-occupational exposure to asbestos; asks Member States to facilitate recognition of and compensation for proven work-related cancers and to reinforce the monitoring of work-related exposure by labour inspectorates;

35. Encourages the Commission and the Member States to achieve the UN SDGs that target communicable diseases in order to promote the prevention of cancers related to infectious diseases; welcomes vaccination programmes in the fight against HPV transmission; insists that a gender-neutral and publicly-financed HPV vaccination programme be implemented in the Member States in order to ensure the elimination of all HPV-related cancers, and calls for 90% of girls to be fully vaccinated, and for a significant increase in the vaccination of boys, with the HPV vaccine by the age of 15 by 2030; urges that progress towards the goals of Europe’s Beating Cancer Plan on HPV vaccination be reported in the Cancer Inequalities Registry; calls on Member States to implement the Council recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases in order to reduce immunisation inequalities among vulnerable groups and to improve childhood immunisation; welcomes the Commission’s intention to propose a Council recommendation on vaccine-preventable cancers; stresses, in this context, the need for coordinated actions targeting carcinogenic viruses, such as HPV and the hepatitis B virus (HBV), in order to prevent their transmission; calls for more harmonisation of HPV and HBV vaccination within Member States’ national programmes, while ensuring the provision of information about vaccination and promoting equal access for vulnerable and at-risk adult groups; encourages the regular monitoring of current HPV and HBV vaccination at EU level using a tracking system similar to the COVID-19 vaccine tracker developed by the European Centre for Disease Prevention and Control (ECDC), that will also encourage Member States to adopt best practice and maintain momentum; calls on the Member States for data harmonisation, interoperability and enhanced development of national immunisation data systems; underlines that the ECDC should play a key role in tracking Member States’ progress; supports further research on vaccine development against other viruses such as the hepatitis C virus and the human immunodeficiency virus (HIV); considers that in the meantime therapeutic solutions ought to be used

massively to reach the WHO’s goal of eradicating hepatitis C by 2030, and calls on the Commission to use financial resources under the Recovery and Resilience Fund to reach these targets by funding screening efforts; calls for cooperation with Member States and international organisations to combat the impact of misinformation on vaccination and to address vaccine hesitancy; calls for the EU4Health and other EU funding streams to be used for this purpose, including for supporting awareness-raising efforts for citizens, education providers and healthcare professionals, as well as for support to behavioural research under the Horizon Europe programme; recommends a strengthened application of the EU’s Code of Practice on Disinformation particularly with regard to vaccine misinformation;

36. Points out that recent data confirms that people suffering from chronic inflammation, including from rheumatic and musculoskeletal diseases (RMDs), are at a higher risk of developing cancer and other malignancies; calls on the Commission and Member States to boost research on the relationship between chronic inflammation, cancer and RMDs;

37. Calls on the Commission and Member States to further invest in research into the causes of adult and also paediatric and adolescent cancers;

38. Recommends that breastfeeding be encouraged so as to limit the risk of breast cancer in women by means of informing and educating mothers on the benefits of breastfeeding;

39. Points out that genetic predisposition to cancer linked to mutations of specific genes has been demonstrated; highlights that methods to detect these mutations are available, either at birth for early detection of certain paediatric cancers or over the course of a lifetime, especially for breast, ovarian and colorectal cancers, and that the detection of these mutations may help to prevent or detect early-stage cancer and guide treatment choices; recommends therefore that Member States support increased access for patients in all age groups to genetic testing coupled with medical counselling and advanced sequencing diagnostics by earmarking financing and creating clear pathways for fast and efficient reimbursement, and raise awareness about to what extent citizens can access such services in the Union; recommends boosting investment in infrastructure and skills related to genetic sequencing platforms and the training of specialised genetic counsellors in specific units, such as already exist in some centres; calls on the Commission to support research in genetics in order to find genotypes with higher likelihood of developing certain cancers, including childhood cancers, as diseases with short exposure to external agents;

40. Highlights that techniques such as molecular epidemiology can provide new insights into the gene-environment interactions in cancer compared to in regular epidemiology; points out that these insights, together with further studies in epigenetics, can be used to improve the understanding of risk factors contributing to cancer causes and increase early detection;

41. Strongly supports the planned revision of the ECAC in order to develop, share and implement best practices in cancer prevention programmes, with a dedicated focus on disadvantaged groups, and the launch of a user-friendly EU mobile application which supports people and covers from cancer prevention and education to care, as announced in the Plan; highlights that in addition to being available on mobile applications, all up-to-date information should also be made available in non-digital formats to ensure inclusiveness; stresses that the ECAC should be systematically evaluated by IARC and
that the evaluation work should continue to be coordinated by the Commission;

42. Encourages the Commission and the Member States to further promote health literacy on cancer risks and determinants as well as digital literacy that is linked to it, to develop educational tools for prevention, and to support the creation of e-learning platforms and applications; calls for particular attention be paid to disadvantaged, vulnerable, socially excluded, and marginalised people, and underlines that specific awareness-raising campaigns for groups with particular health literacy needs are essential; notes the importance of increasing health literacy on carcinogenic substances at work, and calls on the Commission and Member States to ensure that employers provide appropriate training; underlines that primary healthcare providers have an important role in health promotion among several population groups, since they can adapt their health promotion actions to the needs of patients in the light of patients’ digital skills, or even if they have no digital skills at all; considers cancer prevention to be a first step towards a European public health education policy;

43. Calls for the continuous strengthening of the Knowledge Centre on Cancer, which should be tasked with establishing a European roadmap for devising and coordinating large-scale prevention campaigns, in synergy with national programmes, and effective communication campaigns on health promotion in educational programmes (harmless behaviours, healthy nutrition, physical activity, transmission routes of carcinogenic viruses and vaccination and treatment opportunities for such infections, etc.), with a special focus on young people and disadvantaged groups; notes the importance of cooperating with national and local civil society organisations when developing the messaging for these campaigns;

44. Underlines that tobacco and alcohol consumption, poor nutrition, a high body mass index, a sedentary lifestyle and environmental pollution are risk factors common to other chronic diseases; believes, therefore, that cancer prevention and risk reduction measures have to be implemented in the context of an integrated chronic disease prevention programme, in close cooperation with the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases; calls for a stock-taking and prevention summit focusing on commercially-produced determinants of cancer and other chronic diseases, which would bring together the EU institutions, Member States, patient associations and civil society organisations active in the field of health;

45. Calls for the implementation of prevention programmes to be inclusive by involving regions and municipalities, citizens, the social partners, civil society and patient associations at all steps of the decision-making process, especially through the Conference on the Future of Europe;

II. Inclusive screening and detection of cancer

46. Deplores the frequent delays to and shortcomings in the timely diagnosis of symptomatic cancers related to a lack of information or adherence to cancer screening and detection processes; recognises the need to pay particular attention to the continuity of screening programmes and early detection and cancer care services during a health crisis (such as the COVID-19 crisis) or in situations where the capacity of the healthcare systems decreases; encourages the Commission and Member States to organise, in partnership with cancer stakeholders, public health campaigns to address any delays in
screening, early detection and care that a health crisis might cause; stresses the importance of quick and up-to-date data on cancer screening programmes in order to enable swift reaction and follow-up in case of disruptions to regular screening capabilities with the goal of reducing the number of postponed screenings to an absolute minimum;

47. Regrets the inequalities between Member States in access to cancer screening, resulting in lower chances of survival due to late diagnosis of cancer, which represents an unacceptable discrimination of EU citizens based on their country of residence; underlines that in the case of breast cancer screening, differences in coverage are at least tenfold across the EU according to Eurostat; points out that the ‘Health at a Glance: Europe 2018’ publication noted that for cervical cancer screening, the difference between Member States in coverage of the target population ranges from 25 % to 80 %; notes that, for instance, only 18 Member States reported having national or regional population-based screening programmes for breast, cervical and colorectal cancers, according to the most recent report by the IARC on the implementation of the 2003 Council Recommendations on screening; calls on the Commission to support projects, for example via EU4Health, Horizon Europe Mission on Cancer or other relevant programmes, to explore the barriers limiting the early detection and early diagnosis of cancer in Europe;

48. Invites Member States to work together, especially in cross-border regions and isolated areas (including mountain areas and urban areas remote from screening centres), to reduce social and geographical inequalities in cancer screening and early diagnosis services;

49. Supports the launch of a new EU-supported cancer screening scheme, as announced in the Plan, to help Member States to ensure that 90 % of the EU population who qualify for breast, cervical and colorectal cancer screenings are offered screening by 2025; calls on the Commission to include other cancers in the scheme, based on the latest scientific evidence, with clear targets for each type of cancer; supports research on other types of cancers which may be effectively detected by screening; calls on the Commission to evaluate every two years the results of the cancer screening scheme in terms of equal access of the target population, to keep track of inequalities between Member States and regions, propose appropriate new measures and correlate screening programmes with the latest cancer screening research results, and if necessary, present measures for increasing the coverage of screening and prevention services in the Member States; urges the Member States and the Commission to report and monitor the achievement of screening targets in the Cancer Inequalities Registry;

50. Encourages Member States to promote cancer screening for breast, cervical and colorectal cancers, as part of organised population-based national and regional programmes, including in the remote and outermost regions, and to provide adequate resources for this; reiterates that, at the same time, there should be increased focus under the Plan on screening, diagnosis and treatment initiatives for cancers that cannot be prevented; encourages the Commission and the Member States to promote targeted screening for high-risk groups; strongly recommends that Member States develop a comprehensive screening policy which allows for timely screening when cancers with hereditary characteristics are detected; recommends that Member States establish research programmes into, and the development of, effective, accurate, non-invasive
and innovative early diagnosis methods, such as biomarkers, for different types of cancer;

51. Calls on the Commission and the Member States to fully implement the European guidelines for quality assurance in cancer screening for breast, cervical and colorectal cancers and early detection services to minimise the diagnosis time for such cancers; recommends that inequalities within Member States regarding screening be addressed, possibly by making the criteria for cancer screening, legal frameworks and governance and quality assurance structures more stringent and science-based; considers that in order to address disparities in cancer screening, common standardised screening protocols are needed at EU level, going beyond best practice guidelines, e.g. on algorithms for the organisation of screening programmes and indicators for assessing the quality of screening programmes;

52. Encourages the improvement and harmonisation of cancer screening data collection to allow for an annual European report; encourages, furthermore, the regular monitoring of current screening programmes at EU level; highlights the need to link data sets on cancer incidence from screening programmes with occupational categories, which can help to identify appropriate preventive measures; considers that stepping up public health services (including financing, infrastructure and aspects involving health professionals) is key to improving cancer prevention, screening and diagnosis; stresses the importance of screening for and collecting data on common cancer comorbidities in order to better anticipate them; underlines that scientific advances in cancer risk prediction should allow for the development of risk-appropriate screening programmes;

53. Stresses the need to closely monitor current and former hepatitis B and C patients to prevent cancer development;

54. Encourages the Commission to consider the possibility of facilitating a ‘second opinion’ system within the Cross-Border Healthcare Directive63 for difficult or atypical cancer cases, and recommends that the Member States introduce the right of patients to request that specialists from one Member State seek the advice of specialists from another Member State within a single coherent system;

55. Welcomes the process initiated by the Commission’s Group of Chief Scientific Advisors and the Scientific Advice Mechanism on the upcoming update of the 2003 Council recommendation on breast, cervical and colorectal cancer screening, which will take into account new screening tests and the most recent data on the best screening protocols (magnetic resonance imaging, HPV testing, risk-stratified approaches and risk calculators); emphasises that information on those screening programmes should be transmitted to the Joint Research Centre’s Knowledge Centre on Cancer (age of initiation and subsequent uptake, impact on survival, cost-effectiveness etc.) and that they should be regularly evaluated by the competent national authorities; calls on the Commission to develop EU guidelines for fostering research efforts in order to assess the inclusion of new science-based cancer screening programmes (including lung, prostate, stomach and ovarian cancers) and the role of artificial intelligence as part of the update of the Council recommendation in 2022, in close cooperation with the IARC, the WHO, healthcare professionals and patient organisations; calls for the evidence that

proves the positive effect of targeted lung cancer screening on mortality to be recognised; encourages the Council, based on the outcome of the above-mentioned assessment, to consider including lung and prostate cancer screening in the update of the Council recommendation in 2022; calls, further to the opinion of the Commission’s Group of Chief Scientific Advisors and the 2022 update of the Council recommendation on cancer screening, for clear and tangible targets to be set for any new cancers that need to be tackled;

56. Advocates the launch by the Commission and the Member States of an EU platform for national screening centres, drawing on the experience of similar platforms for exchange and cooperation such as the European Network for Health Technology Assessment and the Heads of Medicines Agencies; recommends that this platform be entrusted with sharing expertise and implementing best practices, discussing common challenges, encouraging collaboration, training and capacity-building for improving quality in screening programmes, acting as a central hub for projects and initiatives on cancer screening supported by the EU, and maintaining in the long term the network of providers of data to the implementation report by the IARC on cancer screening;

57. Stresses the importance of increasing awareness about and the uptake of cancer screening and early detection among people in the EU via a Union-wide awareness-raising campaign as part of the European awareness days, motivation surveys and better implementation of existing communication campaigns; calls on the Commission and the Member States to support, fund and implement further actions aimed at raising awareness of cancer screening and promoting participation in screening both among the general population and to eligible residents via direct notifications; encourages the Member States to actively work on educational strategies in primary healthcare centres; encourages research into behavioural adherence factors and obstacles impeding early detection and diagnosis of cancer to boost participation in screening programmes, supported by EU funding such as that provided under the Horizon Europe research programme;

58. Calls for reinforced cooperation with non-EU countries and especially with the broader European region to encourage the organisation of screening campaigns and early diagnosis programmes, in particular for women’s cancers and especially in low- and middle-income countries and for minority communities, while also taking into account the specificities of women’s cancers in those countries; stresses that this can mark an important contribution by the EU to the achievement of international goals in cancer, such as the WHO goal to eliminate cervical cancer as a public health problem;

59. Recognises the importance of health mediators, patient navigators and non-governmental organisations and calls for their inclusion in decision-making processes and resource allocation strategies; acknowledges the vital role they play, especially in prevention and vaccination campaigns, by helping to break down barriers between authorities and society, including vulnerable groups;

60. Calls on the EU and the Member States to reinforce cooperation with the WHO and to work towards the implementation of WHO policy recommendations and guidelines;

IIIa. Equal access to cancer care: towards best quality care

61. Deplores the fact that EU patients still face challenges in accessing healthcare services
and participating in clinical trials in other Member States and that only a minority of patients, and not all healthcare professionals, are aware of the right of patients to seek cross-border healthcare under the two existing frameworks: the Cross-Border Healthcare Directive and the Social Security Regulation; calls for a reform of the Cross-Border Healthcare Directive, notably to allow for mobility and access to highly specialised equipment and care through the reinforcement of the national contact points by providing them with more budgetary resources, and to allow for the development of Commission guidelines setting acceptable and harmonised review and approval timelines to expedite time-to-treatment in the EU under the Social Security Regulation; calls for an increase in the number of information campaigns on patients’ rights to cross-border healthcare, including those aimed at health professionals, as well as the development of a one-stop-shop for information on the EU’s cross-border access pathways; emphasises the need to reduce logistic and linguistic barriers faced by patients when accessing healthcare in another EU Member State; stresses the need to provide patients with clear information on prior authorisation requirements that apply to certain Member States; emphasises the need to facilitate the process through a holistic revision of the cross-border healthcare frameworks, giving equal weight to the Cross-Border Healthcare Directive and the Social Security Regulation, for patients who, in view of unmet needs and potential benefits, travel abroad for clinical trials and may face issues such as a lack of clarity on follow-up protocols after their return home and on coverage of costs related to their clinical trial participation by national insurance agencies; emphasises the need for clarification regarding access to cross-border clinical trials, as this is not clear in the Cross-Border Healthcare Directive; underlines that all costs related to a treatment should be financed before it begins to avoid the exclusion of low-income patients; calls on the Commission to consider, in the context of the next revision of the existing frameworks, the setting up of a single set of authorisation and reimbursement rules for the access to cross-border healthcare, including a right to a second opinion; calls on the Commission and the Member States to work together to conduct regular evaluations of the Commission’s eHealth strategy from 2018 to ensure interconnected electronic health records, better interoperability, and improved data quality, privacy and security for cancer patients at regional, national and EU level, while ensuring strict adherence to patient health data privacy and security rules; notes the potential of the Cancer Inequalities Registry as a means of reporting and measuring improvement in these areas;

62. Notes the importance of rapidly administering treatment and providing the results of relevant medical exams to cancer patients in a timely fashion, since the more time this takes, the more the disease progresses, threatening the patient’s survival; regrets that in certain Member States, public resources are inadequate to guarantee timely detection and treatment, which leaves patients who depend on publicly provided social insurance with lower chances of survival, thus leaving them with no other option but the private sector;

63. Calls for the mutual recognition of health-related qualifications in cancer care across the EU and a common recognition scheme for non-EU countries to be considered, as requested in Directive 2005/36/EC, ensuring that it is facilitative for oncology-related

specialties; calls for the development of upskilling programmes to enable those wishing to move into oncology to do so at any point in their career;

64. Calls for full recognition of medical oncology and paediatric oncology as specialist disciplines, the establishment of pan-European quality standards for administering and supervising medical treatments for cancer, both for adults and children, and the facilitation of patient access to cancer specialists so that they may benefit from innovations and access to early clinical trials on new promising drugs, health technologies and reference centres for complex treatments like cell and gene therapy; highlights the need to ensure that access to innovation in early clinical trials for relapsed or difficult-to-treat malignancies is covered by the relevant provisions;

65. Calls for surgical skills in the EU to be strengthened via the recognition of surgical oncology as a specialist discipline, the establishment of pan-European quality standards for cancer surgery, the facilitation of patients’ access to ‘high-volume’ centres for cancer surgery and access to innovative surgical procedures; calls for the recognition of high-quality surgery and highlights its importance in curing cancers detected at an early stage; stresses the need to promote the development of a core curriculum in surgical oncology as well as individual specialist training in surgical oncology, and calls for programmes to harmonise surgical oncology education in the EU; supports the development of clinical trials in surgical oncology as part of local-regional treatment and promotes greater investment of EU and national research and innovation funds in surgical oncology research; stresses the importance of standardised surgical oncology treatments to improve long-term quality of life for cancer survivors;

66. Supports the improvement of and increased and equal access to high-quality radiation therapy in the EU through the recognition of medical physics and radiation therapy as dedicated disciplines, the promotion of common education and training standards, increased EU funding for Member States to expand their radiation therapy infrastructure, and greater investment of EU and national research and innovation funds in radiation therapy research;

67. Calls for the promotion of geriatric oncology as a branch that deserves special consideration and needs to be enriched by scientific research in order to ascertain best treatment and diagnostic methods for elderly patients; recalls that in the EU, over 60% of new cancer cases and over 70% of cancer deaths occur in people aged 65 and older; notes that this proportion is expected to increase as the population in the EU ages, thus representing a crucial challenge for healthcare systems; calls on the Commission and the Member States to urgently address this situation with concrete actions; specifically asks the Commission and the Member States to take action in order to facilitate clinical trials in the elderly, the implementation of multidisciplinary and comprehensive oncogeriatric care models in routine clinical pathways, and the creation of centres of excellence in geriatric oncology; calls on the Commission and the Member States to foster opportunities for the training and upskilling of the oncology workforce in the principles of geriatrics;

68. Calls on the Commission and the Member States to plan actions that promote, in the context of care and treatment, greater attention to the protection of patients’ fertility, in particular in the case of paediatric and juvenile cancers;

69. Welcomes the new action plan under the strategic agenda for medical ionising radiation
applications, which will support the security of production capacities for and supply of radioisotopes through the replacement of the current ageing fleet and the implementation of existing technologies, notably reactors and particle accelerators, under existing financial instruments, avoid shortages of radioisotopes by facilitating the crossing of borders and exemptions for transportation, and enhance the quality and safety of radiation technology in medicine, which is currently not equally available in all EU Member States, through the evaluation of radioisotopes via health technology assessments, the harmonisation of market access, the affirmation of nuclear medicine as a fully independent medical specialty, the promotion of training standards, and investment in nuclear medicine research;

70. Calls on the Commission to promote, and on the Member States to strengthen, the role of general practitioners, paediatricians, nurses, primary care professionals and specialist physicians, given the important role they play in referring patients for diagnostic tests and to oncology specialists, as well as the role of specialised nutritionists or dieticians, psychologists and rehabilitation specialists during cancer treatment and follow-up care, in order to ensure access to the right treatment and care at the right time via an optimal care pathway; calls for the development of multidisciplinary teams to manage cancer patients throughout their treatment journey, and multidisciplinary decision-making in the framework of dedicated cross-discipline concertation meetings (consilium) bringing together various cancer specialists and primary care professionals; underlines the importance of constant training for health professionals to keep them updated on new cancer treatment options; calls for the role of treatment coordinator to be made more widespread in order to ensure that patient treatment is appropriately coordinated, and to give patients easy access to updated information related to cancer diagnosis and advice on how to use the health system;

71. Considers that the scope of Directive 2005/36/EC should be revised to allow for the mutual recognition of cancer nursing education and education for other medical staff supporting the treatment process;

72. Calls on the Member States to develop, within their national cancer control programmes (NCCPs), strategies that encompass and implement preventive measures against the risk of burnout among cancer care professionals; urges the Commission and EU-OSHA to pay attention to this concern, and stresses that they should be considered important implementation partners of the Plan in this respect;

73. Encourages, where feasible and safe, the use of ambulatory cancer treatments in order to preserve the quality of life of patients and their families; stresses, in particular, that ambulatory treatments for children should be promoted, provided that the relevant spaces/environments and medical devices available are designed in such a way as to cater for the needs of paediatric patients; stresses the role of pharmacists, oncologists and nurses in the multidisciplinary follow-up of patients taking oral anticancer medicines; calls on the Member States to implement or improve e-health technologies, telemedicine and telecare services to ensure the continuity of inpatient and outpatient cancer care as well as community care; urges the Commission to deploy Horizon Europe research funding to support the use of telemedicine and to assist with the

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establishment of evidence-based guidelines; calls for actions to ensure equal access to telemedicine services across the Member States, and for EU4Health and Digital Europe funding to support an increase in digital literacy for patients and healthcare professionals;

74. Calls on the Member States to provide integral and multidisciplinary palliative care services for cancer patients in order to ease their pain and discomfort, promoting comfort care and ensuring the presence of nurses or carers, while preserving their dignity and taking into account advance care planning and the autonomy of the patient; calls on the Commission to support and coordinate regular exchanges of information and the implementation of best practices on hospice and home palliative care at EU level; calls for the development of child-specific palliative care, especially in Member States where this type of care is not yet widely provided; encourages the Member States to address palliative care in their NCCPs, maximise the number of palliative units in each region in order to appropriately adjust their number to the needs of patients, minimise waiting times, and ensure sustainable funding and sufficient numbers of well-trained staff; considers that the EU regulatory framework for the recognition of professional qualifications should be broadened to allow for the standardisation of palliative care education and best practices of health professionals; emphasises the need for reference networks for palliative care and their integration with cancer pathways at all levels, namely specialist hospitals, primary healthcare centres, hospice and home care, as well as the need for hospital-territory integration; stress that patient access to supportive and palliative care (including psycho-oncology services) across the EU should be measured and reported via the Cancer Inequalities Registry; calls for deeper cooperation between healthcare systems and social assistance systems in all Member States;

75. Encourages the Commission and the Member States to adopt specific quality assurance criteria and schemes (including common standards of care, adequate organisation, infrastructure and competences, multidisciplinary practice, continuing education for professionals, patient education and participation in clinical research), and joint clinical guidelines to ensure accreditation standards are applied to public and private hospitals treating cancer patients, in order to guarantee efficient, safe and equal management of cancers all over the EU; insists that these criteria must adhere to the highest available standards of evidence-based science that have been published in peer-reviewed scientific journals; insists that both public and private institutions that meet the quality assurance criteria should be included in NCCPs as part of the Plan with the goal of providing the highest quality of cancer treatment to all patients across the EU; calls on the Member States to create maps of oncology health needs, coupling them with realistic mappings and inventories of their existing oncological infrastructure; takes the view that this mapping exercise will allow Member States to better plan access to existing medical infrastructure, determine clear areas of action and prioritise the allocation of resources, and plan cross-border cooperation between the oncological reference centres;

76. Welcomes the planned establishment, as announced in the Plan, of an EU network linking recognised national comprehensive cancer centres (reference centres) in every Member State to facilitate the uptake of quality-assured diagnosis and treatments, including through training in, research on and the promotion of clinical trials across the EU; calls on the Member States and the Commission to support the establishment of
such centres for rare cancers and cancers requiring complex treatments; calls on the Commission to identify existing centres of this type within the EU, to promote the establishment of at least one national comprehensive cancer centre in each Member State and to support the coordination of the network of these centres; stresses that the objectives of that network should include the reduction of inequalities and the strengthening of translational, clinical and outcome research; highlights that the promotion and development of translational research should be considered as an important core objective of the EU Network of Comprehensive Cancer Centres; notes that when developing this EU network, the Commission should consider the need to invest in state-of-the-art equipment and well-trained physicians and other healthcare specialists with various specialties, and recommends that a variety of well-developed cancer specialties and medical disciplines be involved from the start in the work of the envisioned EU Network of Comprehensive Cancer Centres to reinforce multidisciplinary cooperation, therefore improving outcomes for patients; calls on the Commission and the Member States to support the sustainability of pre-existing cross-border collaborations, such as the European Reference Networks and those relating to paediatric cancer; calls on the Commission to support the Member States by earmarking some of the budget in the cohesion and regional funds to support the establishment of these centres to ensure full coverage of the population;

77. Calls for the identification, reinforcement or creation in each Member State of an NCCP, in line with WHO guidance on NCCPs, consisting of a unique structure, possibly a national cancer institute, in charge of the implementation and follow-up of the respective NCCPs, with adequate objectives and resources; calls for the content of the NCCPs to be aligned as closely as possible with the Plan in order to facilitate the successful implementation of the latter; recommends that the NCCPs are set up in accordance with the European Guide for Quality National Cancer Control Programmes initiated by the European Partnership for Action Against Cancer (EPAAC) and calls for the inclusion of a dedicated paediatric cancer and rare cancers component in all NCCPs to ensure that appropriate resources are allocated and adequate implementation programmes are introduced to meet the specific needs of these patients; welcomes the setting up of a network of these organisations; stresses that NCCPs should include provisions on adequate staff capacities so as to guarantee a sufficient number of oncology workers in each Member State, commensurate with the overall population number;

IIIb. Equal access to cancer care and medicines in the EU

78. Calls on the Commission to strengthen the EU medicines market in order to improve equal access to treatment, including innovations and personalised medicine, reduce medicine shortages, overcome the problem of high prices for innovative technologies and treatments, encourage the use of generic and biosimilar medicines and improve cancer treatments for adults and children; calls on the Commission and the national competition authorities to assess the EU medicines market, focusing on acquisitions of SMEs by large pharmaceutical companies that undermine fair competition; encourages a multi-stakeholder dialogue on access to medicines and innovations based on models such as ACCELERATE67 in the paediatric cancer sector and involving all relevant

67 https://www.accelerate-platform.org/
actors including academics, industry, health professionals and patient representatives;

79. Calls on the Member States to step up national research and production capacity for medicines and other health products, including by establishing national pharmaceutical laboratories, with a view to providing equal access to treatment, reducing medicine shortages and dependence on the pharmaceutical industry, securing cost-free access to innovative treatments and improving cancer treatments for adults and children; calls on the Member States, furthermore, to provide cost-free access to treatments and medicines used by cancer patients by means of their public health services and to consider medicine policies that provide cost-free access to medicine for users over the age of 65, the chronically ill and families in economic need;


81. Notes that cancer patients are frequently affected by medicine shortages and that severe disruptions in the supply of cancer treatments are highly detrimental to them, their carers and their families; calls on the Commission and the Member States to work together to prevent and manage shortages of all medicines and medical products and of cancer medicines in particular, including shortages of inexpensive essential cancer medicines; supports the development of a common basket of cancer drugs of which there may be shortages to ensure that patients have continuous access to appropriate treatment, based on transparently and appropriately defined patient needs;

82. Calls for the reinforcement and diversification of the supply chain, in particular that of cancer drugs, within the EU, close monitoring of supply tensions and shortages, and the creation of a strategic stockpile of such critical medicines, active ingredients and raw materials, particularly where the number of suppliers is limited; calls for EU pharmaceutical legislation to introduce a legal obligation for pharmaceutical companies to report information to the EMA on adequate safety stocks of essential cancer medicines; stresses the importance of the role of sustainable procurement practices in preventing medicine shortages; urges the Commission, in the context of the EU Public Procurement Directive, to develop guidelines to support public procurement practices in the pharmaceutical field for cancer drugs, in particular with regard to the implementation of the criteria for the most economically advantageous tender, aimed at ensuring long-term sustainability, competition and security of supply and stimulating investment in manufacturing;

83. Points out that generic and biosimilar medicines enable efficient and safe cancer care, increased competition, innovation and savings for healthcare systems, thus helping to
improve access to medicines; calls for the introduction of a strategic objective in the Plan and the NCCPs to actively promote the use of off-patent medicines, where appropriate and beneficial for patients; stresses that their market entry should not be hampered or delayed and their development process should be promoted and funded; calls on the Commission to ensure healthy competition on the expiry of intellectual property rights as a matter of urgency by ensuring the accessibility of biosimilar medicines from day one and removing all barriers to access to competition, for example through patent linkage, by banning intellectual property evergreening practices that unduly delay access to medicines and by allowing single global development;

84. Considers that Member States should converge on the evaluation of medical technologies; welcomes, therefore, the agreement on the Health Technology Assessment Regulation reached by the European Parliament and the Council on 22 June 2021 to support harmonised assessment of, and faster access to, innovative cancer diagnosis and treatments and considers that a more efficient decision-making process could, among other measures, play a role in facilitating it; welcomes that cancer medicines is one of the first medicinal product groups to be jointly assessed under the Health Technology Assessment Regulation; calls on the Commission and Member States to take further measures aimed at encouraging the uptake and use of Joint Clinical Assessments that are to be carried out under the regulation; highlights the existence of tools being used by the WHO to incorporate cancer medicines on the WHO Model List of Essential Medicines;

85. Recalls that all patients have the right to optimal treatment, regardless of their financial means, gender, age or nationality; notes with concern that there is a great disparity in the availability of and access to different cancer therapies, with unaffordability being one of the main reasons; insists, therefore, on the need to ensure equal access to safe, effective and affordable drugs, in particular cancer drugs, within the EU; calls on the Member States to consider joint price negotiation with pharmaceutical companies, as per the Benelux Initiative on Pharmaceutical Policy and the Valletta Declaration; calls on the Commission to make fair pricing and affordability of new treatments a core element of the Plan and the Pharmaceutical Strategy for Europe, notably by attaching conditionalities to EU public funding (e.g. under Horizon Europe and the Innovative Health Initiative), and to ensure that public investment in R&D is accounted for and that medicines resulting from publicly funded research are available at fair and affordable prices; underlines that this should also be the case for medicines benefiting from specific regulatory or market protection such as medicines developed to treat rare or paediatric cancers; calls for more transparency throughout the pharmaceutical system, especially regarding pricing components, reimbursement criteria and the actual (net) prices of medicines in different Member States to ensure fairer prices and bring public accountability to the pharmaceutical sector;

86. Strongly advocates the extension of joint procurement procedures, especially for (ultra) rare, paediatric and novel cancer medicines and treatments, diagnostic procedures, companion diagnostic tests, and cancer-preventing vaccines like the HPV and hepatitis B vaccines, to counter shortages and improve affordability and access to cancer treatments at EU level; notes that joint procurement procedures should improve response times and be transparent; highlights that joint public procurement should not hinder patient access and medical innovation;
87. Calls on the Commission to support a regulatory framework which strengthens incentives for rare cancer treatment in the EU to effectively address existing shortcomings; underlines that patent systems all over the world are drafted in a way that for a specific period of time – i.e. only for the duration of the patent – only the inventor is allowed to commercially exploit their patent, whereas thereafter the invention can be freely produced by anyone; calls on the Commission to develop new targeted incentives to ensure equitable access to cancer medicines also in areas where the development of products would otherwise not be sustainable;

88. Calls on the Commission to submit a proposal for the revision of Council Directive 89/105/EEC in order to ensure effective controls and full transparency of the procedures used to determine the price of and reimbursement amount for medicines, in particular cancer medicines, in Member States; encourages the competent authorities to ask pharmaceutical companies to provide information on research and development costs, including the financing from public resources, prior to market authorisation, as well as on the tax benefits and subsidies they have received; requests that the calculation of drug costs take into account the use of public funds; calls on the EMA to increase the number of audits in order to assess pharmaceutical companies’ compliance with the requirements on transparency;

89. Notes that huge advances in biology have revealed that cancer is an umbrella term for more than 200 diseases, and that precision or personalised medicine can be made available through the drug targeting of various mutations; considers that precision or personalised medicine, consisting of a treatment choice based on individual tumour biomarkers reflecting genotypes or phenotypes, is a promising way to improve cancer treatment; encourages the Member States, therefore, to develop personalised medicine across the EU through cooperation among them and to promote the implementation of regional molecular genetics platforms and facilitate equal and rapid access to advanced diagnostics and personalised treatment for patients, in full respect of data privacy and ensuring that patients are informed and consent to the use of their health data for research; notes that the fragmentation and classification of cancers based on specific genotypes should not lead to them being defined as ‘artificial rare diseases’ with the aim of increasing financial compensation;

90. Recalls that in the context of personalised medicine, gender-based medicine and therapies are considered to be effective treatment strategies for curing cancer, taking into consideration differences between men and women at the biological, genetic and musculoskeletal levels; calls on the Commission and the Member States to facilitate the development of gender-based treatment for cancer, in line with the indications coming from medical practitioners and physicians;

91. Welcomes the Genomic for Public Health project and the establishment of a roadmap to personalised prevention in the Plan to identify gaps in research and innovation and support an approach to map all known biological anomalies leading to cancer susceptibility, including hereditary cancers, which amount to between 5 and 10 % of

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cancer cases;

92. Calls for the full and rapid application of Regulation (EU) No 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use; considers that the application of the regulation would facilitate the launch of large clinical trials across Europe carried out in a harmonised, efficient and coordinated manner at European level in order to facilitate research into cancer drugs and improve the quality of life of cancer patients and their families; considers, furthermore, that the regulation should be applied in a consistent manner in all Member States with the aim of rationalising procedures for carrying out clinical research; highlights the importance of undertaking a fresh review of opportunities to reduce the administrative burden associated with clinical trials; calls for long-term learning from the COVID-19 pandemic on future forms of international trial cooperation and information sharing;

93. Points out that the PRIME scheme launched by the EMA can be a highly efficient instrument to enhance support for the development of innovative medicines in oncology, so that they can reach the patient sooner;

94. Calls for a more sustainable environment, including as regards financial support, for conducting research into and analysing existing research about the repurposing of medicines for cancer treatment, especially by third parties with no commercial intent, and for the creation of an additional project that uses high-performance computing to rapidly test existing molecules and new drug combinations, starting with high unmet needs, such as treatment for cancers with a poor prognosis, metastatic cancers and rare cancers;

95. Highlights the importance of addressing the issue of the off-label use of medicines, including inexpensive medicines and medicines used for rare cancers; calls on the Commission to analyse the existing situation concerning the off-label use of medicines;

96. Acknowledges that many upcoming technologies will require complex regulations (cell and gene therapies, for example); considers that the Union should fund, incentivise and ensure a regulatory process that actively encourages research and innovation, anticipates the needs of researchers in academia, industry and at clinics, actively informs and guides them on regulatory processes, prepares the ground for future technologies, evaluates those technologies step by step and fosters the entry of safe and effective new treatments into the market;

97. Reiterates the importance of generating and reporting strong evidence on the efficacy and safety profiles of medicines, both in clinical trials and in post-market entry follow-up studies; supports the development of clinical trials on the use of new and affordable cancer drugs in adults and children; supports the development of multi-centric clinical trials across Europe for the discovery of improved forms of treatment and care for patients, including children and older patients; underlines that authorities must ensure transparency, compliance with study conduct requirements and the early communication of relevant data to the EMA and the general public;

98. Takes note of the Commission’s legislative proposal to establish a Health Emergency Preparedness and Response Authority (HERA); notes that, by 2023 and every two years

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thereafter, the Commission should carry out an in-depth review of the implementation of the operations of HERA, including its structure, governance, funding and human resources; notes that these reviews must address, in particular, any need to modify HERA’s structure, including but not limited to the possibility of upgrading it to a stand-alone agency, revising its mandate and understanding the financial implications of any such modification; notes that the Commission should report on the findings of the reviews to the European Parliament and the Council and that these findings should be made public; notes that these reviews should be accompanied, where appropriate, by a legislative proposal to address the outlined issues, fully respecting the European Parliament’s role as co-legislator; considers that if HERA is upgraded to a stand-alone agency, it could, at that point, be able to anticipate, incentivise, co-develop and facilitate rapid, equal and sustainable access to cancer innovations for cancer patients, including diagnostic procedures as well as companion diagnostic tests; considers that HERA could, in the long term, closely collaborate with public and private entities to plan, coordinate and build an ecosystem of private and public capabilities that can provide suitable emergency frameworks for EU access to key raw materials in case of global supply shocks;

99. Stresses the need to promote the innovation of life-saving cancer treatments; calls therefore on the Commission to create a pharmaceutical legislation framework for oncological medicines and therapies that promotes real breakthrough innovations and not the so-called ‘me too’ pharmaceuticals, which are just another substance with the same use without major benefits or highly expensive pharmaceuticals that offer only minor improvements for patients; calls for a large consortium of public authorities, private companies and NGOs, including patient and survivors associations and academia, to work together to guarantee the accessibility and affordability of cancer treatment options requiring complex technologies, for instance, complex treatments like cell therapy (CAR T cells), gene therapy, adoptive immunotherapy through the use of tumour genome extracts (messenger RNA) and nanotechnologies; stresses that, to facilitate the wider utilisation of innovative therapies, the EU and the Member States must not only do their best to finance currently available therapies but also support the development of more cost-efficient methods; believes that lowering the costs of the most innovative and effective therapies will increase their wider availability to the benefit of patients in the EU and beyond; calls for securing equal access to innovative therapies, both in densely populated urban regions and smaller rural or remote areas;

IIIc. Equal access to multidisciplinary and quality cancer care: towards a better response to the impact of health crises on cancer patients

100. Underlines that the COVID-19 crisis has had, and is still having, a significant impact on cancer patients’ survival and quality of life at all stages of the disease, due to delays in prevention activities such as vaccination, postponements of prevention schemes, clinical trials, screenings, referrals, diagnoses, surgical procedures and treatments, shortages in the supply of medicine and other medical supplies, specialised workforce shortages, reduced communication with health professionals and patients’ fear of infection; highlights that evidence suggests that clinicians across Europe saw 1.5 million fewer cancer patients in the first year of the pandemic and performed an estimated 100 million fewer cancer screening tests, and therefore, one million citizens in the EU may presently
be undiagnosed with cancer as a consequence of the COVID-19 pandemic;\textsuperscript{73}

101. Considers that the COVID-19 pandemic was a real stress test for the EU’s health systems; underlines that the main lesson learned should be the need to build an emergency strategy to allow Member States to react in a coordinated manner against any future health crises; stresses that vulnerable groups, including cancer patients, are particularly exposed during a health crisis; stresses that specific measures under this emergency strategy should be aimed at the protection of vulnerable groups, including cancer patients, who cannot wait until the end of the crisis; stresses that these specific measures should support the development, production and stockpiling of products to protect these vulnerable groups;

102. Calls on the Commission and the Member States to diligently collect data via suitable registries to monitor the effects of vaccines against COVID-19 in vulnerable populations, including patients with cancer, and their subsequent immune responses;

103. Notes with concern that the COVID-19 pandemic has exacerbated pre-existing health workforce shortages; acknowledges the urgency of ensuring a sufficient number of specialised health professionals in cancer care; reiterates that specific measures under the emergency strategy should be aimed at addressing workforce shortages through the recruitment of health professionals, in both primary and specialised care, and their retraining, should they be specialists in other fields; suggests that the Cancer Inequalities Registry may serve as a tool in measuring and reporting on pre-existing workforce shortages; underlines that new approaches to human-centred healthcare are required in order to ensure access to diagnostics, therapeutics and quality public health services for all; stresses the need for work on a skill mix in order to optimise the response to staffing needs in the health sector; supports the exchange of good practices between Member States in this regard; calls on the Commission and the Member States to create online training platforms for healthcare professionals such as carers, and to create therapeutic care programmes granting qualifications and recognising their competences;

104. Deplores the fact that patients still face many difficulties in accessing quality, public healthcare services since many oncology departments at public hospitals are suffering from workforce shortages and a lack of capacity; calls, therefore, for the creation of high-quality radiotherapy departments and modern oncology centres at public hospitals, based on European guidelines and in line with the most recent scientific evidence;

105. Calls on the Member States and relevant authorities to recognise the pivotal role of informal carers, integrate them into health and care teams and empower them with the possibility of making informed choices regarding available supportive measures with the support of healthcare professionals; recognises that the pandemic has exacerbated the crucial role of informal carers, who provide most of the daily care for cancer patients and who face a clear lack of practical and policy support, including as regards social rights, training, psychological help, information and recognition; points to the high percentage of informal carers among the EU population and to the disparities regarding the way in which they are supported and how their rights are recognised across Member States; calls on the Commission to consider the formalisation of

informal care, which would ensure the recognition of a certain minimum standard of rights, especially for those who are providing long-term care;

106. Advocates the development of a digital health communication channel to monitor symptoms remotely and ensure continued cancer treatment in out-of-hospital care; calls for permanent access to medical consultations, psychosocial services and contact between the patient and health professionals and between the attending health professional and the patient’s family, to be guaranteed through the use of telemedicine and telecare and their integration into healthcare systems, in health threat-free environments in hospitals, or, where possible and safe, in pharmacies; calls for the stimulation of the development of therapeutics that can support a transition to home care;

107. Asks for enhanced communication between health professionals, patients, survivors, caregivers, parents and public authorities regarding the effectiveness and safety of health interventions, in particular cancer screening, diagnosis and treatment, and for increased awareness campaigns for prevention in times of crises;

108. Calls on the Commission and the Member States to adopt European prevention and management plans as part of a coherent and holistic contingency strategy to prevent and address shortages of medicines, devices, products and staff in times of health crises; underlines the responsibilities of market authorisation holders and wholesale distributors with respect to relevant EU legislation;

IV. Strong support to cancer patients, survivors and caregivers

109. Stresses that cancer patients should not suffer a ‘double punishment’ in their daily lives; calls for the adoption of an anti-discrimination directive, as well as for the fair and equal implementation of directives on financial services, such as the Consumer Credit Directive74, without any discrimination against cancer patients and survivors;

110. Notes that there is a need to focus on the quality of life for a rising number of chronic cancer patients whose illnesses cannot be cured but may be stabilised for a number of years; emphasises the importance of specific EU recommendations to improve the quality of life of patients and survivors, including via comprehensive supportive care integrated into cancer care starting with the diagnosis and continuing throughout the course of the disease (including pain relief, psychological services, adapted physical activity, scientific evidence-based complementary therapies, access to education, nutritional support, social assistance encompassing all day-to-day tasks such as household help or childcare, access to reproductive health and the restoration of aesthetic integrity) and access to specialised supportive centres; asks the Member States to recognise sequelae (physical or mental disabilities), as well as social discrimination, including in the workplace; asks the Commission to propose guidelines for the Member States to address the importance of establishing comprehensive coverage systems that guarantee that these needs are met; recognises that cancer is a financially burdensome disease, even beyond cancer treatments; calls on the Commission to set up a platform for the exchange of best practices in palliative care and to support research on palliative care;

74 OJ L 133, 22.5.2008, p. 66.
111. Calls on the Commission to consider an EU strategy on care and caring to ensure appropriate, accessible and high-quality long-term care;

112. Highlights the fact that scientifically recognised integrative medicine approved by public health authorities can bring benefits to patients in relation to the parallel effects of several diseases, such as cancer, and their treatment; stresses the importance of developing a holistic, integrative and patient-centred approach and encouraging, where appropriate, the complementary use of these therapies under the supervision of healthcare professionals;

113. Underlines that the results of cancer treatment can be hampered by malnutrition, therefore optimal nutritional care is an essential part of cancer care; calls on the Member States to develop recommendations for incorporating clinical nutrition into all aspects of cancer care, including treatment, support and research; considers that, wherever indicated, cancer patients must be provided with clinical nutritional support by a dietitian specialist to be included in the multidisciplinary team; welcomes, therefore, the planned inter-speciality training on nutrition support and calls on the Commission and the Member States to develop minimum standards for continuous training on nutritional care for the multidisciplinary workforce; recommends that nutrition management be an integral and ethical part of all clinical research involving cancer patients; recommends, furthermore, that proper nutritional support be included in the cancer patients’ Charter of Rights;

114. Strongly urges the Member States to ensure that all cancer patients are fully informed about the possibility of fertility preservation procedures prior to the start of active treatment; calls for the development of guidelines at EU level for health professionals, defining the age at which cancer patients should be informed about the availability of reproductive health procedures; encourages, furthermore, the Member States to make provision for all cancer patients covered by compulsory national health insurance to be reimbursed for such services by national health insurance schemes;

115. Encourages the Member States to take into account the frequent exhaustion of the families and relatives of cancer patients and to provide them with psychological and socioeconomic assistance, especially to the most vulnerable, and rest periods in the workplace, throughout the course of the disease, as well as with bereavement support; encourages, furthermore, the development of integrated, adequate and accessible support schemes for cancer patients and their families, that take health, community and social services into account;

116. Recalls that patient empowerment and health literacy is crucial for the European cancer strategy and that patient-centredness and participatory decision-making must be at the heart of treatment and care development processes; encourages the promotion of well-informed patients who are actively involved in their own treatment and calls for the therapeutic education of caregivers and patients and their empowerment in the care programmes; considers that a specifically tailored methodology should be used for the training and empowerment process of paediatric patients, given their specific characteristics and needs; calls for participatory decision-making, with personalised and understandable evidence-based information to be provided to patients, as an integral part of the NCCPs, supported by the Plan; calls for the support of such initiatives and actions to empower cancer patients through EU funding, especially the EU4Health Programme;
117. Acknowledges the central role of independent patients’ and carers’ associations in relation to patient advocacy and accompaniment, services provided to cancer patients and caregivers, dissemination of health literacy, awareness raising and ongoing support both at EU and national level; calls on the Commission and the Member States to take into account the formal participation of these associations, as well as their requests and recommendations, when formulating cancer-related policies and legislation, and to provide them with public support in the form of both operating grants and project-related grants in order to guarantee their independence from private funding; calls on the Commission to set clear criteria according to which public financial support can be awarded; considers that paediatric patients should play a role, both individually and collectively, in improving healthcare and research procedures for all patients by contributing with their specific experiences; takes the view, therefore, that adequate learning and educational tools should be developed and properly financed to plan and ensure the involvement of children;

118. Stresses the importance of securing proper compensation claim options for workers in cases of occupational cancer; calls on the Member States to fully implement the Commission recommendation of 19 September 2003 on occupational diseases and ensure that proper compensation claim options exist for workers in cases of occupational cancer, which would secure every worker a chance to be properly compensated after being exposed to harmful substances or affected by work-related cancer; calls on the Commission to create a minimum list of occupational diseases with comparable recognition criteria across the EU;

119. Calls on the Member States to improve the reintegration of cancer survivors into social activities and the labour market, helping them transition into new professional roles in case sequelae prevents them from continuing in the same job and facilitate the return of paediatric cancer survivors to school or higher education; notes the general undervaluation of aftercare compared to equally important cancer prevention; recalls the recommendations and tools developed by the CHRODIS+ Joint Action to foster patients’ retention at work, ability to return to work and their reintegration into the labour market and encourages the Commission to support the implementation of these recommendations and tools across the Member States; advocates specific EU recommendations for measures for cancer survivors to prevent the recurrence of primary cancer and the development of new cancers as well as measures for their rehabilitation, including specific provisions for long-term follow-up care for childhood cancer survivors as they transition into adulthood; stresses the need for medical and psychological aftercare for cancer survivors;

120. Considers that EU-OSHA should be mandated to play a stronger role in promoting good practices in Member States with respect to the integration of cancer patients and survivors into the workplace and their protection from discrimination; looks forward to the new study, announced in the Plan, on the return to work of cancer survivors, which will map national employment and social protection policies and identify obstacles and the remaining challenges;

121. Underlines the essential role of labour inspectorates in securing compliance with health and safety legislation and preventing work-related cancers; calls on the Member States to strengthen labour inspectorates and ensure that they are adequately funded; emphasises that monitoring and verification is of particular importance for mobile
workers; calls for the fastest possible implementation of the European Labour Authority (ELA) and for it to be made operational as soon as possible, and calls for the ELA to provide real labour inspection power in cross-border cases and monitor compliance with health and safety legislation; calls on the Commission and the Member States to involve the ELA in cross-border situations to secure proper enforcement of health and safety legislation;

122. Urges the Commission to pay attention to shifts in the EU labour market, and secure sufficient funding for proper data collection; believes that extensive and thorough information and data collection is of the absolute importance and is a continued priority for the Commission in order to respond with necessary legislative and non-legislative initiatives concerning the prevention of work-related cancers; stresses the need to establish comprehensive national registers for all Member States, which would enable EU-wide data collection on carcinogen exposure and stresses that these registers should cover all relevant carcinogens; calls for close cooperation between EU institutions, Member States, EU-OSHA and relevant stakeholders, while also strongly involving social partners; calls for making use of the collected data to follow up with necessary legislative and non-legislative measures to combat work-related cancers;

123. Supports the upcoming roll-out of a Cancer Survivor Smart Card, as announced in the Plan, to all European cancer survivors, especially survivors of childhood and adolescent cancers, for whom the Survivorship Passport model exists as a basis, which will summarise their clinical history, including patients’ own experience, and facilitate and monitor follow-up care; stresses the sensitive nature of individual health data and hence the need for the Smart Card to be fully protected under the EU’s General Data Protection Regulation (GDPR);

124. Considers that insurers and banks should not take into account the medical history of people who have been affected by cancer; calls for national legislation to ensure that cancer survivors are not discriminated against compared to other consumers; notes the Commission’s intention to engage with businesses to develop a code of conduct to ensure that developments in cancer treatments and their improved effectiveness are reflected in the business practices of financial service providers; supports, in parallel, the promotion of advances made in France, Belgium, Luxembourg and the Netherlands, where cancer survivors enjoy the ‘right to be forgotten’; requests that by 2025, at the latest, all Member States should guarantee the right to be forgotten to all European patients 10 years after the end of their treatment, and up to five years after the end of treatment for patients whose diagnosis was made before the age of 18; calls for the introduction of common standards for the right to be forgotten under the relevant provisions on consumer protection policy of the Treaty on the Functioning of the European Union, in order to remedy the fragmented national practices in the area of creditworthiness assessment and ensure equal access to credit for cancer survivors; calls for embedding the right to be forgotten for cancer survivors into relevant EU legislation to prevent discrimination and improve cancer survivors’ access to financial services;

125. Calls on the Commission to promote the European Code of Cancer Care Practice launched by the European Cancer Organisation, which is an empowering and

informative tool to ensure that the best available care is provided to European patients;

126. Sees an urgent need for a European charter of the rights of cancer patients; calls for this charter to take the cancer care pathway (i.e. access to prevention, initial diagnosis and throughout their treatment) into account at every stage and for it to apply equally to all EU citizens, regardless of the country or region in which they live;

V. Challenges in cancer among children, adolescents and young adults

127. Welcomes the childhood cancer spotlight initiatives announced by the Commission; calls for clear policy requirements on paediatric cancer research needs; calls on the Member States and the Commission to redress the unequal allocation of investment to paediatric cancers; considers that a clear and specific EU funding stream should be dedicated to paediatric cancer research and treatment and that budget allocations should be earmarked across all relevant EU programmes; highlights the importance of supporting international academic research platforms focusing on paediatric cancers, informed by research performed by other relevant actors;

128. Notes that the current bureaucratic workload of trial activation in Europe is too burdensome for many rare diseases including childhood cancers because investigator-led trials suffer from a lack of commercial sponsorship and many non-commercial organisations are still unwilling to undertake the role of sponsor at a pan-European level for multinational trials in children; calls on the Commission to review the existing legislation, in this regard, and to facilitate multinational trials for children;

129. Calls for the promotion of bone marrow donation in the Member States so that the lives of thousands of people diagnosed with leukaemia can be saved, a number that is constantly increasing and which includes many children, since it is the most common childhood cancer; highlights that bone marrow transplantation is the only hope for many people affected by leukaemia and other blood diseases, and that three out of four patients will not have a compatible family member, so they will need a donor;

130. Calls on the Commission and the Member States to focus on ensuring equal and geographically balanced access to the best specialist diagnostics and multidisciplinary treatments for children with cancer and to improve cancer treatment outcomes in all Member States; considers that the academic specialty and the professional figure of the paediatric oncologist should be recognised in all Member States; believes that every patient who has experienced cancer as a child or adolescent should receive ongoing medical care and monitoring even after reaching adulthood, and therefore calls for measures to make cooperation between paediatric and adult health professionals more flexible; encourages the exchange of knowledge on the course of cancers among children and adolescents;

131. Stresses the need for comprehensive population-based childhood cancer registries based on internationally agreed childhood cancer classification systems, to ensure high-quality comparable data across Europe; reiterates the need for publishing, on at least an annual basis, the number of cancer cases in children and adolescents in the Union and in each Member State;

132. Calls for adolescents and young adults (AYAs) with cancer to be recognised at EU level as a particular group with specific medical and psychosocial needs, and for the creation
of school programmes dedicated to them;

133. Underlines the need to effectively address mental health issues in children and AYA cancer patients and survivors; calls on the Commission and the Member States to ensure equal access to and availability of appropriate psychosocial support measures for this group of patients;

134. Stresses the need to strengthen the right to cross-border care for children and AYA cancer patients when the best treatment is not available in their country of residence, and ensure that access to innovation via clinical trials for relapsed or difficult-to-treat malignancies is covered by the relevant legislation, by enhancing the sustainability of existing cross-border collaborations including the European Reference Networks (ERNs), in particular the ERN on paediatric cancer; emphasises the need for clarification regarding access to cross-border clinical trials, which is not clearly specified in the Cross-Border Healthcare Directive;

135. Notes that both regulations on paediatric\(^76\) and orphan\(^77\) medicinal products have fostered the development and availability of medicines for patients with rare diseases and for children, and have redirected private and public investments towards previously neglected areas; calls for an ambitious revision of the regulations on paediatric and orphan medicinal products in order to ensure the development of and affordable access to innovative cancer drugs, identify the most important drugs to meet the needs of children with poor prognostic cancers, support academic research and SME involvement, reduce delays so that children can have faster access to paediatric drugs and gene and cell therapies, stimulate competition by adapting the regulatory framework and encouraging investments in off-patent orphan and paediatric medicines, and address limited access to certain essential medicines due to drug shortages and the high price of innovative medicines; recommends an increase of 20% in the available new paediatric cancer drugs by 2027, as well as an increase in the accessibility of personalised medicine; considers, consequently, that a clear obligation to include paediatric research should be considered as a condition for an application for funding; calls on the Commission, where appropriate, in dialogue with the Member States, to work on a system that favours access to real breakthrough innovations for paediatric cancer patients; calls on the Commission to facilitate the repurposing of medicines that fail in adults when there is scientific and preclinical rationale, and to provide more effective and tailored incentives to foster the development of medicines for cancer in children and the First-in-Child development of new paediatric anticancer medicines; calls on the Commission to encourage timely paediatric medicine development and reduce delays, such as by means of early proportionate rewards allocated incrementally and not exclusively at the end of the supplementary protection certificate; calls on the Commission to remove Article 11(b) of the Paediatric Regulation in the upcoming review to allow paediatric cancer medicine development to be driven by science and the medicine’s mechanism of action;

136. Calls for the creation of an EU-level advisory group of stakeholders dedicated to childhood and AYA cancers, which would support the goal-driven and coherent implementation of relevant actions across the Plan, Horizon Europe, the Pharmaceutical

\(^{76}\) OJ L 378, 27.12.2006, p. 1 (‘Paediatric Regulation’).

Strategy for Europe and EU4Health Programme;

137. Stresses the importance of implementing and monitoring the European Pillar of Social Rights and calls on the Member States to fully transpose Directive (EU) 2019/1158 of 20 June 2019 on work-life balance for parents and carers\(^78\), which introduces leave for carers and the possibility to request flexible working time arrangements so that workers have the right to carers’ leave of five working days per year in order to provide personal care or support to a relative or to a person who lives in the same household as the worker and who is in need of significant care or support for a serious medical reason, as defined by each Member State;

138. Welcomes the creation of an EU Network of Youth Cancer Survivors announced by the Commission;

139. Supports the recommendation of the JARC for the roll-out of a European unique patient identifier, the Survivorship Passport, and guidelines on long-term surveillance and the transition from paediatric to adult care, in order to ensure the monitoring of long-term outcomes in childhood cancer survivors in a cross-border setting; stresses the need for the right to be forgotten’ to be fit for purpose for this population;

VI. Challenges of rare adult cancers

140. Acknowledges that rare adult cancers are a public health challenge; recalls that patients affected by rare adult cancers share the challenges linked to the rarity and uncommon nature of their disease, including long delays to diagnosis, and sometimes misdiagnosis, and difficulty accessing timely and adequate care and treatments; notes that patients often feel alone and isolated and suffer from a greatly reduced quality of life, and that their carers are also significantly and negatively impacted; calls for the Cancer Inequalities Registry to integrate information on rare cancers, which amount to about 24 % of new cancer cases occurring in all age groups;

141. Supports the introduction of a dedicated flagship initiative on rare adult cancers within the Plan to tackle the specific challenges faced by this patient community and make the best use of the recommendations set out in the Rare Cancer Agenda 2030 to foster research and improve care in each step of the rare cancer patient journey; stresses the importance of ensuring that rare adult cancers are included in all initiatives across the four pillars of the Plan;

142. Calls for dedicated funding for rare adult cancer research projects under Horizon Europe, including under the Mission on Cancer (for instance, under UNCAN.eu – the European Initiative to Understand Cancer), to develop targeted therapies and support the development of databases, registries and biobanks relevant to rare adult cancers;

143. Stresses the difficulty of diagnosing rare adult cancers in a more timely way; recommends, therefore, easier and quicker access to molecular testing that can help patients receive an accurate diagnosis and targeted therapy, and even access to relevant

\(^78\) OJ L 188, 12.7.2019, p. 79.
clinical trials where appropriate; stresses, moreover, that research on biomarkers is critical in this area;

144. Calls for increasing awareness as regards rare adult cancers among primary and secondary healthcare professionals and implementing adequate referrals to specialised multidisciplinary expert centres at both national and European level;

145. Encourages the Member States to establish national networks for rare adult cancers to optimise the referral of patients to specialised centres in a timely fashion and facilitate interactions with ERNs to maximise the exchange of multidisciplinary knowledge and high-quality care, as well as to foster clinical research;

146. Calls for improving access to clinical trials and compassionate use programmes for rare adult cancer patients; regrets that it continues to be very difficult for rare adult cancer patients from many countries to access compassionate use programmes and trials abroad; calls for a better implementation of EU schemes for rare adult cancer patients to access healthcare abroad, and considers that national healthcare systems should facilitate access to trials and compassionate use programmes for patients with rare adult cancers who have few treatment options;

147. Encourages novel regulatory approaches to enable rare adult cancer patients to access new innovative therapies under safe monitoring, while facilitating the collection of real-world data in addition to data collected in clinical trials;

148. Emphasises the need to include rare adult cancers in the ‘inter-specialty cancer training programme’ that also includes specialised nursing training, in conjunction with ERNs for rare adult cancers; emphasises the need to support educational programmes targeting rare adult cancer patients, carers and patient representatives in conjunction with ERNs to increase the level of health literacy and ultimately help patients and their families to make informed choices about treatment options and follow-up care;

149. Acknowledges the specificities of rare adult cancers in programmes dedicated to improving the quality of life of cancer patients, survivors and carers; calls on the Commission and the Member States to implement specific training for professionals other than healthcare providers (e.g. social workers, case managers, etc.), who are taking care of rare adult cancer patients; stresses that rare adult cancer patients need to receive adequate psychological support, rehabilitation and monitoring of long-term side effects of treatments by professionals who understand their rare disease and its specificities; recommends that all patients with rare adult cancers also be provided with a survivorship care plan; considers that carers for rare adult cancer patients (often family members) also need access to specific psychosocial support to cope with the severity and complexity of the disease, and the significant burden of care that they take on;

150. Calls on the Member States to include a specific section on the management of rare adult cancers in their NCCPs (along with a dedicated section on cancers in children) as recommended in the Rare Cancer Agenda 2030; considers that these specificities should be acknowledged in dedicated sections in all NCCPs, including relevant synergies with
rare disease national plans, to foster research and improve care management and care pathways for these patients, from primary care up to highly specialised multidisciplinary healthcare centres that are a part of or in close contact with the relevant ERNs; notes that, to date, many of the Member States’ NCCPs do not sufficiently include rare cancers in adults and paediatric cancers;

151. Urges relevant national authorities to involve rare adult cancer patient organisations as partners in NCCPs to voice the needs and expectations of rare adult cancer patients, and to actively participate in the implementation of dedicated measures for rare adult cancers;

B. Tools for action

I. Holistic research and its implications

152. Stresses that the Plan should be implemented in close cooperation with the Mission on Cancer under Horizon Europe and its objectives of promoting EU investment in cancer research, public production and innovation; welcomes the fact that Horizon Europe will fund research infrastructures, cloud computing and European Innovation Council actions; calls on the Commission to consider paediatric cancer as a topic for a European partnership under Horizon Europe’s next strategic programme; recommends that appropriate funding be given to projects under Horizon Europe dedicated to new paediatric cancer medicines in order to fill the existing gap in paediatric medicines;

153. Recalls that multidisciplinary cancer research, and its translation into everyday clinical practice, is fundamental to ensuring continuous improvements in cancer prevention, diagnosis, treatment and follow-up care for survivors; welcomes, therefore, the launch of Horizon Europe partnerships to translate scientific knowledge into innovations that reach patients; asks the Commission to closely follow the activity of the Horizon Europe partnerships and the translation of research into real added value for current medical practice;

154. Welcomes the Commission’s communication on a new European Research Area for Research and Innovation, which sets out the strategic objectives and actions to be implemented in close cooperation with the Member States; supports the target of investing 3% of EU GDP in research and development which will help to promote research excellence across the EU and enable research results to reach the scientific community, society and the real economy; deplores the significant inequalities in research funding across the EU; calls on the Member States to adopt a pact on research and innovation in Europe that includes the commitment to increase public spending on research and innovation to 1.25% of the GDP by 2030 in a coordinated manner across the EU;

155. Calls on the Member States to promote and ensure attractive scientific careers for researchers in Europe, with a particular focus on women; calls on the Member States to establish a well-structured scientific workforce and infrastructure, and to ensure continuous funding for their research centres; welcomes that the proposed innovative health initiative will help create an EU-wide research and innovation ecosystem, promoting cooperation between the health industry, academia and other stakeholders to translate scientific knowledge into innovations that address prevention, diagnosis, treatment and management of diseases, including cancer;
156. Reiterates its call for sustainable and adequate funding for competitive European research on cancer; stresses that such research should aim to address areas of highly unmet needs and should be conducted across all parts of the cancer care continuum, including for all treatment modalities; calls on the Member States to increase by at least 20% the mobilisation of public research on therapeutic, diagnostic and screening cancer innovations, covering all patient populations concerned; calls, furthermore, for Horizon Europe and national research programmes to support research into paediatric and orphan medicines through innovation prize funds; considers that the conditions for access to public funding should be revised, ensuring transparency of the contracts stipulated between public and private entities as well as conditionalities as regards the accessibility and affordability of new innovations when projects are successful;

157. Supports the recommendation by the Conquering Cancer Mission Board to establish a research programme tasked with identifying effective cancer prevention strategies and methods with regard to commercial determinants of health and exposure to occupational carcinogens79; supports the recommendation for the creation of a Policy Support Facility to enhance knowledge-sharing and support the implementation of cancer-related prevention policies at EU, national and local level;

158. Calls on the Member States and the Commission to establish programmes to provide the necessary support for the recently consolidated European cell-based interceptive medicine community that will create and integrate breakthrough cellular and artificial intelligence technologies to understand early events in cancer and therapy response, and use this knowledge to improve patient outcomes; supports the creation of a platform for cell-based interceptive medicine to coordinate and establish synergies between research, innovation and multi-sectoral activities; stresses the need for investment in research and innovation approaches to create innovative cell-based early detection and personalised treatment strategies for cancer;

159. Stresses the need for independent and multidisciplinary research on cancer ‘from bench to bedside’, that is from the laboratory to applied studies in patients, and also for the regular re-evaluation of the effectiveness of medicines already on the market; stresses the need for the results of this research to be made public in a transparent and simple way; calls for the establishment of measures to limit the health risks posed by disinformation and misinformation, especially on social media, with special attention to measures protecting children and young people; calls for support for science dissemination initiatives;

160. Stresses the importance of investing in the development of non-animal new research methodologies, such as in silico and organoids, in order to shorten preclinical observation periods, increase efficiency in research, and reduce unnecessary and often less reliable experiments on animals; underlines that non-animal methods for testing the carcinogenicity of environmental chemicals, such as testing strategies focused on the underlying biological mechanisms that lead to cancer, should provide more relevant information than the animal-based methods currently in use for chemical safety assessment, thus enabling authorities to take swifter measures to limit exposure to harmful chemicals that could lead to cancer;

161. Calls on the Member States to make a strong commitment to encouraging public-private cooperation, driven by public health needs, and breaking down the barriers to competitiveness across the EU;

162. Considers the significant potential impact of the use of artificial intelligence, ‘big data’ algorithmic analysis and other modern technologies in diagnosis and decision-making for cancers in the coming years; underlines that the combination of real-world data, mathematical modelling, artificial intelligence and digital tools will significantly help to develop innovative treatments in a more cost-efficient way, and potentially reduce the number of patients required for clinical trials and the use of animals in research; encourages the Commission and the Member States to promote the knowledge of cancer biology through the implementation of genomics and informatics infrastructures; urges all implementation partners to be ever mindful of the principles of data privacy and security, trust, transparency, patient centricity and patient involvement at all times;

163. Highlights the crucial importance of clinical research and calls on the Member States to facilitate the conciliation of patient care with research and innovation initiatives, especially in smaller centres, reducing the workload and the ratio of patients per health professional;

164. Calls for research into the potential positive impact of artificial intelligence and modern technologies in cancer diagnosis, monitoring, decision-making and care; welcomes the launch of the Genomics for Public Health project which will give secure access to large amounts of genomic data to be used in P4 medicine (preventive, predictive, personalised and participatory);

165. Supports the creation of new digital resources and platforms, such as the European Cancer Imaging Initiative, and the strengthening of the European Cancer Information System, which will enable competent authorities to make good use of artificial intelligence applied to big data in the years to come; stresses the need for equal and transparent access to the information included in these platforms;

166. Welcomes the launch of the ‘Cancer Diagnostic and Treatment for All’ flagship initiative under the Plan, which aims to improve access to innovative cancer diagnosis and treatment and promote the use of the ‘next generation sequencing’ technology for quick and efficient genetic profiles of tumour cells, allowing researchers and clinicians to share cancer profiles and apply the same or similar diagnostic and therapeutic approaches to patients with comparable cancer profiles; stresses the need to consider personalised treatments based on well-designed clinical trials with proven added therapeutic value for patients;

167. Welcomes the planned Partnership for Personalised Medicine, announced in the Plan and to be funded under Horizon Europe, which will identify priorities for research and education in personalised medicine, support research projects on cancer prevention, diagnosis and treatment, and make recommendations for the roll-out of personalised medicine approaches in daily medical practice; stresses the need to establish a well-defined, globally consistent terminology for personalised medicines that would streamline investment in research and benefit the health literacy of patients; supports the establishment of a roadmap for personalised prevention allowing for the identification of gaps in research and innovation and for the mapping of all known biological anomalies leading to cancer susceptibility, including hereditary and environmental
factors and paediatric issues; calls these solutions to potentially be made accessible through public healthcare systems;

168. Calls for enhanced capacity-building, infrastructure, collaboration and funding of research on non-profit clinical trials to improve treatment strategies, with a focus on the elderly as well as on vulnerable and underrepresented patient populations, including women and children; calls for EU support for the health system and treatment optimisation agenda;

169. Calls on the Commission and the Member States to promote studies dedicated to human and social sciences, in particular those addressing health inequalities at the different stages of cancer diseases, as well as research on optimising the organisation of cancer treatment, the financing of healthcare services and providers, the organisation of the delivery of healthcare services, and the functioning of management institutions; calls for the studies to include inequalities in cancer care that are related to factors such as gender, age and socioeconomic status, with a particular focus on marginalised and vulnerable groups in society;

170. Calls on the Commission and the Member States to support the development of European multicentre clinical trials, in particular in the case of low-incidence cancers and/or cancers with reduced treatment options, and to strengthen multinational cooperation and the conduct of cross-border clinical trials, building on existing structures where appropriate, such as the European Clinical Research Council in the paediatric cancer sector, and to encourage the engagement of smaller countries; highlights, furthermore, the need for all EU cancer policy initiatives to be coordinated towards defined and shared aims;

171. Supports clinical research to evaluate the feasibility, efficacy and cost-effectiveness of non-treatment-related interventions, such as studies on health determinants (including environmental factors) and quality of life;

172. Strongly believes that patients and independent patient associations, as well as parents and carers, should be involved in defining research priorities and endpoints for clinical trials, in order to ensure that the trials address the unmet needs of European patients, including quality of life as the primary endpoint; considers that the final results of the trials should be communicated to the participating patients and to the public; calls for paediatric patients to be involved in the definition of unmet needs to provide input into the design of the clinical trials protocol, improve communication with the target population and enhance methods for the dissemination of findings; stresses that the extent to which transparency provisions within the Clinical Trials Regulation are being met should be kept under surveillance and regularly reported on;

173. Advocates more robust scrutiny of clinical trials and more transparency in the process of research into and the development of cancer treatments, including the establishment of a portal to allow patients access to information on the available clinical trials in Europe; calls for transparency on the access to, and use of, data from clinical trials at EU level, including those that have been abandoned; underlines that this should also include information tailored to children and young patients;

174. Recommends that research be a parameter of the Cancer Inequalities Registry in order to measure and monitor inequalities with respect to access to clinical trials as well as to
better understand and respond to regional and national disparities in trial activity, and to track improvement from initiatives to be taken up via the Plan, such as the EU Network of Comprehensive Cancer Centres;

175. Highlights that gender-associated differences in cancer research should be taken into consideration, both at preclinical and clinical stages, to describe differences in the physiopathology of the disease and related comorbidities, and in drug pharmacokinetics/pharmacodynamics, among others;

176. Applauds the 2021 Porto Declaration on Cancer Research that highlights opportunities for a comprehensive translational cancer research approach with the potential to achieve a ten-year cancer-specific survival for 75% of patients diagnosed in 2030 in Member States with well-developed healthcare systems; urges the Commission to be actively involved and play a leading role in achieving this goal;

177. Welcomes the fact that the Marie Skłodowska-Curie Actions will continue educating and training researchers in cancer prevention, prediction, detection, diagnosis and treatments;

II. Shared knowledge

178. Considers that the sharing of expertise, data, training programmes and communication tools is needed to improve the knowledge of cancer among health professionals, researchers and patients; highlights that cross-sector and cross-border collaboration and knowledge-sharing is crucial for further enhancing the quality of cancer care in the EU; notes that data-sharing is key to applying artificial intelligence and machine learning tools to research provided that there is human oversight, as well as to enable the digital transformation of healthcare, to tackle disparities in cancer prevention, diagnosis, and treatment around Europe and to optimise the use of healthcare systems resources by increasing efficiency and thus allowing for wider availability of oncological care data, including in less urbanised and more remote areas; stresses the sensitive nature of health data; calls for full compliance with Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)\(^80\) to avoid unnecessary restrictions on cross-border healthcare; stresses the need for a harmonised interpretation and implementation of the GDPR, especially by data protection authorities, including its Recitals 33 and 157, and its interaction with the Clinical Trials Regulation, once applicable, including Recital 29 and Article 28 (2) of that regulation, across the EU to facilitate scientific research; requests the European Data Protection Board to ensure that its guidelines concerning health research are updated with the aim of fostering research, and calls on the Commission to make concrete proposals by the end of 2022;

179. Asks the Commission to assess the functioning of the ERNs, especially their role in gathering and sharing expertise and best practices, thus rationalising patient referral in the management of rare cancers, which affect an estimated 5.1 million patients across Europe and require cooperation on a large scale; emphasises the importance of the ERNs with regard to overcoming health inequalities and ensuring safer and high-quality

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treatment across EU borders;

180. Calls on the Commission and the Member States to secure appropriate and sustained long-term funding for the ERNs, and to integrate them into national health systems; calls for the funding to cover, inter alia, compensation of virtual consultations, support for twinning and education programmes, and effective reimbursement of patient travel in line with the Cross-Border Healthcare Directive when this is required, in order to foster improved standards of care and equal access to the best possible interventions to all patients who require them across Europe; calls also for support for the roll-out, upgrade and smooth functioning of digital infrastructure that simplifies and facilitates access to the ERNs, as well as for the creation of an EU health data strategy to improve current rare disease registries in a common and uniform data space; stresses the need to guarantee funding for the continued functioning of the ERNs through the EU4Health Programme, Horizon Europe, the European Semester programme, structural funds, and through Article 195 of the Financial Regulation; supports the expansion of the four existing ERNs (PaedCan on paediatric cancers, EURACAN on rare adult solid cancer, EuroBloodNet on rare haematological diseases including rare haematological malignancies and GENTURIS on genetic tumour risk syndromes) to include rare, complex, poorly curable cancers and paediatric cancers, as this could facilitate equal access for patients, including children and AYA, to the best available care across Europe and would improve the functionality of the ERNs and health outcomes in rare disease patient populations;

181. Believes that the further development and optimisation of the ERNs will require the participation of all Member States in existing ERNs, with each Member State having at least one ‘full’ or ‘affiliate’ member in each ERN and in each sub-clinical domain/thematic network of ERNs, the facilitation of the individual patient journey through the effective collaboration of national contact points with ERNs, the evaluation of the functioning of the ERNs by sharing data on their performance and networking in the field of rare cancers, the deployment of efficient telemedicine tools allowing for the sharing of case records and imaging results in a secured fashion to discuss complex rare cancer cases, and the allocation of adequate and long-term funding, both at Union (EU4Health) and national level;

182. Calls on the Member States to give due consideration to the importance of non-governmental local, regional and national organisations in uniting cancer patients, survivors and their relatives, in terms of their participation in the knowledge-sharing process, in the fight against cancer, in terms of legislative support, and in terms of the provision of separate funding for these organisations, especially those involved in programmes to combat cancer;

183. Encourages Member States to support a dedicated and tailored approach to rare cancers in adults and paediatric cancers, taking stock of EU initiatives, and to fully integrate ERNs into their national healthcare systems; calls for the creation of common and consistent protocols governing the collection of data, and for the creation of a single set of definitions explaining the data collected; calls for rare cancer patient organisations to be associated with the ERNs and the European reference centre;

184. Recalls that the Joint Research Centre has taken an active role in supporting the activities and harnessing the data of cancer registries; considers that the mandate, funding and political support for the Joint Research Centre to continue and accelerate its
coordinating work with cancer registries should be strengthened, particularly in terms of the collection of patient outcomes and real-world evidence and the identification of cancer clusters, and their integration in existing cancer registries;

185. Welcomes the development of a European research infrastructure entirely dedicated to paediatric research, including oncology, that will facilitate basic, preclinical and transnational paediatric research that underpins the availability of clinical trials and medicines for children;

186. Welcomes the launch of the Knowledge Centre on Cancer in 2021 in order to contribute to the exchanges and coordination of scientific and technical initiatives related to cancer at EU level; considers that the knowledge centre should involve all stakeholders (representatives of each NCCP, patients’ and caregivers’ associations, learned societies, relevant EU bodies and agencies, representatives of economic operators, etc.); believes that this knowledge centre should be based on data screening, ERN reports and cancer registries; considers that its mission should be clearly defined and include:

a) coordinating the network of all NCCPs;

b) producing a European roadmap to trigger large-scale prevention campaigns and educational programmes on health promotion;

c) coordinating the establishment of common quality criteria to guide the national accreditation of screening programmes, cancer registries and cancer care centres;

d) developing, on the basis of the latest scientific evidence, clinical practice guidelines and quality assurance schemes to improve the entire care pathway for all cancer types, and in particular for rare and paediatric cancers;

e) drafting annual reports and establishing frameworks to improve data collection from screening programmes, cancer registries and ERNs at EU level;

f) presenting studies on the impact of prevention and diagnosis, including estimates concerning the reduction of economic costs generated through increased investment in prevention and diagnosis;

g) coordinating the exchange of best practices and results between the ERNs and the Comprehensive Cancer Centres;

h) generating a comprehensive model based on the Plan and Horizon Europe, and with input from patients and carers, in order to identify research priorities and possibly enable the development of a coordinated and efficient cancer research force in Europe;

i) facilitating the sharing of anonymised data, collected in a European Cancer Cloud, for clinicians and researchers, as well as for entities developing health services and modern technological solutions for cancer patients;

j) supporting common training programmes for health professionals, patients and caregivers;

k) delivering updated, certified and transparent information to citizens and professionals on cancer causes, treatments and EU legislation;

l) monitoring the level of implementation of relevant recommendations in the Member States’ NCCPs, and regularly making available the results of this monitoring;
m) proposing measurable and reproducible indicators for the main outcomes outlined in the Plan;

187. Recalls that researchers have to work together to find the best possible treatment especially for patients suffering from rare cancer, but that they are facing serious obstacles; calls therefore for the Commission to systematically look, via its scientific advice mechanism or through the appointment of a Special Envoy on cross-border cancer research, at all the obstacles in cross-border cancer research and cooperation, including regulation, in order to promote cross-border cancer research;

188. Recommends the creation of at least one cancer registry in each EU region, including remote and outermost regions; considers it pivotal to ensure the smooth functioning of the cancer registries; supports the strengthening of the capacity of national cancer registries to collect standardised patient-reported outcomes, to better map the lifestyles of EU citizens, including socioeconomic conditions, occupational information, environmental factors, and other data, and to identify the causes of inequalities in cancer incidence, prevalence and survival; stresses the essential need to collect data collaboratively across all Member States; calls for the comparability of data sources and the interoperability of regional and national cancer registries via the harmonisation of the scope and quality of data collection, and for secure access to such data; calls for mandating national cancer registries to analyse disparities in morbidity and to make recommendations to national cancer councils and the Joint Research Centre on the need for interventions; calls for the use of modern epidemiological and molecular genetics methods to analyse the prevalence of cancer and to identify its causes; calls for the implementation of specific cancer registries for paediatric malignancies in line with the International Classification of Childhood Cancer; calls for improved access to clinical trials and compassionate use for rare adult cancer patients;

189. Strongly supports the creation of a Cancer Inequalities Registry at European level, as announced in the Plan, in order to identify trends, disparities, inequalities and inequities between and within Member States; believes that this registry will help to identify challenges and specific areas of action so as to guide investment and intervention, and facilitate research into inequalities, at EU, national and regional level; calls for the Registry to be made accessible to the public; stresses the need for the Registry to also cover social inequalities such as those related to socioeconomic status, occupation and gender;

190. Calls on the Commission to promote the publication of scientific results in open access, to make them easily available to all health professionals and researchers;

191. Supports the Commission’s intention to enable cancer patients to securely access and share electronic health records across borders; considers that the Commission could lay the foundation for the European Health Data Space, in association with Digital Health Europe, by collecting, analysing and exchanging anonymised medical data (from cancer registries, hospitals, academic clinical trials and cohorts) and biological data (from blood and tumour samples) in a European Cancer Cloud; underlines that a harmonised interpretation of the GDPR in all Member States is the foundation for new data-sharing initiatives such as the European Health Data Space; encourages the use of health data for research purposes (data altruism); welcomes the planned creation of a virtual European Cancer Patient Digital Centre under Horizon Europe’s Mission on Cancer in order to support a standardised approach to the participation of willing patients in the
deposit and exchange of their standardised and uniformly defined health data; recommends the inclusion of patients in any actions related to the storage and use of health data for policy-making and research purposes; welcomes the planned expansion of the European Cancer Information System before 2022;

192. Calls for improved standards in the education and training of health professionals; encourages common and multidisciplinary training programmes for health professionals in close collaboration with European learned societies; welcomes the launch of an inter-specialty cancer training programme at every stage of the treatment and care pathway, including diagnosis, treatment, complications and comorbidities, survivorship and end-of-life care;

III. Financing Europe’s Beating Cancer Plan

193. Emphasises that the Plan should not only be seen as a political commitment to driving change but as a set of concrete and ambitious initiatives that will support, coordinate and complement Member States’ efforts to reduce the physical and mental suffering caused by cancer; encourages the Commission to optimise the coherent implementation of the initiatives outlined in the Plan, with clear guidance for Member States regarding concrete actions against unequal access to cancer diagnosis and treatment, as well as adequate funding, especially in order to address unequal access; underlines, however, the differing capacity of Member States to absorb the funds dedicated to healthcare programmes thus far; calls on the Commission to provide Member States with guidance and a clear overview of the dedicated EU resources, the specifically defined pathways that link the actions outlined in the Plan with the EU funding mechanisms identified in it, and the possible synergies and complementarities between the EU4Health Programme and others – such as Digital Europe, Horizon Europe, NextGenerationEU/Recovery and Resilience Facility, structural and cohesion funds – in order to enhance equitable access to quality diagnosis and care, ensure adequate investment in cancer prevention and innovation, and improve the resilience of health systems; emphasises the importance of cohesion funds in achieving equality of access to healthcare, in particular in less developed parts of the EU, including rural regions, by investing in health infrastructure and workforce;

194. Calls on the Member States to ensure that sufficient funds are allocated for the appropriate implementation of the Plan and of their respective NCCPs; considers that no more than 30% of the Plan should be allocated to the implementation of the NCCPs;

195. Welcomes the funding plan of EUR 4 billion and notes the complementarity of the sources of funding as set out in the Plan itself; notes that the proposed budget should be seen as a first step towards the realisation of all actions under the Plan; recalls that the Plan will benefit from different sources of funding, such as the EU4Health, Horizon Europe and Digital Europe programmes, cohesion policy funds, and the Recovery and Resilience Facility; highlights the need to include the fight against cancer across all funding sources in a coherent and transparent manner; stresses, in particular, the importance of enhancing cancer research, innovation and prevention and the need to dedicate more funds to them; stresses the need for regular revision of the proposed budget allocation for the Plan, with a view to potentially increasing it when possible; stresses the need for the mobilisation of these funds by the Member States so that they are in line with the needs identified by each country, and are geared towards benefiting public interest and public health services;
196. Instructs its President to forward this resolution to the Council, the Commission, the European Economic and Social Committee, the European Committee of the Regions, the governments and parliaments of the Member States, and the World Health Organization.
## INFORMATION ON ADOPTION IN COMMITTEE RESPONSIBLE

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| Result of final vote | +: 29  
| | −: 1  
| | 0: 4  |
| Members present for the final vote | Maria Arena, Bartosz Arłukowicz, Sara Cerdas, Angelo Ciocca, Tudor Ciuhodaru, Nathalie Colin-Oesterlé, Antoni Comín i Oliveres, Margarita de la Pisa Carrión, Cyrus Engerer, Pietro Fiocchi, Loucas Fourlas, Cindy Franssen, Søren Gade, Giorgos Georgiou, Nicolás González Casares, Ivars Ijabs, Lívia Járóka, Ondřej Knotek, Kateřina Konečná, Ewa Kopacz, Joanna Kopcińska, Peter Liese, Marian-Jean Marinescu, Joëlle Mélina, Dolors Montserrat, Alessandra Moretti, Manuela Ripa, Michèle Rivasi, Bronis Ropė, Maria Spyra, Nicolae Ţeţeanu, Véronique Trillet-Lenoir, Stefania Zambelli |
| Substitutes present for the final vote | Romana Jerković |
### FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

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**Key to symbols:**
- **+**: in favour
- **-**: against
- **0**: abstention
PART 2.
ACTIVITIES OF THE COMMITTEE
IX. Committee Meetings & Public Hearings
NB. Given the restrictions linked to the COVID-19-pandemic, BECA conducted its work almost exclusively in a virtual setting.

1. Committee’s activities in numbers

- Constitutive meeting on 23.09.2020
- The BECA Committee held:
  - 11 ordinary meetings from October 2020 until December 2021;
  - 10 public hearings from October 2020 until May 2021;
  - 1 joint public hearing with AIDA on 27.05.2021;
  - 1 Interparliamentary Committee Meeting on 27.09.2021
  - BECA organised an online consultation from 04.02.2021 to 11.03.2021
  - BECA Committee organised a mission to Geneva and Lyon from 2 - 4 November 2021

113 high level experts and key stakeholders have shared their expertise and recommendations with BECA Members during 11 public hearings and numerous exchanges of views, including during the BECA mission to Geneva and Lyon. The BECA online consultation on COVID and cancer received 33 contributions representing 360 organisations.

2. List of speakers (Committee meetings/ Public hearings /Mission)

**Public Hearing: “Beating Breast Cancer: Challenges and opportunities”**
Tuesday, 27 October 2020 - 13.45 – 15.45

- Dr Isabel T. RUBIO, President, European Society of Breast Cancer Specialists (EUSOMA)
- Jürgen VANPRAET, Managing Director, Think Pink Europe

**Public Hearing: “Supporting research on cancer - New mission on cancer within Horizon Europe”**
Thursday, 12 November 2020, 16.45 – 18.45

- Walter RICCIARDI, President, Horizon Europe Mission Board for Cancer
- Elisabete WEIDERPASS, Director, International Agency for Research on Cancer (IARC)
- Pamela KEARNS, President SIOP Europe, Clinical Paediatric Oncology at the University of Birmingham
- Freddie BRAY, Leader, International Agency for Research on Cancer, Global Initiative for Cancer Registration development
Public Hearing: “Facilitating a healthy lifestyle: how to reduce cancer related lifestyle risk factors”
Wednesday, 2 December 2020, 9:00 - 12:00,

- Ute MONS, Professor, University of Cologne and German Cancer Research Center (DKFZ)
- Nataliya CHILINGIROVA, Associate Professor, Science and Research Institute, Medical University Pleven
- Carina FERREIRA-BORGES, Programme Manager, Division of NCDs, WHO European Office for Prevention and Control of Noncommunicable Diseases
- Mariann SKAR, Secretary General, European Alcohol Policy Alliance
- João BREDA, Head of Department, WHO European Office for Prevention and Control of Noncommunicable Diseases
- Piotr RUTKOWSKI, Head of Department, Department of Soft Tissue/Bone Sarcoma and Melanoma, Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology
- Daniel KELLY, Co-Chair Royal, College of Nursing, Cardiff University, European Cancer Organisation HPV Action Network
- Joachim SCHÜZ, Head of Section, International Agency for Research on Cancer (IARC)

Public hearing: “Environmental & occupational cancers: understanding their risk factors”
Friday, 11 December 2020, 09:30 - 12:30

- Gunnar JOHANSON, Professor of occupational toxicology and risk assessment Institute of Environmental Medicine, Karolinska Institute
- Maria NEIRA, Director of public health and the environment World Health Organization (WHO)
- Cristina MARTINEZ GONZALEZ, Coordinator for respiratory illnesses of occupational and environmental origin, Spanish Society of Pulmonology and Thoracic Surgery (SEPAR)
- Tim NAWROT, Professor of environmental epidemiology, Hasselt University
- Rémy SLAMA, Senior Investigator, INSERM (French National Institute of Health and Medical Research)

Public Hearing: “Beating cancer - empowering patients and their caregivers”
Monday, 11 January 2021, 13:45 - 16:15 - 16:45 - 18:45

- Jan GEISSLER, Managing Director, “Patvocates”
- Willy PALM, Head of Unit, World Health Organization
- Françoise MEUNIER, Vice-President, Federation of European Academies of Medicines
- Stefan GIJSSELS, Chief Executive Officer, “Digestive Cancers Europe”
- Stanimir HASARDZHIEV, Chairperson & Secretary General, Bulgarian National Patients’ Organisation, Patient Access Partnership (PACT)
- Matti AAPRO, President, European Cancer Organisation
- Katie RIZVI, Co-Founder & Executive Director, Youth Cancer Europe
- Nicòlò BATTISTI, President-Elect, International Society of Geriatric Oncology
- Andreas CHARALAMBOUS, President, European Oncology Nursing Society
- Claire CHAMPEI, Policy and Project Officer, “Eurocarers”

Public Hearing: “Mind the gap: For equal access to cancer medicines and treatments”
Thursday, 28 January 2021, 13:45 - 16:15 - 16:45 - 18:45

- Emer COOKE, Executive Director, European Medicines Agency
- Maciej KRZAKOWSKI, Chairman, Polish National Council for Oncology at the Ministry of Health
- Denis LACOMBE, Director-General, European Organisation for Research and Treatment of Cancer
- Thierry PHILIP, President, Institut Curie, President of the Organisation of European Cancer Institutes
- Ward ROMMEL, Chair, ‘Access to Medicines’ Task Force of the Association of European Cancer Leagues
- Vlad MIXICH, Executive Director, Romanian Health Observatory
- Ruth LADENSTEIN, Board Member, European Society of Paediatric Oncology (SIOPE) and ERN PaedCan Cooperator
- Kateřina KOPEČKOVÁ, Oncologist, Charles University and University Hospital in Motol
- Mark LAWLER, Board Member, European Cancer Organisation
- Kathi APOSTOLIDIS, Board Member, European Cancer Patient Coalition

Thursday, 4 February 2021, 13:45-16:15

- Andreas KUHN, Vice President, RNA Biochemistry & Manufacturing, BioNTech
- Mirjam CRUL, Co-Chair, European Cancer Organisation’s Special Network on the Impact of COVID-19 on Cancer
- Seamus O’REILLY, Professor, Cork University Hospital
- Anna ZORZET, Doctor, ReAct Europe
Public Hearing: “From lab to life: transforming childhood, adolescent and rare cancer care”
Tuesday, 23 February 2021, 13:45 - 16:15 16:45 - 18:15

- Gilles VASSAL, Board Member, European Society of Paediatric Oncology (SIOP Europe)
- Carmelo RIZZARI, President-Elect, European Society of Paediatric Oncology (SIOP Europe)
- Paolo CASALI, Director, Fondazione IRCCS Istituto Nazionale Tumori, European Policy Committee, European Society for Medical Oncology
- Wojciech MLYNARSKI, Board Member, Polish Society of Paediatric Oncology and Haematology
- Eva STELIAROVA-FOUCHER, Scientist, IARC International Agency for Research on Cancer, Section of Cancer Information
- Delphine HEENEN, Committee Member, Childhood Cancer International – Europe and KickCancer
- Andrea FERRARI, Chair, European Society of Paediatric Oncology (SIOP Europe) Adolescents and Young Adult (AYA) Committee
- Patricia BLANC, President, Imagine for Margo, Childhood Cancer International-Europe, Cancer Mission Assembly
- Alicja CHYBICKA, Head of the Department, Clinic of Marrow Transplantation, Oncology and Paediatric Haematology at Medical University of Wrocław
- Lydie MEHEUS, Managing Director, Anticancer Fund

Public Hearing: “Why screening and early detection of cancer matter”
Thursday, 18 March 2021, 13:45 - 15:45 / 16:15 - 18:15

- Rui MEDEIROS, President, Association of European Cancer Leagues
- Josep TABERNERO, Director, Medical Oncology Department at the Vall d’Hebron University Hospital, Vall d’Hebron Institute of Oncology (VHIO), European Society for Medical Oncology (ESMO)
- Mozziyar ETEmADI, Research Assistant, Professor Northwestern University
- Adam MACIEJCZYK, Chair of the Managing Board, Polish Cancer Society
- Carmen UNGUREAN, Cancer screening coordinator, National Institute of Public Health, Romania
- Tanja SPANIC, President Europa Donna, the European Breast Cancer Coalition
- Zorana MARAVIC, Acting CEO Director, Digestive Cancers Europe
- Enriqueta FELIP, Vice-President, Spanish Society of Medical Oncology
- Hendrik VAN POPPEL, Adjunct Secretary General, European Association of Urology
Public Hearing: “Sharing knowledge and data, improving cross-border care to beat cancer”
Thursday, 15 April 2021, 13:45 - 15:45 16:15 - 18:15

- Carmelo RIZZARI, President-Elect, SIOP Europe Clinical Research Council
- Ruth LODENSTEIN, Board Member, European Reference Network on Paediatric Cancer (ERN PaedCan), EU Cancer Mission
- Jean- Yves BLAY, Director, Centre Léon Bérard, cancer centre of Lyon and the Rhône-Alpes region, ERN-EURACAN
- George ASTRAS, Director, American Medical Center and Platonas Medical Center, Cyprus
- Mariana COUTINHO, Youth Cancer Europe Activist, rare cancer survivor
- Krassimira ZAYKOVA, Youth Ambassador, Association of European Cancer Leagues (ECL) - for Bulgaria
- Tit ALBREHT, Senior adviser, WHO Regional office for Europe
- Francis ARICKX, Head of Directorate Reimbursement, National Institute for Health and Disability Insurance

Exchange of Views: “The impact of the COVID-19 pandemic on cancer prevention, health services and cancer patients and research: Lessons from a public health crisis”
Monday, 10 May 2021, 11:15 - 12:00

- Mark LAWLER & Mirjam CRUL, Co-Chairs, European Cancer Organisation Special Network on Impact of COVID-19 on Cancer
- Solange PETERS, President, European Society for Medical Oncology (ESMO)
- Dineke ZEEGERS PAGET, Executive Director, European Public Health Association (EUPHA)
- Amparo ALONSO BETANZOS, President, Spanish Association for Artificial Intelligence, University of Coruña
- Regina BEETS-TAN, Co-Chair, European Cancer Organisation’s Digital Health Network
- Domenico M. D'UGO, President, European Society of Surgical Oncology (ESSO), Catholic University of Rome
- Emilio ALBA CONEJO, Director, Virgen de la Victoria University Hospitals, Málaga
- Artur KOWALIK, Head of the Department, Institute of Biology, Jan Kochanowski University
- Geneviève ALMOUZNI, Research Director, Institut Curie, LifeTime project
Public Hearing: “Unlocking the potential of artificial intelligence in cancer care”
Thursday, 27 May 2021, 13:45 - 15:45   16:15 - 18:15

- Xosé M. FERNANDEZ, Chief Data Officer, Institut Curie
- Jelena MALININA, Digital Health Policy Officer, European Consumer Organisation (BEUC)
- Marilyse Anne CORBEX, Senior Technical Officer, WHO Regional Office for Europe: The rationale behind the NCCPs, NCCPs and the WHO cancer control framework

Exchange of Views with the “World Health Organisation (WHO), the European Commission and Member States on National Cancer Control Programmes (NCCPs)”
Wednesday, 16 June 2021, 09:00 - 12:00

- Tit ALBREHT, Senior adviser, WHO Regional office for Europe
- Thomas DUBOIS, Head of European and International Affairs, French National Cancer Institute
- Marc VAN den BULcke, Head of Service Sciensano, Belgian National Public Health Institute
- Csaba POLGÁR, Director General, Hungarian National Institute of Oncology
- Ondřej MÁJEK, Head of Department, National Screening Centre, Institute of Health Information and Statistics of the Czech Republic
- Matthias SCHUPPE, Team leader, Europe’s Beating Cancer Plan Task Force at European Commission, DG SANTE

Joint debate on:
BECA meeting Thursday, 1 July 2021, 16:15 - 18:45

- a “Pharmaceutical Strategy for Europe [2021/2013(INI)]”;
- the “Proposal for a regulation on health technology assessment [2018/0018(COD)]”;
- the “Aspen case - antitrust investigation into the pricing of certain cancer medicines”

Exchange of views on “serious cross-border threats to health repealing Decision No 1082/2013/EU [2020/0322(COD)]”
BECA meeting Thursday, 1 July 2021, 16:15 - 18:45

- Rainer BECKER, Head of Unit, Antitrust for Pharma and Health Services, DG Competition
- Andrzej Ryś, Director, European Commission, DG SANTE
- John RYAN, Director, European Commission, DG SANTE
Exchange of views on:
Thursday, 9 September 2021, 13:15 - 15:45, BECA meeting

- “Development of a European Health Data Space: health data exchange and digitalisation in cancer prevention and care”
- “Progress in the implementation of the Chemicals Strategy for Sustainability (COM(2020) 667) in the context of cancer prevention”

- Ioana-Maria GLIGOR, Head of Unit, European Commission, DG SANTE
- Ceri THOMPSON, Deputy Head of Unit, eHealth, European Commission, DG CNECT
- Kestutis SADAUSKAS, Director European, Commission, DG ENV

Interparliamentary Committee Meeting on “Turning the tide on cancer: the view of national parliaments on Europe's Beating Cancer Plan”
Monday, 27 September 2021, 09:00 - 12:00,

- Stella KYRIAKIDES, Commissioner for Health and Food Safety
- Iva DIMIC, Chair Sub-committee on Monitoring Cancer in the Republic of Slovenia
- Birgitta SACRÉDEUS, Rapporteur for the opinion on Europe's Beating Cancer Plan, Committee of the Regions
- Małgorzata BOGUSZ, Rapporteur for the opinion on Europe's Beating Cancer Plan, European Economic and Social Committee (EESC)
- John RYAN, Director, European Commission DG SANTE
Mission of the Special Committee on Beating Cancer (BECA) to Geneva (Switzerland) and Lyon (France)
Wednesday, 3 November and Thursday 4 November 2021

- Lotte KNUDSEN Head of the Delegation EU Delegation to the United Nations, Geneva
- Canice NOLAN, Minister Counselor for Health and Food Safety, Delegation of the European Union to the United Nations
- Tedros Adhanom GHEBREYESUS, WHO Director-General
- Zsuzsanna JAKAB, WHO Deputy Director-General
- Hans KLUGE, WHO Regional Director
- Oxana DOMENTI, WHO Representative to the European Union
- Samira ASMA, WHO Assistant Director-General, Data, Analytics and Delivery
- Hanan BALKHY, WHO Assistant Director-General, Antimicrobial resistance (to be confirmed)
- Mariangela SIMÂO, WHO Assistant Director-General, Access to Medicines and Health Products
- Naoko YAMAMOTO, WHO Assistant Director-General, UHC / Healthier Populations
- Princess Nono SIMELELA, WHO Special Adviser to DG on Strategic Programmatic Initiatives
- Bente MIKKELSEN, WHO Director, Department of Noncommunicable Diseases
- André ILBAWI, WHO cancer team lead (acting), Department of Noncommunicable Diseases
- Maria NEIRA Director of the Department of Public Health and Environment
- Ren MINGHUI Assistant Director-General, Universal Health Coverage / Communicable and Noncommunicable Diseases (WHO) Universal Health Coverage / Communicable and Non-communicable Diseases
- Carina FERREIRA-BORGES, WHO Acting Director, Division of NCDs (virtual)
- Marilys CORBEX, WHO Senior technical officer, Department of Noncommunicable Disease
- Patricia LAMAS SANCHEZ, WHO External Relations Officer
- Elisabete WEIDERPASS, Director (virtual) The International Agency for Research on Cancer (IARC)
- Clement CHAUVET Strategic Engagement and Resource Mobilization Specialist The International Agency for Research on Cancer (IARC)
- Freddie BRAY Section Head of the Cancer Surveillance Section The International Agency for Research on Cancer (IARC)
- Joachim SCHÜZ Section Head of Environment and Radiation The International Agency for Research on Cancer (IARC)
3. List of public hearings
Public Hearing “Beating Breast Cancer: Challenges and opportunities”

27 October 2020

Summary:
The first BECA public hearing was organized in association with the Committee on Women’s Rights and Gender Equality (FEMM) in the context of the October Breast Cancer Awareness Month and was part of the programme of the European Gender Equality Week, promoted by FEMM.

Female breast cancer is the most commonly diagnosed cancer. In 2020, around 355,000 women in the 27 member states have been diagnosed with breast cancer. The event represented the opportunity to hear the experts’ contributions on the state of play of the disease concerning research, prevention, detection, shared knowledge and expertise, equal access to treatment and support to patients and caregivers. There is robust evidence that treatment in multidisciplinary units leads to overall cost savings as well as higher quality of care. However, only 55% of EU member states have the required Specialist Breast Centres in place, and only 34% of European countries have a certification/accreditation system, despite European Parliament resolutions, EU guidelines and EUSOMA recommendations.

The “right to be forgotten” (the possibility to take up mortgages, loans or life insurance by cancer survivors without being penalized by their disease) has so far only been enshrined in law in Belgium, France and Luxembourg.

The hearing highlighted the persisting inequalities in and between member states with regards to survival rates for breast cancer, that sometimes amount to up to 30%.

Further reading
- Expert presentations and biographies
- Summary of the hearing
- European Parliament Gender equality Week - video
- Catch up with the hearing

Themes
- main challenges and recommendations to tackle breast cancer.
- how to enhance research and innovation, early detection and screening
- ensure quality of life for patients and their families
- Specialist Breast Centres with dedicated breast specialists working in multidisciplinary teams

Programme of the hearing

Speakers
- Isabel T. RUBIO, President, European Society of Breast Cancer Specialists – EUSOMA
- Jürgen VANPRAET, Managing Director, Think Pink Europe
PUBLIC HEARING

“Beating Breast Cancer: Challenges and opportunities”

Brussels, European Parliament, Room: ANTALL 4Q1
Tuesday 27 October 2020, 13:45-14:30

DRAFT PROGRAMME

13:45 - 13:50 Welcome and opening remarks by Bartosz Arłukowicz, Chair of the Special Committee on Beating Cancer (BECA) and Evelyn Regner, Chair of the Committee on Women’s Rights and Gender Equality (FEMM)

13:50 - 14:00 Presentations by the speakers

➢ Isabel T. RUBIO, President, European Society of Breast Cancer Specialists – EUSOMA
➢ Jürgen VANPRAET, Managing Director, Think Pink Europe

14:00 - 14:25 Q&A session with FEMM and BECA Members

14:25 - 14:30 Conclusions and closing remarks by Bartosz Arłukowicz, Chair of BECA

The hearing can be followed online: https://multimedia.europarl.europa.eu/en/webstreaming
Public Hearing “Supporting research on cancer - New mission on cancer within Horizon Europe”

12 November 2020

THEMES
- Mission on Cancer within Horizon Europe Framework Programme for Research and Innovation
- Cancer research: elevating the standards of cancer care in the EU

Programme of the hearing

SPEAKERS
- Walter Ricciardi, President of the Horizon Europe Mission Board for Cancer
- Elisabete Weiderpass, Director at the International Agency for Research on Cancer
- Pamela Kearns, SIOP Europe President
- Freddie Bray, Section Head of the Cancer Surveillance Section at the International Agency for Research on Cancer

SUMMARY:
During this public hearing, four high-level experts provided the Beating Cancer Committee Members with in-depth information on how to support cancer research in terms of strengthening prevention, diagnosis, treatment and innovation, also with a view to achieving the new Mission on Cancer within Horizon Europe, including financial support. The hearing addressed areas where Member States alone cannot be successful, as in the case of child cancer, rare cancers or research into unknown causes of cancer, which represent 50% of the cases.

Members discussed the issue of occupational cancer, the primary cause of work-related deaths, inequalities in access to treatment and research programmes, the importance of personalized medicines and access to clinical trials for children and adolescents. Members furthermore underlined the importance of establishing a common database in the EU and adequate funding for research.

Supporting cancer research is an integral part of the BECA committee's mandate according to Parliament's decision of 18 June 2020.

FURTHER READING
- Expert presentations and biographies
- Summary of the hearing
- Catch up with the hearing
Special Committee on Beating Cancer

PUBLIC HEARING

“Supporting research on cancer - New mission on cancer within Horizon Europe”

Brussels, European Parliament, Room: ANTALL 4Q1 (TBC)
Thursday 12 November 2020, 16:45-18:45

(remote participation)

PROGRAMME

16:45 - 16:50 Welcome and opening remarks by Bartosz Arłukowicz, BECA Chair

16:50 - 17:10 Mission on Cancer within Horizon Europe Framework Programme for Research and Innovation

- Walter Ricciardi, President of the Horizon Europe Mission Board for Cancer, Professor of Hygiene and Public Health at the “Università Cattolica del Sacro Cuore”, Rome
- Elisabete Weiderpass, Member of the Horizon Europe Mission Board for Cancer and Director at the International Agency for Research on Cancer

17:10 - 17:45 Q&A session with BECA Members

17:45 - 18:05 Cancer research: elevating the standards of cancer care in the EU

- Pamela Kearns, SIOP Europe President, Professor of Clinical Paediatric Oncology at the University of Birmingham
- Freddie Bray, Section Head of the Cancer Surveillance Section at the International Agency for Research on Cancer, leader of the Global Initiative for Cancer Registration development

18:05 - 18:40 Q&A session with BECA Members

18:40 - 18:45 Conclusions and closing remarks by Bartosz Arłukowicz, BECA Chair

The hearing can be followed online: https://multimedia.europarl.europa.eu/en/webstreaming
Public Hearing “Facilitating a healthy lifestyle: how to reduce cancer related lifestyle risk factors”

2 December 2020

THEMES
- Lifestyle risk factors for cancer: Tobacco, alcohol and nutrition
- Prevention of cancer: vaccination and risks of UV exposure

Programme of the hearing

SUMMARY:
During the first hearing on prevention, BECA committee Members looked at the most common causes of cancer related to lifestyle such as tobacco - and alcohol use, nutrition and physical activity, and prevention strategies, and discussed with seven leading specialists in cancer prevention.

40 % of all cancers are preventable in the EU. The EU has competences to regulate products that are risk factors for cancer, such as tobacco products. The EU also regulates for example on air quality and the protection of workers from risks related to exposure to chemicals at work.

During the hearing, it was underlined that cigarettes are a leading cause of cancer and the most dangerous consumer product on the EU market, with lung cancer being the top cause of cancer-related death worldwide in 2018. However, nearly half of European countries make insufficient tobacco control efforts. Europeans are generally not aware of the link between alcohol consumption and cancer: there is no ‘safe’ level of drinking because all levels bring some added risk of cancer. The hearing also addressed the issue of obesity that is becoming a major public health issue.

The number of skin cancer cases has doubled since 2000 with UV radiation undoubtedly being the major cause of skin cancer. More awareness raising is needed about the risks of sun exposure and sunbeds. The last topic of the hearing was HPV that causes about 67,500 cancer cases each year in the EU, even though all HPV-related diseases are preventable through vaccination and screening.

FURTHER READING
- Expert presentations and biographies
- Summary of the hearing
- Background note
- Catch up with the hearing

SPEAKERS
- **Prof. Dr. Ute Mons**, Professor of Cardiovascular Epidemiology of Aging at Heart Centre Cologne, University of Cologne and German Cancer Research Center (DKFZ)
- **Dr. Nataliya Chilingirova**, Associate Professor of Oncology, Science and Research Institute, Medical University Pleven, Bulgaria
- **Dr. Carina Ferreira-Borges**, Programme Manager, Division of NCDs, WHO European Office for Prevention and Control of Noncommunicable Diseases
- **Mariann Skar**, Secretary General, European Alcohol Policy Alliance
- **Dr. João Breda**, Head WHO European Office for Prevention and Control of Noncommunicable Diseases
- **Prof. Piotr Rutkowski**, Professor of Surgical Oncology, Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland.
- **Prof. Daniel Kelly**, Co-Chair of the European Cancer Organisation HPV Action Network
PUBLIC HEARING

“Facilitating a healthy lifestyle: how to reduce cancer related lifestyle risk factors?”

Brussels, European Parliament, József Antall (4Q1) and with remote participation

Wednesday, 2 December, 9:00 - 12:00

DRAFT PROGRAMME

9:00 - 9:05 Welcome and opening remarks by Bartosz Arłukowicz, BECA Chair

9:05 - 9:40 Part 1: Lifestyle risk factors for cancer: Tobacco, alcohol and nutrition

- Speaker 1: Prof. Dr. Ute Mons, Professor of Cardiovascular Epidemiology of Aging at Heart Centre Cologne, University of Cologne and German Cancer Research Center (DKFZ), Germany
- Speaker 2: Dr. Nataliya Chilingirova, Associate Professor of Oncology, Science and Research Institute, Medical University Pleven, Bulgaria
- Speaker 3: Dr. Carina Ferreira-Borges, Programme Manager, Division of NCDs, WHO European Office for Prevention and Control of Noncommunicable Diseases
- Speaker 4: Mariann Skar, Secretary General, European Alcohol Policy Alliance
- Speaker 5: Dr. João Breda, Head WHO European Office for Prevention and Control of Noncommunicable Diseases

9:40 - 11:00 First Q&A session with BECA Members

11:00 - 11:15 Part 2: Prevention of cancer: vaccination and risks of UV exposure

- Speaker 6: Prof. Piotr Rutkowski, Professor of Surgical Oncology, Head of the Department of Soft Tissue/Bone Sarcoma and Melanoma, Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland.
- Speaker 7: Prof. Daniel Kelly, Royal College of Nursing Chair of Nursing Research, Cardiff University, UK and Co-Chair of the European Cancer Organisation HPV Action Network

11:15 - 11:55 Second Q&A session with BECA Members

11:55 - 12:00 Conclusions and closing remarks by Bartosz Arłukowicz, BECA Chair

The hearing can be followed online: https://multimedia.europarl.europa.eu/en/webstreaming
Public Hearing “Environmental and occupational cancers: understanding the factors shown to influence cancer risk”

11 December 2020

THEMES
- Introduction to environmental risk factors for cancer, radiation and occupational exposure to carcinogens
- Exposure to air pollution, chemicals and pesticides

Programme of the hearing

SPEAKERS
- Dr Joachim Schüz, Head of Section, Environment and Radiation at the International Agency for Research on Cancer (IARC)
- Prof Gunnar Johanson, Professor of occupational toxicology and risk assessment at the Institute of Environmental Medicine, Karolinska Institute
- Dr Maria Neira, Director of public health and the environment at the World Health Organization (WHO)
- Dr Cristina Martinez Gonzalez, Coordinator for respiratory illnesses of occupational and environmental origin, Spanish Society of Pulmonology and Thoracic Surgery (SEPAR)
- Prof Dr Tim Nawrot, Professor of environmental epidemiology at Hasselt University
- Dr Rémy Slama, Senior Investigator, INSERM (French National Institute of Health and Medical Research)

SUMMARY:
The second hearing on prevention looked at environmental and occupational risk factors for cancer. The BECA committee heard from seven leading specialists in cancer prevention and representatives from DG SANTE, DG EMPL and DG ENV about the effect the environment can have on everybody’s risk of developing cancer, including radiation, air pollution, exposure to chemicals and pesticides, and being exposed to carcinogens at work. Up to 40 % of all cancer cases are preventable through coordinated actions on individual, social, environmental and commercial health determinants.

The hearing provided for an overview of the environmental risk factors for cancer, including a warning of an epidemic of cancer in Europe, with 100 million new cancer patients predicted over the next 20-25 years. Concerning occupational risk factors it was highlighted that 52% of work-related fatalities can be attributed to cancer and advice was given on Occupational Exposure Limits (OELs).

24% of deaths globally are linked to the environment, and 91% of the global population breathes polluted air that contains known human carcinogens. Lung cancer is the fourth most common cancer, but the first cause of cancer death. A study was cited where black carbon particles were recorded at much higher numbers in the urine of people living near coal-fired plants and heavy traffic roads. Endocrine disruptors were also discussed and the multifactorial and cumulative effects of carcinogens.

FURTHER READING
- Expert presentations and biographies
- Summary of the hearing
- Background note
- Catch up with the hearing
PUBLIC HEARING

“Environmental and occupational cancers: understanding the factors shown to influence cancer risk”

Brussels, European Parliament, Room: ANTALL 2Q2
11 December 2020, 09:30-12:30

DRAFT PROGRAMME

09:30 - 09:35 Welcome and opening remarks by Bartosz Arłukowicz, BECA Chair

09:35 - 09:55 Part 1: Introduction to environmental risk factors for cancer, radiation and occupational exposure to carcinogens

- Speaker 1: Dr Joachim Schüz, Head of Section, Environment and Radiation at the International Agency for Research on Cancer (IARC)
- Speaker 2: Prof Gunnar Johanson, Professor of occupational toxicology and risk assessment at the Institute of Environmental Medicine, Karolinska Institute

09:55 - 11:00 First Q&A session with BECA Members

11:00 - 11:30 Part 2: Exposure to air pollution, chemicals and pesticides

- Speaker 3: Dr Maria Neira, Director of public health and the environment at the World Health Organization (WHO)
- Speaker 4: Dr Cristina Martinez Gonzalez, Coordinator for respiratory illnesses of occupational and environmental origin, Spanish Society of Pulmonology and Thoracic Surgery (SEPAR)
- Speaker 5: Prof Dr Tim Nawrot, Professor of environmental epidemiology at Hasselt University
- Speaker 6: Dr Rémy Slama, Senior Investigator, INSERM (French National Institute of Health and Medical Research)

11:30 - 12:25 Second Q&A session with BECA Members

12:25 - 12:30 Conclusions and closing remarks by Bartosz Arłukowicz, BECA Chair

The hearing can be followed online: https://multimedia.europarl.europa.eu/en/webstreaming
Public Hearing “Beating cancer – empowering patients and their caregivers”

11 January 2021

SUMMARY:
During this public hearing, ten high-level experts addressed patients’ rights, including the “Right to be forgotten”, as well as patient-centred healthcare systems. Despite the existence of different patient codes and guidelines, there are still important gaps in the definition of patients’ rights and their implementation within and between Member States. To tackle those problems, speakers suggested namely to promote a pan-European cooperation of healthcare systems, address inequalities between Member States (including within the Cross-Border Healthcare Directive), as well as synergise European initiatives such as the upcoming “Europe’s Beating Cancer Plan”, the EU Cancer Mission within Horizon Europe, and the existing European Reference Networks. There are more than 14 mn cancer survivors in the EU nowadays and they are facing challenges such as the psychological impact of their treatments, workplace marginalisation and limited access to financial services. It is, at least, encouraging that legislation on the “Right to be Forgotten” has been adopted in a few Members States. Experts insisted that patient organisations are able to offer a “Total Patient Support”, advising hospitals which hospitals can offer the best treatment and assisting them throughout their pathway. The BECA rapporteur stressed the urgency of setting up a European Charter for cancer patients. Experts also addressed the issues of survivorship and quality of life, as well as the challenging situation of caregivers. They focused on integrated supportive and palliative care, survivorship and rehabilitation, as well as reintegration. Experts addressed the urgent need to support caregivers, provide them with access to training and officially recognise their skills.

FURTHER READING
- Expert presentations and biographies
- Summary of the hearing
- Background note
- Catch up with the hearing - part 1
- Catch up with the hearing - part 2

THEMES
- Patients’ Rights, including the right to be forgotten, as well as patient-centred healthcare systems
- Survivorship, Quality of Life and Caregivers

Programme of the hearing

SPEAKERS
- **Prof. Françoise Meunier**, Vice-President of the Federation of European Academies of Medicines
- **Stefan Gijssels**, Chief Executive Officer of “Digestive Cancers Europe”
- **Dr Stanimir Hasardzhiev**, Chairperson of the Bulgarian National Patients’ Organisation, Secretary General of the Patient Access Partnership (PACT)
- **Dr Matti Aapro**, President of the European Cancer Organisation
- **Katie Rizvi**, Co-Founder & Executive Director, Youth Cancer Europe
- **Dr Nicolò Battisti**, Medical oncologist, President-Elect of the International Society of Geriatric Oncology
- **Prof. Andreas Charalambous**, President of the European Oncology Nursing Society
- **Claire Champeix**, Policy and Project Officer at “Eurocarers”
**Special Committee on Beating Cancer**

**PUBLIC HEARING**

“Beating cancer – empowering patients and their caregivers"

Brussels, European Parliament, Room: József ANTALL 4Q1
11 January 2021, 13:45 to 16:15 & 16:45 to 18:45

**DRAFT PROGRAMME**

13:45 - 13:50 Welcome and opening remarks by Bartosz Arłukowicz, BECA Chair

Part 1: Patient Rights, including the right to be forgotten, as well as patient-centred healthcare systems

13:50 - 14:40 Presentations by:
- Dr. Jan Geissler, founder and managing director of “Patvocates”
- Dr. Stanimir Hasardzhiev, founder and Chairperson of the Bulgarian National Patients’ Organization
- Prof. Françoise Meunier, Vice-President of the Federation of European Academies of Medicines
- Willy Palm, Unit Head, Regional Governance and Languages at World Health Organization
- Stefan Gijssels, Chief Executive Officer of “Digestive Cancers Europe”

14:40 - 16:15 First Q&A session with BECA Members

16:15 - 16:45 Break

Part 2: Survivorship, Quality of Life and Caregivers

16:45 - 17:30 Presentations by:
- Dr Matti Aapro, President of the European Cancer Organisation
- Katie Rizvi, Co-Founder & Executive Director, Youth Cancer Europe
- Prof. Andreas Charalambous, President of the European Oncology Nursing Society
- Claire Champeix, Policy and Project Officer at “Eurocarers”
- Dr Niccolò Battisti, Medical oncologist, President-Elect of the International Society of Geriatric Oncology

17:30 - 18:40 Second Q&A session with BECA Members

18:40 - 18:45 Conclusions and closing remarks by Bartosz Arłukowicz, BECA Chair

*Note: Representatives of the European Commission will intervene to respond to Members’ questions.*

Public Hearing “Mind the gap: For equal access to cancer medicines and treatments"

28 January 2021

THEMES

- Research and innovation, cancer drug development, multidisciplinary cancer care and authorisation
- Pricing and affordability of cancer treatment
- Rare cancers and paediatric cancers: access to treatments and clinical trials
- Social determinants in accessing cancer care

Programme of the hearing

SUMMARY:

The hearing took a holistic view on the entire cancer continuum, from the development of drugs and other treatment to the delivery of preventive care and treatment, and assessed possible problems hampering access to cancer care. Leading experts and the representative of the Commission discussed with BECA Members the current situation, the geographical and social divide in accessing cancer care, and possible solutions.

Surgery, radiotherapy and chemotherapy are the most common treatments; and for certain types of cancers or as complementary treatment, other therapies are possible, e.g. hormone therapy, interventional radiology. After successful treatment, the patient may need rehabilitation and specialised care; and when the treatment cannot cure the disease, supportive and palliative care are essential, helping to maintain the highest possible quality of life. Paediatric and rare cancers, which, due to their small patient population, face specific challenges. On the patients’ side it is translated into the difficulty to access timely and accurate diagnosis, highly specialised care and adequate treatments; and on the side of the health care system, it manifests in poor research opportunities, difficulties in clinical trials and lack of therapies. Delivering quality cancer care requires infrastructure, equipment and medicines, trained and specialised oncology workforce, and an appropriate cancer budget. The share of direct cancer costs within the overall health budget is around 4-7% across Europe; the direct costs of cancer per capita differ greatly between countries, and a clear social divide in accessing cancer care can also be observed.

FURTHER READING

- Expert presentations and biographies
- Summary of the hearing
- Background note
- Catch up with the hearing - part 1
- Catch up with the hearing - part 2

SPEAKERS

- Emer COOKE, Executive Director of the European Medicines Agency
- Prof. Maciej KRZAKOWSKI, Chairman of the Polish National Council for Oncology at the Ministry of Health
- Dr Denis LACOMBE, Director-General of the European Organisation for Research and Treatment of Cancer
- Prof. Thierry PHILIP, President of Institut Curie, President of the Organisation of European Cancer Institutes
- Dr Ward ROMMEL, Chair of the ‘Access to Medicines’ Task Force of the Association of European Cancer Leagues
- Dr Vlad MIXICH, Executive Director of the Romanian Health Observatory
- Prof. Ruth LADENSTEIN, Board Member of the European Society of Paediatric Oncology (SIOPE), and ERN PaedCan Coordinator
- Dr Kateřina KOPEČKOVÁ, Oncologist at Charles University and University Hospital in Motol
- Prof. Mark LAWLER, European Cancer Organisation Board Member
- Kathi APOSTOLIDIS, Board Member of the European Cancer Patient Coalition
**DRAFT PROGRAMME**

<table>
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<th>Time</th>
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<tr>
<td>13:45 - 13:50</td>
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| 13:50 - 14:20 | Panel 1: Research and innovation, cancer drug development, multidisciplinarity of cancer care and authorisation  
|              | - Emer COOKE, Executive Director of the European Medicines Agency                          |
|              | - Prof. Maciej KRZAKOWSKI, Chairman of the Polish National Council for Oncology at the Ministry of Health |
|              | - Dr Denis LACOMBE, Director-General of the European Organisation for Research and Treatment of Cancer |
| 14:20 - 14:50 | Q&A session with BECA Members                                                              |
| 14:50 - 15:20 | Panel 2: Pricing and affordability of cancer treatment                                     |
|              | - Prof. Thierry PHILIP, President of Institut Curie, President of the Organisation of European Cancer Institutes |
|              | - Dr Ward ROMMEL, Chair of the ‘Access to Medicines’ Task Force of the Association of European Cancer Leagues |
|              | - Dr Vlad MIXICH, Executive Director of the Romanian Health Observatory                    |
| 15:20 - 15:50 | Q&A session with BECA Members                                                              |
| 15:50 - 16:05 | European Commission, DG SANTE (representative tbc)                                         |
| 16:05 - 16:15 | Véronique TRILLET-LENOIR, Rapporteur                                                      |
| 16:45 - 17:05 | Panel 3: Rare cancers and paediatric cancers: access to treatments and clinical trials     |
|              | - Prof. Ruth LADENSTEIN, Board Member of the European Society of Paediatric Oncology (SIOPE), and ERN PaedCan Coordinator |
|              | - Dr Kateřina KOPEČKOVÁ, Oncologist at Charles University and University Hospital in Motol |
| 17:05 - 17:30 | Q&A session with BECA Members                                                              |
| 17:30 - 17:50 | Panel 4: Social determinants in accessing cancer care                                      |
|              | - Prof. Mark LAWLER, European Cancer Organisation Board Member                            |
|              | - Kathi APOSTOLIDIS, Board Member of the European Cancer Patient Coalition                  |
| 17:50 - 18:15 | Q&A session with BECA Members                                                              |
| 18:15 - 18:30 | European Commission, DG SANTE (representative tbc)                                         |
| 18:30 - 18:40 | Véronique TRILLET-LENOIR, Rapporteur                                                      |
| 18:40 - 18:45 | Conclusions and closing remarks by Bartosz ARŁUKOWICZ, BECA Chair                         |


4 February 2021

THEMES

- RNA technology: Could the technology behind some COVID-19 vaccines be used against cancer?
- Experiences on the ground: diagnosing and treating cancer through the COVID-19 pandemic
- A growing concern for cancer: antimicrobial resistance

Programme of the hearing

SPEAKERS

- Dr Andreas Kuhn, Vice President RNA Biochemistry & Manufacturing, BioNTech
- Dr Mirjam Crul, Co-Chair, European Cancer Organisation’s Special Network on the Impact of COVID-19 on Cancer
- Professor Seamus O’Reilly, Cork University Hospital
- Dr Anna Zorzet, ReAct Europe

SUMMARY:

The hearing focused on the impact of health threats on cancer, with experts discussing three main areas. Cancer patients are at increased risk of developing severe cases of COVID-19 and dying from the infection. Cancer patients have also experienced missed or delayed diagnosis or treatment, because of the burden COVID-19 has placed on healthcare systems. Finally, the diversion of resources into fighting the pandemic has meant that cancer research and charitable organisations in many cases have faced severe cuts. The hearing explored these issues, together with other health threats, such as antimicrobial resistance, which have a huge effect on cancer patients.

Firstly, the hearing considered the potential use of mRNA technologies in the fight against cancer. Research and development of mRNA therapeutics, including vaccines, has been ongoing for two decades. The recent success of two mRNA vaccines for the use against COVID19 has proven the technology can be a reality, and has raised the potential of such medicines in the use against cancer. Recommendations to accelerate the speed of development and roll-out of mRNA therapeutics were made. Next, experts highlighted the devastating impact of cancer medicine shortages, particularly during the current pandemic, as well as the reduction in cancer screening and diagnosis. Due to missed screening and diagnosis, the number of cancer diagnoses in years to follow is likely to be higher. Speakers proposed mechanisms to resolve medicines shortages, for example by encouraging European cooperation to address regional shortages across the Union. The implementation of incentive mechanisms to encourage work on antimicrobial resistance was recommended.

FURTHER READING

- Expert presentations and biographies
- Summary of the hearing
- Background note
- Catch up with the hearing
PUBLIC HEARING

“World cancer day: the impact of COVID19 and other health threats on cancer"

Brussels, European Parliament, Room: Paul-Henry Spaak (3C050)
and with remote participation

Thursday, 4 February 2021, 13:45-16:15

DRAFT PROGRAMME

13:45 - 13:50 Welcome and opening remarks by Bartosz Arłukowicz, BECA Chair

13:50 - 14:00 RNA technology: Could the technology behind some COVID19 vaccines be used against cancer?
- Dr Andreas KUHN, Vice President RNA Biochemistry & Manufacturing, BioNTech

14:00 - 14:30 Q&A session with BECA Members

14:30 - 14:50 Experiences on the ground: diagnosing and treating cancer through the COVID19 pandemic
- Dr Mirjam CRUL, Co-Chair, European Cancer Organisation’s Special Network on the Impact of COVID-19 on Cancer
- Professor Seamus O’REILLY, Cork University Hospital

14:50 - 15:30 Q&A session with BECA Members

15:30 - 15:40 A growing concern for cancer: antimicrobial resistance
- Dr Anna ZORZET, ReAct Europe

15:40 - 16:05 Q&A session with BECA Members

16:05 - 16:10 Comments from Véronique Trillet-Lenoir, BECA rapporteur

16:10 - 16:15 Conclusions and closing remarks by Bartosz Arłukowicz, BECA Chair

The hearing can be followed online: https://multimedia.europarl.europa.eu/en/webstreaming
Public Hearing “From lab to life: transforming childhood, adolescent and rare cancer care"

23 February 2021

THEMES

- Research, treatment and care of paediatric, adolescent and rare cancer”,
- Rights and needs of rare cancer and paediatric cancer patients, survivors, parents and caregivers

Programme of the hearing

SUMMARY:

Every year, 35,000 children & adolescents are diagnosed with cancer in Europe. 6,000 of them die.

The discussion focused among others on the following issues:

- Difference (up to 20%) in survival rates across EU for children and adolescents with cancer
- More than 80% of paediatric patients with cancer are cured, but big inequalities in access to specialist services exist including radiotherapy, surgery, high dose chemotherapy and to essential medicines
- Affordability and availability of medicines, on/off label drugs for paediatric use
- Lack of development of innovative anti-cancer medicines and treatments for rare and paediatric cancers compared to adult oncology
- The specific challenges related to adolescents and young adults (AYA) with cancer
- Lack of access to clinical trials for children, adolescents and young adults with cancer

The following solutions were proposed, among others:

- Revise the Paediatric and Orphan Regulations;
- Explore new business models to accelerate innovation in paediatric oncology therapeutics;
- Increase access to high quality care and treatment through the European Reference network PaedCan;
- Improve quality of life for paediatric cancer survivors by using a survivor passport, active screening for chronic complications, facilitate transition from paediatric to adult care
- Improve availability, quality and quantity of data
- European Network for Teenagers and Young Adults with Cancer (ENTYAC)

FURTHER READING

- Expert presentations and biographies
- Summary of the hearing
- Background note
- Catch up with the hearing - Part 1, Part 2
PUBLIC HEARING

“From lab to life: transforming childhood, adolescent and rare cancer care”

Brussels, European Parliament, József Antall (6Q2) and with remote participation
Tuesday, 23 February 2021, 13:45 - 16:15 and 16:45 - 18:15

DRAFT PROGRAMME

13:45 - 13:50 Welcome and opening remarks by Bartosz ARŁUKOWICZ, BECA Chair
13:50 - 13:55 Ewa KOPACZ, Vice-President of the European Parliament and Coordinator on Children’s Rights
13:55 - 14:40 Panel 1: Research, treatment and care of paediatric, adolescent and rare cancer
- Prof. Gilles VASSAL, Board Member of the European Society of Paediatric Oncology (SIOP Europe), Chair of ACCELERATE and Director of Innovative Therapies for Children with Cancer in Europe (ITCC), Head of Paediatric Medico-Scientific Research Programme, Institut Gustave Roussy, France
- Prof. Carmelo RIZZARI, President-Elect of the European Society of Paediatric Oncology (SIOP Europe), Head, Pediatric Hematology Oncology Unit, MBBM Foundation, ASST Monza, University of Milano-Bicocca
- Prof. Paolo CASALI, Director at Fondazione IRCCS Istituto Nazionale Tumori, Milano, Chair of Rare Cancers Europe, Chair of European Policy Committee, European Society for Medical Oncology
- Prof. Wojciech MŁYNARSKI, Board Member of the Polish Society of Paediatric Oncology and Haematology
- Dr Eva STELIAROVA-FOUCHER, Scientist at IARC International Agency for Research on Cancer, Section of Cancer Information

14:40 - 16:05 Q&A session with BECA Members
16:05 - 16:10 Barbara KERSTIENS, European Commission, DG Research and Innovation
16:10 - 16:15 Véronique TRILLET-LENOIR, Rapporteur

16:45 - 17:30 Panel 2: Rights and needs of rare cancer and paediatric cancer patients, survivors, parents and caregivers
- Delphine HEENEN, Committee Member at Childhood Cancer International – Europe and Managing Director of KickCancer
- Dr Andrea FERRARI, Chair of the European Society of Paediatric Oncology (SIOP Europe) Adolescents and Young Adult (AYA) Committee
- Patricia BLANC, President of Imagine for Margo, Member of Childhood Cancer International-Europe, Member of the Cancer Mission Assembly
- Prof. Alicja CHYBICKA, Head of the Department and Clinic of Marrow Transplantation, Oncology and Paediatric Haematology at Medical University of Wrocław
- Dr Lydie MEHEUS, Managing Director of the Anticancer Fund

17:30 - 18:05 Q&A session with BECA Members
18:05 - 18:10 Matthias SCHUPPE, European Commission, Cancer Task Force, DG SANTE
18:10 - 18:15 Conclusions and closing remarks by Bartosz ARŁUKOWICZ, BECA Chair
Public Hearing “Why screening and early detection of cancer matter”

18 March 2021

THEMES
- The importance of screening and early diagnostics, and the role of the cancer registries
- The role of big data and modern technology
- Screening programmes for specific cancers: extending targeted cancer screening?

Programme of the hearing

SUMMARY:
The hearing addressed screening and early diagnosis of cancer (together referred to as early detection of cancer) from a holistic point of view.
The first panel focused on the rationale behind early detection, both as a secondary prevention method, and as a tool allowing for prolonging patients’ survival and quality of life. It also dealt with cancer registries, and the use of data for formulating evidence-based cancer strategies and health policies.

The second panel looked into the use of modern technologies, artificial intelligence and big data for cancer diagnosis; the possibility to integrate it into the clinical workflow; and its potential to expand it in the future to the diagnosis of other diseases as well. The limitations such as AI’s dependence on the quality of data and on human factors like the design of the learning programme were also mentioned.

The third panel looked into those cancers for which population-based screening programmes are rolled out as per the 2003 Council recommendation, i.e. cervical, colorectal and female breast cancers, and the management and efficiency of those screening programmes. The panel also discussed the possibility of broadening the scope of the Council recommendation, and expanding screening programmes to gastric, lung and prostate cancers.

FURTHER READING
- Expert presentations and biographies
- Summary of the hearing
- Background note
- Catch up with the hearing - part 1
- Catch up with the hearing - part 2
PUBLIC HEARING

“Saving lives and improving patient outcomes:
Why screening and early detection of cancer matter”

Brussels, European Parliament, Paul-Henri Spaak 3C50 and remote participation
Thursday, 18 March 2021, 13:45-15:45 and 16:15-18:15

DRAFT PROGRAMME

13:45 - 13:50 Welcome and opening remarks by Bartosz ARLUKOWICZ, BECA Chair
13:50 - 14:10 Panel 1: The importance of screening and early diagnostics, and the role of the cancer registries
   - Rui MEDEIROS, President of the Association of European Cancer Leagues
   - Josep TABERNERO, Head of the Medical Oncology Department at the Vall d’Hebron University Hospital, and Director of the Vall d’Hebron Institute of Oncology (VHIO); Executive Board Member and Past-President of the European Society for Medical Oncology (ESMO)
14:10 - 14:35 Q&A session with BECA Members
14:35 - 14:40 European Commission, Ciarán NICHOLL, Head of the Health in Society Unit, Joint Research Centre
14:40 - 15:00 Panel 2: The role of big data and modern technology
   - Mozziyar ETEMADI, Research Assistant Professor, Northwestern University
   - Adam MACIEJCZYK, Chair of the Managing Board of the Polish Cancer Society
15:00 - 15:35 Q&A session with BECA Members
15:35 - 15:40 European Commission, Ioana-Maria GLIGOR, Head of Digital Health, European Reference Networks, DG SANTE
15:40 - 16:15 Conclusions by Véronique TRILLET-LENOIR, Rapporteur

16:15 - 17:05 Panel 3: Screening programmes for specific cancers: extending targeted cancer screening?
   - Cervical cancer screening: Carmen UNGUREAN, Cancer screening coordinator at the National Institute of Public Health, Romania
   - Breast cancer screening: Tanja SPANIC, President of Europa Donna, the European Breast Cancer Coalition
   - Colorectal and gastric cancer screening: Zorana MARAVIC, Acting CEO Director of Digestive Cancers Europe
   - Lung cancer screening: Enriqueta FELIP, Head of the Medical Oncology Service of the Thoracic Tumors Committee at Vall d’Hebron Hospital, Vice-President of the Spanish Society of Medical Oncology
   - Prostate cancer screening: Hendrik VAN POPPEL, Adjunct Secretary General, European Association of Urology
17:05 - 18:00 Q&A session with BECA Members
18:00 - 18:05 European Commission, Matthias SCHUPPE, Project Leader – Cancer Task Force, DG SANTE
18:05 - 18:10 Conclusions by Véronique TRILLET-LENOIR, Rapporteur
18:10 - 18:15 Closing remarks by Bartosz ARLUKOWICZ, BECA Chair

The hearing can be followed online: https://multimedia.europarl.europa.eu/en/webstreaming
Public Hearing “Sharing knowledge and data, improving cross-border care to beat cancer”

15 April 2021

THEMES
- European Reference Networks - promoting shared expertise
- Shared data & Cancer registries
- Shared training & Shared communication
- How to improve the Cross-Border Healthcare Directive

Programme of the hearing

SUMMARY:
Although public health remains the competence of Member States, there are benefits to be harnessed through the sharing of knowledge and expertise regarding cancer care at a European level. The hearing first considered the implementation of European Reference Networks, that enhance the EU’s ability to address inequalities in paediatric cancer care and survival rates across Member States. Members raised concerns regarding the cost and administrative burden of receiving cross-border treatment. Through the evaluation of the cross-border health care directive, the Commission aims to eliminate challenges arising in this regard. Next, the importance of data sharing in reducing inequalities in care and improving treatment outcomes was considered. In addition to implementing and expanding cancer registries in all Member States, developing uniform guidelines and training is crucial, to ensure that the data regarding cancer incidence, prevalence, mortality and survival available is effectively harnessed. Particularly for rare cancers, this would improve diagnosis and treatment of patients. Another area of focus was enhancing awareness, for patients and health care professionals, of the existing cross-border care services that are available. The Commission highlighted that training programmes on cross-border collaboration are included in Europe’s Beating Cancer Plan. Finally, challenges regarding the follow-up of patients who receive cross-border care were discussed, as well as ensuring the inclusion of smaller Member States in all initiatives. Overall, the hearing emphasised that the interoperability of healthcare systems can be improved and possibilities for patients to receive health care in other Member States when necessary can be expanded.

FURTHER READING
- Expert presentations and biographies
- Summary of the hearing
- Background note
- Catch up with the hearing - part 1
- Catch up with the hearing - part 2
Special Committee on Beating Cancer

PUBLIC HEARING

“Cooperation is strength: sharing knowledge and data, improving cross-border care to beat cancer”.

Brussels, European Parliament, Paul-Henri Spaak 1A002 and remote participation

Thursday, 15 April 2021, 13:45-15:45 and 16:15-18:15

DRAFT PROGRAMME

13:45 - 13:50 Welcome and opening remarks by Bartosz ARŁUKOWICZ, BECA Chair

13:50 - 14:10 Panel 1: European Reference Networks - promoting shared expertise
- Carmelo RIZZARI, President-Elect of SIOP Europe Board, Co-Chair of the SIOP Europe Clinical Research Council
- Ruth LADENSTEIN, Project Coordinator of European Reference Network on Paediatric Cancer (ERN PaedCan), EU Cancer Mission Board Member

14:10 - 14:40 Q&A session with BECA Members

14:40 - 14:45 European Commission - Martin DORAZIL, DG SANTE

14:45 - 15:05 Panel 2: Shared data & Cancer registries
- Jean-Yves BLAY, Director of Centre Léon Bérard, comprehensive cancer centre of Lyon and the Rhône-Alpes region, Director of the ERN-EURACAN, corresponding member of the French Academy of Medicine
- George ASTRAS, Director of Medical Oncology at the American Medical Center and Platonas Medical Center, Cyprus

15:05 - 15:35 Q&A session with BECA Members

15:35 - 15:40 European Commission - Ciarán NICHOLL, Joint Research Centre

15:40 - 15:45 Conclusions by Véronique TRILLET-LENOIR, Rapporteur

16:15 - 16:35 Panel 3: Shared training & Shared communication
- Mariana COUTINHO, Activist from Youth Cancer Europe, rare cancer survivor
- Krassimira ZAYKOVA, Association of European Cancer Leagues (ECL) - Youth Ambassador for Bulgaria

16:35 - 17:05 Q&A session with BECA Members

17:05 - 17:10 European Commission - Matthias SCHUPPE, DG SANTE

17:10 - 17:30 Panel 4: How to improve the Cross-Border Healthcare Directive
- Tit ALBREHT, National Institute of Public Health of Slovenia, Senior adviser to WHO Regional office for Europe
- Francis ARICKX, Head of Directorate Reimbursement of Medicines and Pharmaceutical Policy at the National Institute for Health and Disability Insurance, Belgium

17:30 - 18:00 Q&A session with BECA Members

18:00 - 18:05 European Commission - Caroline HAGER, DG SANTE

18:05 - 18:10 Conclusions by Véronique TRILLET-LENOIR, Rapporteur

18:10 - 18:15 Closing remarks by Bartosz ARŁUKOWICZ, BECA Chair

10 May 2021

THEMES

- COVID-19-induced backlog in screening, diagnosis and treatment of cancer patients, throughout Europe
- How to tackle the current and future effects of the COVID-19 pandemic

Programme of the hearing

SPEAKERS

- Mark LAWLER and Mirjam CRUL, Co-Chairs of the European Cancer Organisation Special Network on Impact of COVID-19 on Cancer
- Solange PETERS, President, European Society for Medical Oncology (ESMO)
- Dineke ZEEGERS PAGET, Executive Director, European Public Health Association (EUPHA)

SUMMARY:

During this exchange of views on the BECA Public Consultation Synopsis Report on the impact of the COVID-19 pandemic on cancer care, representatives from the European Cancer Organisation (ECO), the European Society for Medical Oncology (ESMO) and the European Public Health Association (EUPHA) shared their insights. The pandemic resulting in a significant backlog in screening, diagnosis and treatment of cancer patients, throughout Europe. As a result, the cancer burden on health systems in the next years is likely to be higher than before the pandemic. Therefore, Members highlighted the need for clear communication between patients, health care professionals and authorities, and for real time data on backlogs in cancer care. The important role of the Inequalities Registry and European Health Data Space in this regard was emphasised.

A recent E.C.O. study found a significant decrease in newly diagnosed cancer patients and cancer-screening tests due to the COVID-19 pandemic, resulting in backlogs. Speakers called for a multipronged approach to tackle the current and future effects of the COVID-19 pandemic, inter alia: vaccinating patients highest at-risk against COVID-19, re-start prevention programmes, rebuild and modernize cancer services, invest in the cancer workforce and in more resilient and equal health systems.

FURTHER READING

- Expert presentations and biographies
- Press release: COVID-19 lessons learned: impact of the pandemic on cancer care
- Public Consultation Synopsis Report - The impact of the COVID-19 pandemic on cancer prevention, health services, cancer patients and research: lessons from a public health crisis
- Catch up with the hearing
EXCHANGE OF VIEWS

“The impact of the COVID-19 pandemic on cancer prevention, health services and cancer patients and research:
Lessons from a public health crisis”

Brussels, European Parliament, József Antall (6Q2) and remote participation

Monday, 10 May 2021, 11:15 - 12:00

DRAFT PROGRAMME

11:15 - 11:20 Presentation of the synopsis report of the BECA public consultation ”The impact of the COVID-19 pandemic on cancer prevention, health services and cancer patients and research”
by Bartosz ARŁUKOWICZ, BECA Chair

11:20 - 11:55 Exchange of views with:

- Mark LAWLER and Mirjam CRUL, Co-Chairs of the European Cancer Organisation Special Network on Impact of COVID-19 on Cancer
- Solange PETERS, President, European Society for Medical Oncology (ESMO)
- Dineke ZEEGERS PAGET, Executive Director, European Public Health Association (EUPHA)

11:55 - 12:00 Conclusions and closing remarks:

- Véronique TRILLET-LENOIR, Rapporteur
- Bartosz ARŁUKOWICZ, BECA Chair

The exchange of views can be followed online: https://multimedia.europarl.europa.eu/en/webstreaming
Public Hearing “Unlocking the potential of artificial intelligence in cancer care”

27 May 2021

THEMES
- Effects on the ground: experiences of AI in imaging, detecting and diagnosing cancer
- Effects on the ground: experiences of AI in cancer surgery and treatment
- Towards personalised medicine: AI in cancer research and care
- AI and big data in cancer care: developing technical, organisational and ethical standards

Programme of the hearing

SUMMARY:
In cooperation with the AIDA Special Committee, a hearing to explore how artificial intelligence (AI) can revolutionise cancer research and care was organised. Digitalisation is now an integral part of prevention, diagnosis, drug development and improving patient quality of life. In the first part of the hearing, the discussion focused on the role of AI in imaging, detecting and diagnosing cancer. AI tools are able to support screening of cancer patients and in predicting treatment responses, to ensure that expensive treatments are used in the most efficient manner.

With regards to AI in cancer surgery and treatment, the importance of standardised digital training of health care professionals was emphasised. In addition, the potential of AI in the medical training of health care professionals, for example through the simulation of surgical scenarios, was considered. Several regulatory frameworks were discussed, in order to ensure ethical and transparent development and implementation of AI-based medical devices.

Concerning the role of AI in cancer research, the coordinator of the LifeTime Project presented its role in generating technologies and driving the digital age in medicine. The hearing also considered the development of technical and ethical standards. Through the implementation of electronic health records and health data, integration of new digital tools into patient care has become possible. Nevertheless, in order for AI tools to truly meet expectations, researchers must be able to access health data and train algorithms on these data sets. As a result, the need for harmonised and standardised data collection and processing was emphasised.

FURTHER READING
- Expert presentations and biographies
- Summary of the hearing
- Background note
- Catch up with the hearing - part 1
- Catch up with the hearing - part 2
Special Committee on Beating Cancer

PUBLIC HEARING
“Unlocking the potential of artificial intelligence in cancer research and care”
Brussels, European Parliament, József Antall (2Q2) and remote participation
Thursday, 27 May, 13:45-15:45 and 16:15-18:15

In association with the AIDA Committee

DRAFT PROGRAMME

13:45 - 13:50 Welcome and opening remarks by Bartosz ARŁUKOWICZ, BECA Chair
13:50 - 13:55 Introductory remarks by Dragoș TUDORACHE, AIDA Chair
13:55 - 14:15 Panel 1: Effects on the ground: experiences of AI in imaging, detecting and diagnosing cancer
   - Amparo ALONSO BETANZOS, President, Spanish Association for Artificial Intelligence, Professor Investigation and Development of Artificial Intelligence (LIDIA) at University of A Coruña
   - Regina BEETS-TAN, EU Cancer Mission Board Member, Co-Chair of the European Cancer Organisation’s Digital Health Network
14:15 - 14:45 Q&A session with BECA Members
14:45 - 15:05 Panel 2: Effects on the ground: experiences of AI in cancer surgery and treatment
   - Domenico M. D’UGO, President, European Society of Surgical Oncology (ESSO), Professor of Surgery at Catholic University of Rome, Italy
   - Emilio ALBA CONEJO, Director of Medical Oncology Intercenter Unit of Regional and Virgen de la Victoria University Hospitals, Málaga, Spain
15:05 - 15:35 Q&A session with BECA Members
15:35 - 15:40 European Commission - Yiannos TOLIAS, DG SANTE
15:40 - 15:45 Conclusions by Véronique TRILLET-LENOIR, Rapporteur
16:15 - 16:35 Panel 3: Towards personalised medicine: AI in cancer research and care
   - Artur KOWALIK, Department of Molecular Diagnostic, Holycross Cancer Center, Kielce; Division of Medical Biology, Institute of Biology, Jan Kochanowski University, Kielce
   - Geneviève ALMOUZNI, Research Director, Institut Curie France, coordinator for LifeTime project
16:35 - 17:05 Q&A session with BECA Members
17:05 - 17:10 European Commission - Gabriele MAZZINI, DG CNECT
17:10 - 17:30 Panel 4: AI and big data in cancer care: developing technical, organisational and ethical standards
   - Xosé M. FERNANDEZ, Chief Data Officer, Institut Curie, France
   - Jelena MALININA, Digital Health Policy Officer, European Consumer Organisation (BEUC)
17:30 - 18:00 Q&A session with BECA Members
18:00 - 18:05 European Commission - Owe LANGFELDT, DG JUST and Ander ELUSTONDO JAUREGUI, DG SANTE
18:05 - 18:15 Closing remarks by Bartosz ARŁUKOWICZ, BECA Chair
4. Interparliamentary Committee Meeting “Turning the tide on cancer: the national parliaments' view on Europe's Beating Cancer Plan” - 27.09.2021

In cooperation with the Legislative Dialogue Unit of the Directorate for Relations with national Parliaments, BECA invited members of the national parliaments of the EU Member States to a virtual Interparliamentary Committee Meeting (ICM) on 27 September 2021 to discuss the fight against cancer in Europe.

The Interparliamentary Committee Meeting provided a good forum for debate between European and national parliamentarians on the BECA draft report, prepared by the BECA Rapporteur Véronique Trillet-Lenoir, and on the EU’s flagship initiative against cancer, the Europe's Beating Cancer Plan that had been presented by the European Commission in February 2021. As the implementation of the Plan requires important multi-level cooperation between all stakeholders such as EU institutions, Member States, all regional and local authorities, social partners and civil society organisations, the ICM was a key moment to discuss these implications with national parliamentarians.

Stella Kyriakides, European Commissioner for Health and Food Safety and Iva Dimic, Chair of the Sub-committee on Monitoring Cancer in the Slovenian National Assembly delivered keynote speeches; and Birgitta Sacrédeus, Rapporteur for the opinion of the Committee of the Regions and Ms Malgorzata Bogusz, rapporteur for the opinion of the European Economic and Social Committee on Europe's Beating Cancer Plan gave opening remarks. It was followed by a panel discussion between numerous Members from the national parliaments and MEPs.

This meeting was an opportunity for an exchange of experiences and best practices on how national and EU actions can contribute to improving cancer prevention, supporting excellence in research, improving existing treatments and encouraging new ones, and ensuring equal access to cancer care throughout the Union. Many interventions stressed the necessity to bridge the existing disparities in cancer prevention and access to cancer care between and within European countries. Addressing these inequalities could have a positive impact on cancer incidence rates, survival and mortality across the EU. Numerous Members highlighted the necessity of a more holistic approach in preventing and treating this illness by awareness raising and educating the society; preventing rather than fixing attitude should prevail. Prevention encompasses healthy attitudes like sport, good quality nutriments, regular health checks and avoiding or decreasing the use of dangerous substances like alcohol and cigarettes. The discussion offered as well the opportunity to address how the coronavirus pandemic affected cancer care and cancer patients, and how cancer care could be made more resilient in the future.

- Programme
- Participants’ list
- BECA Committee event page with recording, speeches, biographies
X. Impact of the COVID-19-pandemic on cancer prevention, health services, cancer patients and research
1. Impact of the COVID-19-pandemic on cancer prevention, health services, cancer patients and research: lessons from a public health crisis - Public consultation and synopsis report

The COVID-19-pandemic has taken a huge toll on the continuity of cancer care and has significantly affected the entire cancer pathway. The intense disruption of Europe’s health systems made many victims as it caused delayed cancer screening, resulting in missed diagnosis and delayed treatments. It also affected the quality of life and follow-up care for patients.

To understand better the different ways the COVID-19 pandemic has affected patients, healthcare professionals (HCPs) and all other aspects of cancer care and research in the EU, BECA conducted a stakeholder’s public consultation, running from 04.02.2021 until 11.03.2021. The public consultation was designed to draw lessons from the COVID-19-pandemic and to gain insight and recommendations on questions focusing on:

- Addressing immediate and current impacts of the pandemic on cancer care in the EU;
- Rebuilding cancer services in Europe after the present period of health crisis has passed; and

The survey yielded contributions from stakeholders from the cancer community and public health organisations representing over 360 organisations within all Member States. Their combined expertise and recommendations provided a framework for proposals for short-term and sustainable solutions and for disease preparedness to ensure the continuity of cancer services, also taking into account Europe’s Beating Cancer Plan.

Key recommendations from respondents to the EU and Member States:

- Build more resilient and equal health systems for disease and crisis preparedness across the EU;
- Increase cross-border collaboration for cancer prevention programmes and other cancer services;
- Extend the mandate of the European Centre for Disease Prevention and Control and the European Medicines Agency;
- Tackle the shortages in medicines, equipment and medical staff by investing in European production and pan-European educational programmes;
- Address the mental health challenges related to lockdowns and imposed restrictions and include it as an integral part of cancer care;
- Promote the use of technological solutions in medicine and cancer care;
- Invest in digital health literacy to better equip both patients and health care professionals for daily clinical practice; and
- Take a more ‘holistic’ approach to fight cancer, involving all relevant stakeholders.
BECA Members discussed the findings and recommendations of the report on 10 May 2021 with experts from the European Cancer Organisation (ECO), European Society of Medical Oncology (ESMO) and European Public Health Association (EUPHA).

The recommendations were summarized in a reference guide, which was sent to all national parliaments and published on the BECA committee website.

- **Public Consultation Synopsis Report (Notice to members)**
- **Survey questions**
- **Recording of the BECA exchange of views on 10 May 2021**
- **Read more about the BECA Public Consultation**
NOTICE TO MEMBERS


INTRODUCTION

This report presents the outcome of the stakeholder’s public consultation conducted by the European Parliament’s Special Committee on Beating Cancer (BECA) from 04.02.2021 until 11.03.2021. The aim of the public consultation was to gain insight into the different ways the COVID-19 pandemic has affected patients, healthcare professionals (HCPs) and all other aspects of cancer care and research in the European Union (EU). Furthermore, the public consultation provided a framework for proposals for short-term and sustainable solutions, but also for future health crises (e.g. disease preparedness) to ensure continuity of cancer services, also taking into account Europe’s Beating Cancer Plan (EBCP).

As the consultation was set out to draw lessons from the current COVID-19 pandemic stakeholders from different cancer-related backgrounds were invited to voice their opinions and give their recommendations on questions focusing on:

a) Addressing immediate and current impacts of the pandemic on cancer care in the EU.

b) The rebuilding of cancer services in Europe after the present period of health crisis has passed.

c) The long-term role and means of EU cooperation in health and cancer care after
COVID-19.

The public consultation consisted of nine open questions in English about different topics related to the COVID-19 pandemic and cancer care, research and other services (See Annex A). Only organisations registered in the EU transparency register were invited to send in their contributions. In total, 34 contributions were received through the online survey form on the BECA website (See Annex B). All contributors had to confirm having read the legal notice and privacy statement. Furthermore, they needed to give consent for the processing of personal data.

The BECA Committee wishes to thank the EP services that contributed to the realisation of this consultation and in particular the author of the report, Ms Zineb Ez-Zaitouni.

1. EXECUTIVE SUMMARY

The persistent COVID-19 pandemic has pushed health systems across the world to their limits. To this day, healthcare services face multiple challenges in providing essential care to their patients in the midst of (varying) COVID-19 restrictions across the EU. Cancer care services have endured significant delays or cancellations leading to backlogs of patients furthering the already existing strains on healthcare systems and HCPs. In addition, the COVID-19 health crisis affected cancer research considerably, leaving facilities with financial and logistical challenges. Nonetheless, the COVID-19 pandemic sparked the use of innovative health technologies (e.g. telemedicine) in the mitigation of the detrimental effects on all cancer-related services and research, and fuelled the drive to restructure existing health systems and make them more resilient for future health crises.

1.1. Lifestyle behaviours and mental health

Respondents identified several behavioural changes in European citizens during the COVID-19 pandemic. Overall, they saw an increase in risk behaviour linked to a higher risk for developing cancer, such as smoking and alcohol consumption. In addition, adherence to healthy diets and physical exercise, partly due to imposed restrictions, decreased during the pandemic. Mental health posed a significant challenge as well. For patients, caregivers and HCPs increased stress, anxiety, and other psychological traumas because of the pandemic became part of their daily professional and personal lives.

1.2. Cancer prevention and screening

Both primary prevention and screening programmes for cancer were seriously affected across the EU. Cancer prevention and awareness campaigns (e.g. smoking cessation) were either suspended or cancelled. Cancer-screening services and vaccination programmes (e.g. against Human Papilloma Virus (HPV)) saw significant declines in the number of patients responding to invitations. Respondents expressed their concerns about the created backlog in screening programmes and decline in newly diagnosed cancer patients. As prevention and screening services are expected to resume fully when the COVID-19 health crisis is over, a surplus of cancer patients is expected to increase the burden on our health systems.

1.3. Cancer diagnosis, treatment and follow-up

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1 The National Cancer Control Programme of Ireland (NCCP) was exempted from this requirement by virtue of being a national programme. The NCCP contribution falls under the exemption for interest representation activities in the IIA on the Transparency Register.
All aspects in cancer detection were affected by the imposed COVID-19 restrictions. In line with the decrease in cancer prevention and screening services, respondents highlighted that the number of newly diagnosed malignancies in 2020 were significantly lower compared to 2019. Patients and HCPs experienced disruptions at some point in all cancer treatment modalities. The backlog resulting from these disruptions may potentially lead to advanced disease in patients with severe consequences (e.g. increased cancer morbidity and mortality).

1.4. Workforce and health systems

Many respondents underlined the fact that the COVID-19 pandemic exacerbated pre-existing shortages in specialized medical workforce. This worsened the pressure on health systems and, according to some respondents, exposed the inequalities between EU Member States. Respondents saw significant impacts on the mental health of HCPs and related workers due to, for example, altered working conditions (i.e. working in already overwhelmed health systems) and re-allocation to critical COVID-19 care. In addition, HCPs experienced higher than usual levels of stress, depression and anxiety, which led in certain cases to burnouts and increased work absenteeism.

1.5. Medicines, products and equipment

Next to the workforce shortages, several respondents pointed out that the COVID-19 health crisis either exacerbated or led to shortages in medicines, products (e.g. personal protective equipment (PPE)) and equipment in the Member States. Some stressed that the imposed travel restrictions and limitations led to additional diagnostic and treatment delays in patients. However, several respondents indicated that the COVID-19 pandemic did not pose any serious problems to their supply chain.

1.6. Cancer research, digital innovation and data

Respondents were asked about the effects of the COVID-19 pandemic on cancer research, the availability and deployment of data and the impact on innovation in cancer care services. As regards clinical research, respondents pointed to the suspensions or initiation delays of clinical trials. Patient inclusion was restricted and data processing was deprioritized as research staff were allocated to critical COVID-19 care. HCPs had to reassess their cancer care pathways and as a result increasingly used health technologies (e.g. telemedicine) to ensure continuity of cancer-related services.

1.7. Future perspectives and recommendations for EU public health policies

Overall, the responses show broad consensus on the EU’s role in addressing an array of topics in the aftermath of the COVID-19 pandemic. Respondents felt that the EU should take on a coordinating role in assisting its Member States in building a future robust European healthcare system. Many respondents underlined that the expected additional cancer burden on European health systems needs to be addressed in the short-term. All agreed that the current pandemic has shown several faults and weaknesses in our health systems and that the EU and its Member States need to focus on rebuilding these for future health crises. Moreover, respondents call for the elimination of health inequalities on national levels and between Member States. More resilient and equal health systems are pivotal for disease and crisis preparedness across the EU. In line with this, several respondents called for more cross-border collaboration in cancer
prevention programmes and other cancer-related services. Furthermore, they emphasised the need to extend the mandates of several European institutions, including the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA). The EU and its Member States need to tackle the shortages in medicines, equipment and medical staff by investing in European production and pan-European educational programmes, respectively.

As the COVID-19 pandemic is still ongoing, the mental health effects of the imposed restrictions and lockdowns are another challenge for cancer patients, caregivers and HCPs. Respondents call for a coherent approach by the EU and its Member States to address these mental health challenges and make it an integral part of cancer care.

The COVID-19 pandemic also led to an increase in innovative health technologies. Another recommendation was to promote the use of technological solutions in medicine and, more specifically, in cancer care. Furthermore, the EU and its Member States need to invest in digital health literacy to better equip both patients and HCPs for daily clinical practice.

Respondents broadly welcomed the EBCP, along with its 10 flagship initiatives and 32 supporting actions. According to them, the EBCP, as part of the European Health Union, will be instrumental in improving the overall quality of European cancer care, research and related services.
2. RESULTS: SUMMARY OF RESPONSES RECEIVED

Contributors expressed a high degree of overlap in issues and concerns regarding the COVID-19 pandemic and its effects on cancer care, research and other related services. Some contributions were very detailed and technical; others were more general or country-specific. However, there was an overall strong support for the EBCP and its flagship initiatives. Moreover, stakeholders agreed that the EU and its Member States should take a more ‘holistic’ approach to fight cancer, involving all relevant stakeholders.

<table>
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<tr>
<th>QUESTIONS AND SUMMARY OF RESPONSES RECEIVED</th>
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<tr>
<td>2.1. IMPACT ON LIFESTYLE-RELATED BEHAVIOURS</td>
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<tr>
<td>- What is the impact of the COVID-19-induced lockdowns and quarantines on dietary habits, physical activity, alcohol consumption, smoking and stress and anxiety levels among the European population?</td>
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<tr>
<td>- What measures could the EU take to prevent and to mitigate the negative consequences of lifestyle-related behavioural changes due to the COVID-19 pandemic?</td>
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Almost all respondents reported that the COVID-19 induced lockdowns and quarantines have profoundly affected lifestyle behaviours in multiple ways, which mainly resulted in increased risk behaviour for cancer. For example, the European Association of Urology (EAU), the European Society for Medical Oncology (ESMO), and the European Public Health Association (EUPHA) inter alia identified a higher alcohol consumption amongst European citizens.

Furthermore, most respondents emphasised the escalated use of combustible tobacco products and posed their concerns regarding the health effects. In light of the imposed lockdowns and quarantines, some organisations highlighted the limited access to non-combustible tobacco products and/or other nicotine products in multiple European countries.

In contrast, the National Cancer Control Programme of Ireland (NCCP) concluded there were both positive and negative effects of the COVID-19 imposed restrictions. For example, both an increase as well as a decrease in alcohol and tobacco consumption were reported in the Irish population.

Numerous respondents, such as the Albanian Center for Population and Development (ACPD) and Digestive Cancer Europe (DiCE), were concerned about the negative effects on the level of physical activity due to the imposed restrictions leading to lifestyles that are more sedentary. Examples given for this decreased physical activity were the (extended) closure of community-based physical activity initiatives, outdoor activities, and physical fitness facilities. In addition, several respondents recognised the overall neglect of healthy diets by, for example, a higher consumption of fast foods.

According to several respondents, the imposed restrictions have also negatively affected the mental health of Europeans. Psychological distress, depression, anxiety, domestic violence and loneliness have significantly increased during the COVID-19 health crisis. The NCCP, however, found that in a small proportion of the Irish population the COVID-19
pandemic had positively influenced their mental health.

**RECOMMENDATIONS**

Several recommendations were given by the respondents to mitigate the effects of the COVID-19 health crisis on lifestyle behaviours and mental health:

- **Smoking and alcohol consumption:**
  Respondents emphasised the importance of combating the consumption of tobacco products and alcohol. In order to achieve a tobacco-free generation, several initiatives, such as local, regional and European awareness campaigns on smoking and alcohol consumption as well as targeted prevention programmes should either be established or progressively promoted. Several respondents pointed out that Europe’s Beating Cancer Plan (EBCP) can be a catalyst in achieving these goals. Few mentioned that, in case of failed cessation, alternative nicotine products should be considered.

- **Physical activity and healthy diets:**
  Some respondents underlined the need for promoting healthy lifestyles through European Union (EU) supported and subsidized programmes. The EU should support Member States in sustaining relevant initiatives and supporting communication efforts regarding healthy lifestyles. Moreover, respondents indicated that the EU and its Member States should promote physical activity in specific situations (e.g. health crises) and encourage their citizens to partake in physical activity courses at home. In addition, subsidies on fresh fruits and vegetables need to be promoted to ensure greater access to healthier options for European citizens.

- **Mental health:**
  The EU and its Member States should give more attention to mental health and support further studies into the effects of, for example, physical activity on psychological well-being. Furthermore, respondents emphasised that, as the COVID-19 pandemic is still ongoing, the control and management of the spread of the coronavirus and its variants, including vaccination of citizens, play a pivotal role in positively influencing lifestyle behaviours.
2.2. IMPACT ON CANCER PREVENTION MEASURES

- What is the impact in the short-, middle- and long-term on patients, and health systems of:
  - the suspension or cancellation of campaigns promoting a healthy lifestyle
  - the disruption in (routine) cancer screening services and vaccination programmes
  - the non-referral of persons with suspected cancer symptoms
  - the suspension of diagnostic services for cancer
  - What measures could the EU take, and how should EU policies and legislation contribute to addressing these challenges?

A number of respondents, such as the European Respiratory Society and the European Breast Cancer Coalition (EUROPA DONNA), pointed out that the suspension or cancellation of campaigns promoting a healthy lifestyle and the disruption of smoking cessation services could negatively affect the risk of cancer. According to EUPHA, increased risk behaviour, such as increased tobacco consumption and worsening diets, can have long-term consequences for cancer incidence.

Primary prevention programmes, such as the vaccination against Human Papilloma Virus (HPV), were severely disrupted by the COVID-19 pandemic. In addition, respondents have seen an increased hesitance towards vaccinations as misinformation about the COVID-19 vaccines have been spreading.

Numerous respondents expressed concerns about the disruption and/or (temporary) cessation of several cancer-screening services, such as that for cervical and colorectal cancer. The European Cancer Organisation (ECO) indicated that their member organisations saw a significant decline of cancer screening in their respective countries. According to the respondents, this decline was multifactorial of nature. The imposed COVID-19 restrictions, the limitation in available screening staff, personal protective equipment (PPE), testing facilities, as well as citizens’ hesitance and existing fear of contracting the coronavirus have contributed to this decline. These conclusions were echoed by, among others, the NCCP, EUPHA and the European Society of Surgical Oncology (ESSO).

Respondents indicated that due to the disruption of cancer screening there would be an expected delay in cancer diagnosis possibly leading to higher mortality and worse clinical outcomes in patients. In addition, others stated that at the start of the pandemic only emergency cases were referred to specialised doctors or clinics, which may contribute to this delay in diagnosis. Moreover, as diagnostic and staging procedures were delayed, cancer cases may be more severe at time of discovery possibly resulting in less treatment options for these patients.

The consensus amongst the respondents was that the COVID-19 pandemic has had detrimental effects on both the primary and secondary prevention of cancer as well as the early diagnosis of cancer. Some respondents pointed out that the number of people diagnosed with cancer in 2020 significantly dropped in comparison to 2019. Therefore, they not only expect a significant backlog in screening and vaccination programmes, but also of newly diagnosed cancer patients. This created backlog will have a spill over effect on cancer burden once cancer services operate fully and will further the increased burden on healthcare.

RECOMMENDATIONS

Respondents made the following suggestions to the EU and the Member States:
- sustain financial support to existing cancer screening and vaccination programmes and increase funding for renewed EU cancer awareness campaigns
- re-establish cancer prevention, including vaccination programmes, and screening programmes as soon as possible with (financial) assistance
- invest in mitigating the effects of the COVID-19 pandemic on prevention, screening and early diagnosis of cancer
- promote clear communication to European citizens on the necessity and importance of cancer screening and vaccination programmes
- prioritise cancer patients for COVID-19 vaccination in order to resume cancer services promptly
- address the backlogs in cancer patients by ensuring sustainable and customized support to local hospitals and cancer care facilities in the Member States
- improve the resilience of health systems and by extension their cancer pathways in order to maintain cancer services during future health crises
- incentivise Member States to modernise healthcare infrastructures and their disease preparedness by investing in innovative health solutions inter alia
- focus on improving equal and universal access to cancer screening by providing support and investing in research in post-COVID-19 cancer pathways

2.3. IMPACT ON WELLBEING OF PATIENTS WITH CANCER AND THEIR CAREGIVERS

- **What are the experiences of cancer patients related to the COVID-19-pandemic?** In challenged health care systems, are patients with cancer informed about additional sanitary measures and changes in cancer-specific care? Does the current COVID-19 pandemic discourage patients from undertaking preventive, diagnostic or therapeutic actions?
- **What recommendations are needed to address long-term care challenges and help improve quality of life for patients, their family members and friends or carers?** What measures could the EU take, and how should EU policies and legislation contribute to addressing these challenges?

Overall, respondents agreed that the COVID-19 pandemic and the resulting restrictions have discouraged patients to participate in preventive, diagnostic and therapeutic actions with respects to cancer. This impaired continuity of cancer care and other services has affected patients and their caregivers in several ways.

Various respondents pointed out the challenges in mental health during the COVID-19 pandemic. Increased stress, anxiety, depression and other psychological and emotional trauma were amongst the examples of mental health challenges. Patients felt disregarded and not made a priority because of shifting priorities to critical COVID-19 care leading to the disruption of cancer care. The increased strict restrictions in the number of visitors and accompanying caregivers in clinical care centres (e.g. in-house care and follow-up visits) furthermore exacerbated this psychological distress in cancer patients and their caregivers. In addition, decreased availability of external support services placed more burden on caregivers. According to the European Society for Paediatric Oncology (SIOPE) the measures pertaining to COVID-19 and the fear generated, amongst other things, affected (already vulnerable) children and parents significantly leading to increased isolation and loneliness. Although breast cancer surgeries were not postponed, elective breast reconstructive surgeries were not performed, which Transforming Breast Cancer Together (TBCT) indicates plays an important role in the quality of life of breast cancer patients.
Others emphasised the lack of clear communication or ineffective communication, insufficient reliable resources and guidance regarding the ramifications of the COVID-19 restrictions on cancer care and other services. This resulted in uncertainty in both patients and caregivers and furthered the already existing reluctance to seek medical help or continue follow-up visits with their treating specialists, potentially leading to advanced disease with limited treatment options. The respondents viewed the flawed communication as a contributing factor to the already deteriorating mental health of patients and caregivers. Additionally, some experienced loss in confidence in the national health systems because of the experienced suboptimal communication.

The Asociación Española Contra el Cáncer (Spanish Association against Cancer, ed.) and Transforming Breast Cancer Together (TBCT) identified economic consequences for cancer patients and their families as a result of the COVID-19 pandemic. A recent report of the Asociación Española Contra el Cáncer showed that a significant proportion of Spanish cancer patients, with female cancer patients the most affected, were severely impacted economically. In addition, according to TBCT, patients expressed several concerns regarding different aspects of returning to work during the pandemic.

For some respondents another effect of the COVID-19 pandemic has been the exacerbation of pre-existing inequalities between health care systems, in particular cancer care, in Member States. As a result, countries lacking robust primary care services will endure the greatest number of consequences of the COVID-19 pandemic, according to EUPHA.

**Recommendations**

In order to address the challenges on the wellbeing of patients with cancer and their caregivers, respondents made several recommendations on possible measures the EU and its Member States could take:

- address the psychosocial impact of the pandemic on cancer patients, caregivers, families and friends
- fund mental health programmes, supporting a central role of psycho-oncology within quality cancer care, and make them widely accessible to their target audience
- ensure continuous allocation of resources towards accessible programmes addressing the psychosocial consequences of the COVID-19 pandemic on children and their development
- support the need for more information on coping strategies during health crises
- implement crisis protocols to ensure safe cancer pathways and timely communication on national and cross-border health crisis policies
- improve (crisis) communication with local, regional and national health services, and by extension patients, in order to restore patients’ confidence in their health systems
- invest more in patient organisations and reach out to scientific societies to ensure that reliable information reaches their patients for optimal guidance
- support Member States in the employment of innovative health solutions and technologies, such as telemedicine (e.g. remote patient monitoring) and at-home care, to strengthen cancer systems and to ensure safe access to continued cancer care
- support initiatives for continuation of cancer pathways (during the COVID-19 pandemic) and a holistic approach to optimal care for cancer patients
- promote better primary care in the Member States
- implement programmes to aid cancer patients in all matters related to employment, worker rights and insurance policies pre- and post-treatment
2.4. IMPACT ON CANCER TREATMENT

- How does the COVID19-pandemic effect the availability and timeliness of cancer treatments?
- Can you provide data on surgery postponements or cancellations, changes or cancellations in radiation therapy and systemic anticancer treatments and the consequences of a (partial) transition to telemedicine?
- What concrete EU-initiatives could significantly help to address the cancer-related backlog created by the COVID19-pandemic and ensure continued access of citizens to healthcare services for all their cancer-related needs during the current (or future) health crisis?

Numerous respondents highlighted the significant impact of the COVID-19 health crisis and the imposed restrictions on cancer-related surgeries, radiotherapies and systemic treatments (e.g. chemotherapy). For example, ESMO, ESSO and ECO indicated that hospitals in many European countries experienced serious cuts in available hospital beds and a reduction in surgical procedures. According to the European Society of Oncology Pharmacy (ESOP) there was a severe drop in the administration of chemotherapy globally. Furthermore, the European Trade Association representing the medical imaging, radiotherapy, health information and communications technology (ICT) and electromedical industries (COCIR) addressed the severe effects provoked by the COVID-19 pandemic leading to disruptions, delays and suspensions of radiotherapy.

Several respondents emphasised that the availability and timeliness of cancer treatments were affected by multiple factors. Intrinsic patient factors, such as fear of contracting COVID-19 and reluctance to start therapy, as well as limited resources (e.g. closure of clinical departments/facilities, re-allocation of specialised health staff, PPE shortages, and deprioritization of reimbursement of non-COVID-19 therapies) were mentioned as contributing factors to the discontinuity of cancer care. Few respondents indicated that a large proportion of health systems were able to provide COVID-19-free cancer pathways, however with significant delays or suspension of interventions. Nonetheless, the Motol University Hospital in the Czech Republic indicated they did not experience any limitations in their cancer-related services.

Several expressed their concerns about the potential harm of this interruption of cancer care. As mentioned before, there are significant backlogs in all cancer treatment modalities putting more pressure on already overheated health systems. Respondents underline the possible deleterious effects of these backlogs such as progression to advanced stages of cancer with less treatment options. This in turn can eventually lead to increased cancer morbidity and mortality.

Some respondents observed incompliance to cancer treatment out of fear for increased susceptibility to COVID-19 or, in case of an infection, a more severe disease course. The lack of communication and unclear protocols regarding cancer therapies increased stress and uncertainty about the prognosis of the underlying disease in cancer patients.

Furthermore, others pointed out that the COVID-19 pandemic led to the deterioration of research infrastructures affecting the recruitment and inclusion of cancer patients in clinical trials, halting experimental treatments and the processing of data.
Numerous respondents however saw a boost in the use of telemedicine and other innovative health solutions due to the aforementioned challenges in cancer-related services. The German Social Insurance European Representation concurred with this observation as they registered significant increases in telephone and video consultations by health care professionals (HCPs).

**RECOMMENDATIONS**

Respondents underlined that the lessons learned from this pandemic should play a pivotal role in redefining multimodal cancer services and proposed several ways to address the cancer-related backlog in the EU and its Member States:

- encourage continuation of cancer services by creating a healthy balance between COVID-19 care and chronic illness care
- develop best practices and guidelines in order to return to fully operating multimodal cancer services during the pandemic
- encourage different stakeholders to cooperate to establish proposals for the normalisation of cancer care and research
- increase funding to prepare health systems for the backlog in cancer services and a possible surge of cancer patients
- make cancer care an integral part of national and cross-border disease preparedness to ensure continuity during future health crises
- create continuity of cancer care by creating specific treatment pathways with hospital networks or redirecting cancer-related treatments to specialised centres
- promote the use of telemedicine and enhance collaboration between different health systems on national and cross-border levels to sustain continuity of cancer services
- implement health innovations and technologies to achieve higher quality of cancer care and research
- establish dedicated cancer registries to investigate the impact of COVID-19 by providing real world and accurate health data for policy-making on local, regional and national levels

**2.5. IMPACT ON SHORTAGES OF MEDICINES, PRODUCT AND EQUIPMENT**

- Does the current COVID-19 pandemic have an effect on the shortages of medicines used in cancer care? If yes, which medicines are affected? What measures should be taken, including at EU-level, to prevent and tackle the causes of shortages of medicines and medical equipment and mitigate the impact on patients, clinicians, pharmacists and other stakeholders?
- What initiatives should the EU take to ensure an effective response and equal access to optimal cancer care for all cancer patients when this situation occurs again?
- Please support your answer with data, evidence and/or concrete examples.

According to some respondents, shortages of medicines were pre-existent and already posed challenges for cancer care before the COVID-19 pandemic. Several, such as ESMO, ESOP, COCIR and DiCE, reported significant (temporary) shortages of oncological medicines leading to treatment interruptions. According to EUPHA, in some specific cases medicines were completely unavailable. Some mentioned that despite the specific shortages alternative medicines could be administered in order to continue the treatment of patients. Due to the imposed COVID-19 restrictions (i.e. cross-border movements), additional delays in deliveries of medicines, equipment and cancer-related diagnostic tests exacerbated the pre-existing conditions. In addition, the worsening PPE shortages posed serious problems for
both patients and HCPs, as PPE is needed for the safe administration of chemotherapy inter alia. SIOPE mentioned that, despite identified pre-existing shortages, there were no reliable data on the supply of medicines used in childhood cancers. Furthermore, the EAU reported no shortages, however expressed their concerns about shortages in medical personnel.

The EFPIA highlighted the expected rise of long-term shortages of blood products, as elective non-COVID-19 care starts to resume and operate fully leading to more pressure on health systems.

**Recommendations**

Respondents identified several examples to mitigate the effect of the COVID-19 pandemic but also to prepare for a possible future health crisis by the EU and its Member States:

- improve the robustness of different supply chains and increase their transparency in order to timely manage shortages of medicines, products and equipment
- aim for sufficient supplies of essential medicines and PPE by ensuring stockpiling through cross-border collaboration
- ensure equitable distribution of medicines between Member States
- investigate the root causes of the identified shortages and develop registries to monitor and manage supplies within the Member States in order to diagnose shortages early (e.g. through early warning and information systems) so Member States can take appropriate actions
- address availability, affordability and accessibility of medicines within the Member States
- encourage fair and affordable pricing of (innovative) therapies to fight the disparities between Member States
- invest in promoting the increase of existing manufacturing capacity of pharmaceutical ingredients, products and equipment in Member States
- consider relocating production to the EU altogether and investing in modernising and innovating these manufacturing plants

**2.6. Impact on the EU Cancer Workforce**

- What examples of the negative impact of the COVID-19 pandemic on healthcare professionals working in oncology can you provide? What measures should be taken, including at EU-level, to better safeguard healthcare professionals’ safety at work during the current (or future) health crisis?
- What durable solutions are needed to address cancer workforce shortages in and across the EU?
- Please support your answer with data, evidence and/or concrete examples.

Respondents agreed that the protection of all healthcare providers is an absolute requirement for the delivery of quality cancer care to patients. Several highlighted the pre-existing shortages of specialised medical staff in cancer services, which worsened during the COVID-19 pandemic. Respondents underlined the issue of re-allocation of HCPs to critical COVID-19 care. In addition, COVID-19- infections amongst HCPs and the mandatory quarantine measures led to insufficient staff capacity throughout. Moreover, shortages of other workers, such as supportive personnel, exacerbated because of travel restrictions and restricted hospital access.

Almost all respondents pointed out the altered working conditions (i.e. increased workload)
of HCPs due to overwhelmed health systems, which were ill prepared for this crisis. HCPs endured increased physical stress (e.g. working in PPE for extended hours) and excessive workloads over prolonged periods whilst providing care for their patients. Furthermore, they emphasised the impact on mental health as HCPs experienced high levels of psychological distress leading to (extreme) fatigue, burnouts and increased work absenteeism. HCPs, to their frustration, were not able to provide the standard quality of care and had to make difficult clinical decisions. Moreover, the PPE shortages contributed to the worsening of pre-existing fears of contracting COVID-19 and possibly infecting others, such as (fragile) patients, colleagues and loved ones.

**RECOMMENDATIONS**
Respondents agreed that the EU and its Member States need to invest in strengthening the current medical workforce whilst simultaneously addressing the pre-COVID-19 shortages by:

- promoting vaccination against the coronavirus for HCPs and supporting clinical staff ensuring access to sufficient PPE supplies and bringing more attention to the mental and physical wellbeing of HCPs by addressing the (sometimes dire) working conditions (e.g. through legislation)
- encouraging more cross-border collaboration by sharing and adopting best practices (e.g. decreasing administrative workload).
- promoting the use of telemedicine and deployment of other health solutions as measures to decrease the high work pressure of HCPs
- tackling the cancer workforce shortages through harmonisation and mutual recognition of HCP qualifications across Member States
- looking into cross-border redistribution of specialised workforce in specific situations, for instance health crises
- promoting digital literacy and additional training of HCPs (e.g. by EU-level programmes and cross-border exchange programmes)
- focussing on the recruitment of additional medical workers in cancer-related services and prioritising cancer care
- addressing the salary inequalities of HCPs between Member States
### 2.7. Availability and Deployment of Data

- **What is the concrete impact of the COVID-19 pandemic on cancer data availability?** What measures, including EU initiatives, could significantly help to improve the availability and deployment of data related to cancer care? Please support your answer with data, evidence and/or concrete examples.

- **Have you been informed/are you aware of guidelines issued by EU Member States, regional or local authorities for the systematic collection of data concerning the impact of the COVID19-pandemic on cancer care services?** If so, please provide data, details and/or examples.

- **What initiatives should the EU take to improve access to and sharing of data (including real-time data) on cancer?** How should relevant stakeholders collaborate to create a robust and functional European Health Data Space (EHDS) for better healthcare, innovative research, as well as more data-informed policy-making and regulatory activities in health?

- Please support your answer with evidence and/or concrete examples

Some respondents mentioned that the COVID-19 pandemic had negatively affected the research infrastructure resulting in reduced cancer data availability. Due to suspensions or restrictions of several aspects of clinical trials lost to follow-up patients influenced (real-time) data collection. Moreover, (manual) data entry was interrupted due to staff shortages, leaving policy-makers to rely on outdated data. A number of respondents highlighted the difficulties experienced related to the General Data Protection Regulation (GDPR). They mentioned barriers in the GDPR interpretation and fragmented implementation across institutions and Member States.

### Recommendations

Respondents called for the following actions to contribute to optimal data-informed policy-making and health regulatory activities:

- Construct a European cancer dashboard to research the (in) direct effects of the COVID-19 pandemic on cancer outcomes and monitor vaccination effects

- Encourage uniform health data management and aim for greater harmonisation and establish standardisation of health data (e.g. identify common parameters for policy) to create greater coherence between cancer registries

- Support Member States with (near) real-time cancer data and timely access thereof to improve cancer service delivery and clinical research

- Provide additional (financial) support to the Member States

- Improve the access and sharing of cancer data by creating a European Cancer Measurement Tool

- Create registries for highly prevalent cancers and electronically networked structures providing transparency on drug availability

Furthermore, most respondents believe that the future European Health Data Space (EHDS) can facilitate uniform data transfer and sharing between Member States. Some gave examples of issues that could be addressed within the framework of the EHDS, such as artificial intelligence, big data and uniformity of electronic health records.
### 2.8. IMPACT ON RESEARCH AND INNOVATION

- Do you see any innovative solutions or technologies that arise from the COVID-19 pandemic that could help in strengthening cancer care services?
- What innovative technologies and solutions should be deployed to strengthen cancer systems and provide optimal care to cancer patients?
- Please support your answer with evidence and/or concrete examples

Several respondents, such as the EAU, AstraZeneca and SIOPE, pointed out that the COVID-19 pandemic led to either suspensions or initiation delays of clinical trials. Specifically, recruitment and inclusion of patients were troubled by the imposed restrictions slowing down development in, for example, personalized medicine. Moreover, some indicated that the travel restrictions exacerbated the already restricted access for cancer patients to innovative cancer therapies only available in certain European centres. There were varying messages on the funding of (clinical) cancer research; some indicated that they saw no apparent changes in funding; others saw their funding negatively impacted by the pandemic.

Most respondents mentioned the significant expansion of telemedicine to support and ensure the continuation of cancer care and, in some cases, research. In addition, respondents explained that the deployment of telehealth facilitated the use of real-world data for decision-making.

**Recommendations**

All respondents agreed that the COVID-19 pandemic has exposed an unmet need and that the EU and its Member States should promote and expand the use of innovative health technologies in daily clinical practice. Some emphasised a multidisciplinary approach to create best strategies for telemedicine and remote monitoring in health systems. Frequently mentioned examples in strengthening cancer systems and providing optimal cancer care included:

- supporting independent research to generate robust evidence on telemedicine (equity and equal access across Member States)
- training of HCPs and improving digital literacy of patients
- sharing of best practices on deployment of telemedicine in cancer care between Member States
- setting up clear regulations for telemedicine in cancer care
- increasing funding for cancer research and innovative health solutions (e.g. mobile health applications)
- sustaining European innovation in (cancer-specific) medical technologies (e.g. automation and digitalisation of oncology medication management)
- integrating multipronged cancer intelligence for policy-making
2.9. LONG-TERM POLICIES

- In the aftermath of the COVID-19 pandemic, and its impact on cancer care particularly, what long-term policies should the EU roll out/implement to address identified problems and make health systems more resilient in case of any future health crises?
- Do you see it justified (and if so, how) to change the EU's roles and remits to better combat those problems?
- Do you foresee the need for an EU plan to prevent and to manage of any health crises on Cancer stages or more broadly on non-communicable diseases?

RECOMMENDATIONS

Respondents identified an array of topics to be addressed by the EU and its Member States in the aftermath of the COVID-19 pandemic. The main themes included the future of (European) healthcare, disease and crisis preparedness, health systems and cross-border collaboration, and digitalisation of healthcare. Several respondents mentioned the EU4Health programme, inter alia, as a means for funding the suggested policy changes.

- Health systems

Many respondents stressed the importance of strengthening Member States’ health systems by improving their resilience for future health crises. The EU and Member States should invest in crisis preparedness by developing plans and protocols in protection of cancer services during a health crisis. In other words, cancer control should be part of a comprehensive strategy that anticipates the impact of public health emergencies. This entails, inter alia, ensuring sufficient staff capacity, medicines, products and equipment to cope with health crises in the EU. Several respondents suggested the EU to perform in-depth analyses on the COVID-19 pandemic impact on the full spectrum of cancer services. These data should lead to uniform healthcare strategies and crisis policies between Member States.

- Uniformity

According to several respondents, the COVID-19 crisis underlined the belief that the EU should regard public health not only as a European matter but also as a global priority for which a coherent health strategy is needed. The EU and its Member States need to focus more on uniform cancer prevention strategies (i.e. primary prevention, screening and vaccination programmes). For example, respondents indicated the need for more cross-border collaboration on control of tobacco and alcohol consumption.

- Mental health

Another aspect highlighted by the COVID-19 pandemic is the mental health of European citizens. The current health crisis has exacerbated psychological distress in some, or developed newly due to the drastic consequences for the personal and professional lives of people and their families. Many respondents emphasised that mental healthcare is an integral part of cancer care and should therefore be available to both patients and their families.

- Innovation

As mentioned before, respondents stressed the importance and usefulness of innovative health solutions and digital technologies in cancer care. The EU and its Member States need
to invest in (digital) health literacy programmes for citizens and promote the development of patient-friendly technological solutions (e.g. remote consultation, at-home monitoring and drug administration). Importantly, regulations regarding telemedicine need to be put in place to ensure the patient’s data safety.

- **Equity**

Numerous respondents called for the elimination of inequalities between health systems of Member States. The EU should play a more coordinating role to ensure uniformity of healthcare policies (i.e. all aspects of cancer) whilst simultaneously supporting national and enhance cross-border cooperation. Furthermore, the COVID-19 crisis highlighted the cracks in communication and the need for a coherent approach.

- **Stakeholder participation**

Moreover, there were calls to empower the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) to not only allow for a coordinated and prompt response during health crises but also tackle cancer medicines shortages and securing access to medicines (especially for some Member States). Some noted that the COVID-19 pandemic has shown the advantage of involving different stakeholders in combatting the health crisis. They suggest that in order to improve cancer care and research the EU and its Member States should instate an international multi-stakeholder advisory committee.
ANNEX A - Outline of COVID-19 survey

BECA Online Call for Contributions: Presentation of the online survey

1. Title
Call for Contributions: Impact of the COVID19-pandemic on cancer prevention, health services, cancer patients and research

2. Policy fields
Environment, Public Health and Food Safety, Research and Innovation, Internal market, employment and social affairs.

3. Target group
Organisations registered in the Transparency Register are invited to send their contributions.

4. Period
The call for contributions will be open from 04.02.2021 to 25.02.2021

5. Objectives of the Call for Contributions
The impact of the COVID19-pandemic is visible throughout European healthcare systems. Regular care (other than COVID19) has been scaled back or postponed in many cases. Gradually it is becoming clear that the COVID19 health crisis has lasting consequences on cancer care services and patients.

It is crucial to draw lessons from the pandemic to improve cancer services and research and help prepare for future crises. As part of the preparation of its final report, the Committee therefore invites interested stakeholders to respond to a public call for evidence, focused on the emergent issue of COVID19 and its impact on cancer care.

The questions focus on:
a) Addressing immediate and current impacts of the pandemic on cancer care in the EU
b) The rebuilding of cancer services in Europe after the present period of health crisis has passed
c) The long-term role and means of EU cooperation in health and cancer care after COVID19

A summary of evidence provided from this call will be provided to Members and, possibly, be published on the BECA website. Contributions will be used to inform the final report and advice by the Committee, as well as its further evidence gathering processes ahead of report publication.

This call for contributions is in line with the mandate of the Beating Cancer committee, and in particular paragraph 1, point b and c) thereof:
1. Decides to set up a special committee on beating cancer, vested with the following responsibilities:
   (...) 
   (b) listening to the current evidence and data available and react by identifying policies and priorities that meet patients’ needs; 
   (c) evaluating the possibilities where, in accordance with the TFEU, the EU can take concrete steps to fight cancer and where only recommendations to the Member States and exchange of best practices are possible and focus on the concrete actions;

6. Language
The call for contributions is available in English. Please provide your replies in English.

7. Background
The European Parliament’s Special Committee on Beating Cancer (BECA) was set up to look at ways to elevate and accelerate Europe’s shared fight against cancer. Its work includes identifying legislation and other measures that can help prevent and fight cancer, and looking into the best ways to support research. It is becoming increasingly clear that the COVID19 - pandemic has far-reaching implications for cancer care and services. This issue will therefore be an important part of the BECA report, particularly in formulating recommendations for the future regarding screening, diagnosis, and treatment of cancer patients in the event of a subsequent outbreak or similar major health crisis.

Background documents
- Mandate of the Special Committee on Beating Cancer
8. Practical information

How to submit your contribution
Please take part in the public call for contributions by completing the online survey form.

Please note that to ensure a fair and transparent process, only responses received through the online form will be made available to Members of the Beating Cancer Committee and, possibly, published on the BECA Committee webpage.

Contact details of responsible service
The call for contributions is requested, prepared and administratively coordinated by the Special Committee on Beating Cancer of the European Parliament. For questions related to the Call for Contributions, please contact: European Parliament, Special Committee on Beating Cancer.
E-mail: BECA-secretariat@europarl.europa.eu

Results of the call for contributions and next steps
The results of the call for contributions will help the members of the Beating Cancer committee to map the experiences and recommendations of stakeholders and their expectations with regard to the impact of the COVID19-pandemic on cancer prevention, health services, cancer patients and research. It will also help to define potential next steps and future policies in this regard at EU level.

This call for consultation does not prejudge any future decision on whether or not to propose legislation in this field.

Privacy Statement
I have read the privacy statement and I consent to the processing of my personal data.

Legal notice
I have read the legal notice
ANNEX B - List of contributors

- European Association of Urology (EAU)
- European Respiratory Society (ERS)
- ASSOCIAZIONE NAZIONALE CONSUMATORI VAPORIZZATORI PERSONALI
- Asociación Española Contra el Cáncer (Spanish Society Against Cancer)
- Think Pink Europe
- European Tobacco Harm Reduction Advocates
- BECTON DICKINSON (BD)
- European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries (COCIR)
- Digestive Cancers Europe (DiCE)
- Novartis International AG
- Center of Excellence for the acceleration of Harm Reduction
- Plataforma para la reducción del daño por tabaquismo
- RPP/SPARC-Europe Secretariat
- AstraZeneca
- American Chamber of Commerce to the European Union (AmCham EU)
- Transforming Breast Cancer Together
- European Society for Paediatric Oncology – SIOP Europe (SIOPE) in collaboration with Childhood Cancer International – Europe (CCI-E)
- EUROPA DONNA - The European Breast Cancer Coalition
- German Social Insurance European Representation
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Avicenna Alliance
- European Society for Medical Oncology (ESMO)
- European Hematology Association (EHA)
- Interessengemeinschaft E-Dampfen e.V. (IG-ED)
- Motol University Hospital (Prague, Czech Republic)
- European Society of Surgical Oncology (ESSO)
- European Society of Oncology Pharmacy (ESOP)
- European Parliamentary Forum for Sexual & Reproductive Rights (EPF)
- European Public Health Association (EUPHA)
- Ireland's National Cancer Control Programme (NCCP)
- Albanian Center for Population and Development (ACPД)
- Associazione Igienisti Dentali Italiani (AIDI)
- European Cancer Organisation (ECO)
- Associations collaborating on hepatitis to immunize and eliminate the viruses in Europe (ACHIEVE)
Synopsis Report - Special Committee on Beating Cancer public consultation

THE IMPACT OF THE COVID-19 PANDEMIC ON CANCER PREVENTION, HEALTH SERVICES, CANCER PATIENTS AND RESEARCH:

Lessons from a public health crisis

BECA
Special Committee on Beating Cancer
May 2021
INTRODUCTION

This paper presents the outcome of the stakeholder’s public consultation conducted by the European Parliament’s Special Committee on Beating Cancer (BECA).

The consultation sought to gain insight into the different ways the COVID-19 pandemic affected:
- cancer patients,
- healthcare professionals (HCPs),
- all other aspects of cancer care and research,
- in the European Union (EU).

It also provided a framework for proposals
- for short-term and sustainable solutions,
- for future health crises (e.g. disease preparedness),
- to ensure continuity of cancer services, also taking into account Europe’s Beating Cancer Plan (EBCP).

SUMMARY OF FINDINGS

The persistent COVID-19 pandemic has pushed health systems across the world to their limits. To this day, healthcare services face multiple challenges in providing essential care to their patients in the midst of (varying) COVID-19 restrictions across the EU. Cancer care services have endured significant delays or cancellations leading to backlogs of patients furthering the already existing strains on healthcare systems and HCPs. In addition, the COVID-19 health crisis affected cancer research considerably, leaving facilities with financial and logistical challenges. Nonetheless, the COVID-19 pandemic sparked the use of innovative health technologies (e.g. telemedicine) in the mitigation of the detrimental effects on all cancer-related services and research, and fuelled the drive to restructure existing health systems and make them more resilient for future health crises.

Lifestyle behaviours and mental health

Respondents identified several behavioural changes in European citizens during the COVID-19 pandemic. Overall, they saw an increase in risk behaviour linked to a higher risk for developing cancer, such as smoking and alcohol consumption. In addition, adherence to healthy diets and physical exercise, partly due to imposed restrictions, decreased during the pandemic. Mental health posed a significant challenge as well. For patients, caregivers and HCPs, increased stress, anxiety, and other psychological traumas because of the pandemic became part of their daily professional and personal lives.

Cancer prevention and screening

Both primary prevention and screening programmes for cancer were seriously affected across the EU. Cancer prevention and awareness campaigns (e.g. smoking cessation) were either suspended or cancelled. Cancer-screening services and vaccination programmes (e.g. against Human Papilloma Virus (HPV)) saw significant declines in the number of patients responding to invitations. Respondents expressed their concerns about the created backlog in screening programmes and decline in newly diagnosed cancer patients. As prevention and screening services are expected to resume fully when the COVID-19 health crisis is over, a surplus of cancer patients is expected to increase the burden on our health systems.

Cancer diagnosis, treatment and follow-up

All aspects in cancer detection were affected by the imposed COVID-19 restrictions. In line with the decrease in cancer prevention and screening services, respondents highlighted that the number of newly diagnosed malignancies in 2020 were significantly lower compared to 2019. Patients and HCPs experienced disruptions at some point in all cancer treatment modalities. The backlog resulting from these disruptions may potentially lead to advanced disease in patients with severe consequences (e.g. increased cancer morbidity and mortality).

“I very much welcome the pertinent recommendations from the BECA survey that will feed into our final report.

The COVID-19 pandemic creates huge challenges for cancer patients to access care. But cancer care can’t wait - for these patients, every day counts!

It is the mission of our Committee, together with other politicians, experts and doctors, to do all we can to ensure that cancer patients receive the treatment they need.”

Bartosz Arłukowicz, Chair of the BECA Committee
Workforce and health systems

Many respondents underlined the fact that the COVID-19 pandemic exacerbated pre-existing shortages in specialized medical workforce. This worsened the pressure on health systems and, according to some respondents, exposed the inequalities between EU Member States.

Respondents saw significant impacts on the mental health of HCPs and related workers due to, for example, altered working conditions (i.e. working in already overwhelmed health systems) and re-allocation to critical COVID-19 care. In addition, HCPs experienced higher than usual levels of stress, depression and anxiety, which led in certain cases to burnouts and increased work absenteeism.

Medicines, products and equipment

Next to the workforce shortages, several respondents pointed out that the COVID-19 health crisis either exacerbated or led to shortages in medicines, products (e.g. personal protective equipment (PPE)) and equipment in the Member States. Some stressed that the imposed travel restrictions and limitations led to additional diagnostic and treatment delays in patients. However, several respondents indicated that the COVID-19 pandemic did not pose any serious problems to their supply chain.

Cancer research, digital innovation and data

Respondents were asked about the effects of the COVID-19 pandemic on cancer research, the availability and deployment of data and the impact on innovation in cancer care services. As regards clinical research, respondents pointed to the suspensions or initiation delays of clinical trials. Patient inclusion was restricted and data processing was deprioritized as research staff were allocated to critical COVID-19 care. HCPs had to reassess their cancer care pathways and as a result increasingly used health technologies (e.g. telemedicine) to ensure continuity of cancer-related services.

“The COVID-19 pandemic constitutes a stress test for our healthcare systems with disproportionate negative effects on cancer care and patients. The BECA survey teaches us important lessons about how to make our health systems more resilient to ensure continued cancer care at all times. We need robust digital solutions and tele-medicine to be able to monitor cancer patients remotely and clear communication between patients, healthcare professionals and public authorities on emergency public health measures. A much stronger focus on global prevention measures for cancer and other NCDs, alongside a global strategy to address medicines shortages is crucial, just as ensuring priority access to COVID-19 vaccines for cancer patients.”

Véronique Trillet-Lenoir, BECA Rapporteur
Future perspectives and recommendations for EU public health policies

Overall, the responses show broad consensus on the EU’s role in addressing an array of topics in the aftermath of the COVID-19 pandemic. Respondents felt that the EU should take on a coordinating role in assisting its Member States in building a future robust European healthcare system. Many respondents underlined that the expected additional cancer burden on European health systems needs to be addressed in the short-term. All agreed that the current pandemic has shown several faults and weaknesses in our health systems and that the EU and its Member States need to focus on rebuilding these for future health crises. Moreover, respondents call for the elimination of health inequalities on national levels and between Member States. More resilient and equal health systems are pivotal for disease and crisis preparedness across the EU. In line with this, several respondents called for more cross-border collaboration in cancer prevention programmes and other cancer-related services. Furthermore, they emphasised the need to extend the mandates of several European institutions, including the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA). The EU and its Member States need to tackle the shortages in medicines, equipment and medical staff by investing in European production and pan-European educational programmes, respectively.

As the COVID-19 pandemic is still ongoing, the mental health effects of the imposed restrictions and lockdowns are another challenge for cancer patients, caregivers and HCPs. Respondents call for a coherent approach by the EU and its Member States to address these mental health challenges and make it an integral part of cancer care.

The COVID-19 pandemic also led to an increase in innovative health technologies. Another recommendation was to promote the use of technological solutions in medicine and, more specifically, in cancer care. Furthermore, the EU and its Member States need to invest in digital health literacy to better equip both patients and HCPs for daily clinical practice.

Respondents broadly welcomed the EBCP, along with its 10 flagship initiatives and 32 supporting actions. According to them, the EBCP, as part of the European Health Union, will be instrumental in improving the overall quality of European cancer care, research and related services.
XI. Mission to Geneva and Lyon
2 - 4 November 2021
1. Introduction

The mission was organised to obtain first-hand information and engage in direct exchanges of views with key stakeholders at the international level, as well as health care professionals in the frontline of the fight against cancer. The mission took place at a crucial time, one month ahead of the BECA committee vote and in the middle of the negotiations on compromises on the 1537 amendments tabled to the draft report.

Main themes of interest for the delegation, in line with the BECA mandate, were:

- Impact of the Covid-19-health emergency on the continuity of cancer care delivery;
- Addressing inequalities in cancer prevention and care between and within Member States;
- Strengthening health systems in cancer prevention and control and accelerate research and innovation with a focus on childhood, adolescent and rare cancers; and
- Building strong partnerships with all stakeholders at local, regional, national and global level to reduce the burden of cancer today and for future generations.
2. Programme

TUESDAY, 2 NOVEMBER 2021

- Individual arrivals in Geneva and individual transfers to the hotel
  Check-in Eastwest Hotel (map)
  6 Rue des Pâquis
  1201 Geneva, Switzerland
  Tel: + 41 22 708 17 17
  welcome@eastwesthotel.ch

- Dinner, individual arrangements

WEDNESDAY, 3 NOVEMBER 2021

08.00 - 08.30  Bus Transfer to EU Delegation in Geneva
  (Rue du Grand-Pré 64, CH - 1211 Geneva, Switzerland)

08.15 – 08.30  EP delegation registration/security

08.30 – 08.45  Welcome and setting the scene
  ▪ Lotte KNUDSEN, Head of the Delegation of the European Union to the United Nations and other international organisations in Geneva
  Opening remarks
  ▪ Bartosz ARŁUKOWICZ, BECA Committee Chair

08.45 – 09.25  Exchange of views/open discussion between BECA Members and the Delegation’s health experts:
  ▪ Dr Canice NOLAN, Minister Counselor responsible for health and food safety
  ▪ Mr Jerôme CASSIERS, First Counselor
  ▪ Ms Corinna HULNHAGEN, First Secretary

Refreshments will be offered by the EU Delegation.
09.25 - 09.30 Conclusions and closing
  • Bartosz ARŁUKOWICZ, BECA Committee Chair

09.30 - 09.45 Bus Transfer to WHO Headquarters
(20 Av. Appia, CH - 1202 Geneva, Switzerland)

09.45 – 10.00 Registration/security procedure for access to WHO premises

10.00 – 10.15 Welcome Coffee

  Opportunity for participants to accommodate and discuss
  informally *

10.15 – 10.45 Welcome and setting the scene

  Opening remarks (5 min)
  • Dr Tedros Adhanom GHEBREYESUS, WHO Director-General
  • Bartosz ARŁUKOWICZ, BECA Committee Chair
  • Supporting remarks (10 min) Hans KLUGE, WHO Regional
    Director (virtual)
  • Dr Zsuzsanna JAKAB, WHO Deputy Director-General
  • Dr Oxana DOMENTI, WHO Representative to the European Union

  Strategic discussion
  • Delegation photograph (5 min)

10.45 – 11.15 Healthier lives: tobacco, alcohol, environmental determinants

  Chair: Dr Naoko YAMAMOTO, WHO Assistant Director-General,
  Universal Health Care / Healthier Populations
  • WHO strategic initiatives and activities in cancer prevention
    (5min)
  • BECA delegation response on EU priorities (5min)
  • Thematic discussion in directed topics (20min)

11.15 – 11.25 Coffee break

11.25 – 12.55 Cancer as part of Universal Health Coverage: screening,
treatment (including anti-microbial resistance), access to
medicines and WHO joint procurement mechanism

  Chair: Dr Ren Minghui, WHO Assistant Director-General, Universal
  Health Coverage / Communicable and Noncommunicable Diseases

  Thematic area 1: National cancer control programmes including
  rare cancers/childhood cancer, service models, digital
  health/health literacy (40min)
• WHO strategic initiatives and activities in cancer control (10min)
• BECA delegation response on EU priorities (5min)
• Thematic discussion in directed topics (25min)

Thematic area 2: Increasing access to cancer medicines (20min)
• WHO strategic initiatives and activities in access to cancer medicines (5min)
• BECA delegation response on EU priorities (5min)
• Thematic discussion in directed topics (10min)

12.55 - 13.00 Closing remarks
• Bartosz ARŁUKOWICZ, BECA Committee Chair
• Dr Zsuzsanna JAKAB, WHO Deputy Director-General

13.00 – 13.30 Light lunch offered by WHO (outside meeting room)
*** No interpretation will be provided during lunch ***

* Full list of WHO participants:

**WHO Headquarters**
- Dr Tedros Adhanom GHEBREYESUS, WHO Director-General
- Dr Zsuzsanna JAKAB, WHO Deputy Director-General
- Dr Samira ASMA, WHO Assistant Director-General, Data, Analytics and Delivery
- Prof. Hanan BALKHY, WHO Assistant Director-General, Antimicrobial resistance (to be confirmed)
- Dr Mariangela SIMÃO, WHO Assistant Director-General, Access to Medicines and Health Products
- Dr Naoko YAMAMOTO, WHO Assistant Director-General, UHC / Healthier Populations
- Dr Princess Nono SIMELELA, WHO Special Adviser to DG on Strategic Programmatic Initiatives
- Dr Bente MIKKELSEN, WHO Director, Department of Noncommunicable Diseases
- Dr André ILBAWI, WHO cancer team lead (acting), Department of Noncommunicable Diseases

**WHO European Regional Office**
- Dr Hans KLUGE, WHO Regional Director (virtual)
- Dr Carina FERREIRA-BORGES, WHO Acting Director, Division of NCDs (virtual)
- Dr Marilys CORBEX, WHO Senior technical officer, Department of Noncommunicable Disease

**WHO Office at the European Union**
International Agency for Research on Cancer (IARC)
- Dr Elisabete Weiderpass, Director (virtual)

13.30 - 16.00
Bus transfer to International Agency for Research on Cancer (IARC)
(150 Cours Albert Thomas, 69372 Lyon CEDEX 08, France)

16.00 - 16.30
Welcome coffee

16.30 - 16.40
Welcome and introductions
- Dr Elisabete WEIDERPASS, IARC Director
- Bartosz ARŁUKOWICZ, BECA Committee Chair
- Véronique TRILLET-LENOIR, Rapporteur BECA report
- Delegation photograph

16.40 - 17.00
Presentation about IARC, including the Nouveau Centre project
- Mr Clement CHAUVET, Strategic Engagement and Resource Mobilization Specialist

17.00 - 18.45
Short presentations followed by open discussions on:

Cancer Surveillance and latest data
- Dr Freddie BRAY, Section Head of the Cancer Surveillance Section

Environmental risk factors
- Dr Joachim SCHÜZ, Section Head of Environment and Radiation and Acting Head of the Section of Early Detection and Prevention

Childhood cancers
- Dr STELIAROVA-FOUCHER, Scientist in the Section of Cancer Information

European Code Against Cancer
- Dr Caroline ESPINA, Scientist in the Section of Environment and Lifestyle Epidemiology

Screening in Europe
- Dr A. CARVALHO, Scientist in the section of Early Detection Prevention and Infections

Social inequalities in Europe
• Dr S. VACCARELLA, Scientist in the Section of Cancer Surveillance

_Cervical Cancer control modelling in Europe and beyond_

• Dr Iacopo BAUSSANO, Scientist in the Section of Early Detection Prevention and Infections

**18.45 - 19.00 Conclusions and closing**

• Dr Elisabete WEIDERPASS, IARC Director
• Véronique TRILLET-LENOIR, Rapporteur BECA report
• Bartosz ARŁUKOWICZ, BECA Committee Chair

**19.00 - 20.00 Bus Transfer to hotel**

Check-in Hotel Radisson Blu Part Dieu ([map](#))
(129 Rue Servient, 69003 Lyon, France, Telephone +33 4 78 63 55 00, info.lyon@radissonblu.com)

**20.00 - 20.30 Bus Transfer to Restaurant Bistrot de Lyon**
(Rue Mercière 64, 69002 Lyon, Telephone +33 4 78 38 47 47)

**20.30 - 23.00 Official delegation dinner with invited guests in Bistrot de Lyon**

***No interpretation will be provided during dinner - Working languages: English and French***

• Dr Elisabete Weiderpass, Director IARC
• Prof. Pierre Hainaut, Président du Directoire Cancéropôle CLARA
• Patrick DENIEL, Secretary General Hospices Civils de Lyon
• Prof. Gilles Freyer, Director Cancer Institute HCL
• Dr Bente MIKKELSEN, WHO Director, Department of Noncommunicable Diseases (tbc)
• Dr Oxana DOMENTI, WHO Representative to the European Union

**23.00 Individual departures to hotel Radisson Blu**
(No bus transfer provided) (129 Rue Servient, 69003 Lyon, France)

_End of the second day_
THURSDAY, 4 NOVEMBER 2021

08.15 Check-out from hotel.
(Please take your luggage with you on the bus, there will be no possibility to return to the hotel later)

Meeting point in the hotel lobby – leave from hotel

08.15 - 08.45 Bus Transfer to Hospices Civils de Lyon (HCL), France’s second university hospital centre (CHU)
(Quai des Célestins, 69002 Lyon, France)
Room : Salle des Instances

08.45 - 09.00 Welcome coffee

09.00 - 09.15 Welcome and introductions

- Patrick DENIEL, Secretary General Hospices Civils de Lyon
- Bartosz ARŁUKOWICZ, BECA Committee Chair
- Véronique TRILLET-LENOIR, Rapporteur BECA report

09.15 - 09.40 Strategic proposals for the HCL Institute of Cancerology, impact of the Covid-19 pandemic on cancer care

- Prof. Gilles FREYER, Medical Director of the Cancerology Institute in HCL

09.40 - 10.35 Care and research pathways: innovative coordination mechanisms

Short presentations followed by an open discussion on:

1. Immunotherapy : context, digital follow-up and Datasharing at European level
   - Prof. Stéphane DALLE

2. Oncoral & Pacome : follow-up of outpatients with anticancer drugs from the proof of concept to the French government experimentation Article 51
   - Prof. Catherine RIOUFOL

3. JUMP and PULSSO, graduated organisation of treatment after-effects and accessibility to support care
   - Prof. Cyrille CONFAVEUX / Prof. Sophie JACQUIN-COURTOIS / Prof. Elise PERCEAU
10.35 - 11.15 Vulnerable populations. Short presentations followed by an open discussion on:

1. Secure the diagnostic orientation, the course of care and access to therapeutic innovation for older patients with cancer
   - Prof. Claire FALANDRY

2. Paediatric oncology and collaborations within IHOPé
   - Prof. Yves BERTRAND, Head of the Institute of Pediatric Hematology and Oncology (IHOPé) (in association with Dr Marec Bérard)

11.15 - 12.15 Lyon synergies in the field of research. Short presentations followed by an open discussion on:

1. The Lyon Cancer Research Centre (CRCL)
   - Prof. Charles DUMONTET, Deputy Director of the CRCL

2. How can a large university hospital organise itself to develop multi-disciplinary collaborative clinical research projects in oncology?
   - Prof. Benoit YOU

12.15 - 12.30 Conclusions and closing

- Patrick DENIEL, Secretary General Hospices Civils de Lyon
- Véronique TRILLET-LENOIR, Rapporteur BECA report
- Bartosz ARŁUKOWICZ, BECA Committee Chair

12.15 - 12.30 Press Interviews

- Patrick DENIEL, Secretary General Hospices Civils de Lyon
- Véronique TRILLET-LENOIR, Rapporteur BECA report
- Bartosz ARŁUKOWICZ, BECA Committee Chair

12.30 - 13.30 Lunch buffet at HCL offered by Cancéropôle Lyon Auvergne-Rhône-Alpes (CLARA)
Venue: Salle Célestins

*** No interpretation will be provided during lunch ***
13.30 - 16.00  Cancéropôle Lyon Auvergne-Rhône-Alpes (CLARA)  
(Venue: HCL, Salle des Instances)

Meetings with:

- Prof. Pierre Hainaut, Director Cancéropôle Lyon Auvergne-Rhône-Alpes and other experts

1. Presentation of Cancerople CLARA (25 min)
   - Network
   - Missions
   - Structure
   - Key actions and success stories
   - International outreach

2. CLARA strategic vision 2023-2027 (20 min)
   - 5 strategic research areas
   - Integration within health/cancer plans at territorial level
   - Relevance to national and European strategies

3. The Canceropole model: contribution to Europe’s cancer plan (10 min)

16.00 - 17.00  Bus Transfer to Lyon-Saint Exupéry Airport and individual departures

End of the mission
3. Mission Participants

- Bartosz ARŁUKOWICZ EPP, BECA Chair
- Sara CERDAS S&D, BECA Vice-Chair
- Cindy FRANSSEN EPP
- Nicolás GONZÁLEZ CASARES S&D
- Nicolae ŞTEFĂNUŢĂ Renew
- Joelle MÉLIN ID

Accompanying Member:
- Véronique TRILLET-LENOIR Renew, BECA Rapporteur

4. Main conclusions

The BECA mission reinforced the committee’s international partnerships including with World Health Organisation (WHO) senior management and the International Agency for Research on Cancer (IARC) to deliver on Europe’s Beating Cancer Plan. Members showed leadership and commitment to align initiatives in the fight against cancer globally and to eradicate health inequalities. All parties acknowledged the significant potential for coordinated action and pledged to cooperate even more closely on their shared objectives to advance the fight against cancer. The impact of the COVID-19 pandemic on cancer care and control and the need for building more resilient health systems were amongst the key topics extensively debated.

The intense two-day programme that included multiple and very varied meetings allowed Members to gain a more in-depth understanding of the objectives and policies of the organisations that were visited and the key challenges related to strengthening the fight against cancer at global, national regional and local level.

5. Mission Report

Link to the full Mission Report
PART 3
WRITTEN ANALYSIS & EXPERTISE
XII. Background notes prepared by the BECA Secretariat
BACKGROUND NOTE ON CANCER RESEARCH

Context

Article 168 TFEU empowers the EU to support, coordinate or supplement the actions of the Member States for the protection and improvement of human health. EU action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning and combating of serious cross-border threats to health. To accomplish its task, the EU has been working in close cooperation with the Member States, the World Health Organisation, the Joint Research Centre and the International Agency for Research on Cancer.

Cancer is not a single disease, but a family of more than two hundred diseases. The number of cancer diagnoses is increasing annually; currently it is 2.7 million new diagnoses per year in the EU-27, which is expected to increase by 25% by 2035 under the current trend. Even more alarming is the fact that one quarter of all cancer cases occur in Europe, while Europe represents only 10% of the world’s population. Basic cancer research, translational research (i.e. building on basic research to create new therapies, medical procedures or diagnostics) and clinical research (in which people, data or samples of tissue from people, are studied) are crucial for the continuous advancement in cancer prevention, diagnosis, treatment and follow-up care.

Research and innovation on cancer is a high priority for the EU; however, disparities exist within and between the Member States, which leads to inequalities in outcomes, cancer research and control. Designating cancer as one of the mission areas of Horizon Europe, the next research and innovation funding programme, and putting cancer research high on the agenda of the upcoming Europe’s Beating Cancer Plan will help to address the disparities across the EU.
R&D and cancer research spending in perspective

To put into perspective the EU funding for R&D and cancer research activities, it is worth looking at how much is spent by the Member States and in the big economies.

The Europe 2020 strategy, adopted in 2010, maintains the long-standing objective for the EU to devote 3% of GDP to R&D activities. Though Member States have gradually increased their spending on R&D, the target at EU-level has not been achieved yet. In 2018, Gross Domestic Expenditure on R&D was 294.5 billion EUR in the EU-27; that is equivalent to 60% of the expenditure of the US, more than double the expenditure of Japan, and more than four times as high as in South Korea.

The ratio of this expenditure relative to GDP (the R&D intensity) increased modestly in the EU-27 during 2008-2012, and even more slowly in 2012-2018, where it was fluctuating within the range of 2.10% to 2.18%. Despite these increases, the EU-27’s R&D expenditure relative to GDP remained well below the corresponding ratios of Japan (3.28%) and the US (2.82%), as has been the case for a lengthy period of time. R&D intensity in China has come close to that of the EU-27 since 2015, and in 2018 Chinese R&D expenditure was equivalent to 2.14% of GDP.

In 2018, in the EU-27, business enterprises funded more than half (58.9%) of the total R&D expenditure, while almost one third (29.8%) was funded by government, and a further 9.2% came from abroad (foreign funds). Funding by the higher education and private non-profit sectors was relatively small, around 1% for each.

Assessing the share of cancer research within the overall R&D expenditure is not an easy exercise. In some cases, research projects are clearly linked to cancer (focus on one or more different cancer

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205 Eurostat, R&D expenditure in Europe in 2008-2018. Further information on cancer research in the US and Japan are available from the NIC and AMAD.
types) but there are also cases where links are not obviously clear as they focus on the interventions, basic research and other aspects linked to cancer. It is estimated that EU funding accounts for less than 10% of the total public spend on cancer research and innovation in Europe.

**Cancer research activities and funding under Horizon 2020**

Horizon 2020, the EU’s current research framework programme, runs from 2014 to 2020 with an overall budget of close to 80 billion EUR\(^{206}\). Focussing on the three priorities of ‘excellent science’, ‘industrial leadership’ and ‘societal challenges’, the programme offers support to the whole spectrum of activities of research, technological development, demonstration and innovation.

The biggest share of the budget, 38.5% or nearly 30 billion EUR is allocated to the ‘societal challenges’ priority and its seven so-called specific objectives. One of the specific objectives is health, demographic change and well-being, with a seven-year budget of almost 7.47 billion EUR; this is where cancer-related research and innovation falls.

Multiannual work programmes turn the research policy priorities into concrete research actions. After an extensive consultation process with Member States, the Commission prepares the multiannual work programme, setting out funding opportunities through calls for proposals. The involvement of experts via the SC1 Advisory Group and the Scientific Panel for Health, and the targeted stakeholder consultation ensures that the research agenda is relevant, linked to the reality on the ground, and results can be taken up in clinical practice or used for further research and innovation.

Funding opportunities are allocated to transnational collaborative projects, blue-sky research, training of researchers, support to SMEs, and projects carried out via public-private partnerships.

Over the past seven years, approximately 1400 cancer research projects received a total funding of 2 billion EUR from Horizon 2020 or about 0.3 billion EUR per year. Around 50 projects supported childhood cancer for a total EU funding of 102 million EUR from Horizon 2020. EU funding aims at supporting research throughout the cancer continuum, from prevention, screening and early diagnosis, treatment and care, as well as quality of life for patients living with and after cancer\(^{207}\).


\(^{207}\) Source: Commission inquiry; Cordis paediatric cancer research under Horizon 2020, and cancer research under Horizon 2020; Commission’s Horizon 2020 Dashboard
The research agenda of partnership activities reinforces the efforts of, and creates synergies with, Horizon 2020. These partnership activities are the European Joint Technology Initiative on Innovative Medicines (IMI-2); the two Art.185 initiatives: Ambient Assisted Living (AAL) and the European Developing countries Clinical Trials Partnership (EDCTP); the European Innovation Partnership on Active and Healthy Ageing (EIP AHA); as well as from the three SC1-related Joint Programming Initiatives on Neurodegenerative Diseases (JPND), on Anti-Microbial Resistance (JPIAMR) and on Demographic Change (More Years, Better Lives); and the EIT-KIC Health and Active Ageing.

Furthermore, the Union supports, or has supported, several other initiatives outside the Horizon 2020 framework, through the Health Programme:

- **CanCon**, Cancer Control Joint Action, whose main deliverable was a European guide on quality improvement in comprehensive cancer control;
- **EPAAC**, European Partnership for Action Against Cancer, which brought together the efforts of different stakeholders into a joint response to prevent and control cancer;
- **iPAAC**, Innovative Partnership for Action Against Cancer, which builds upon deliverables of the CANCON Joint Action and implements innovative approaches to cancer control;
- **JARC**, Joint Action Rare Cancers, which is a framework for EU stakeholders and policy makers to set the agenda at national level and help provide diagnostics, healthcare and support to citizens who suffer from rare cancer;
- **ERN PaedCan**, the European Reference Network on Paediatric Cancer, which was funded by the European Union’s Health Programme (2014-2020);
- **ERN EURACAN**, the European Reference Network for rare adult solid tumours;
- **ERN EuroBloodNet**, the European Reference Network for rare haematological diseases including malignant and non-malignant conditions;
- **ERN GENTURIS**, the European Reference Network for rare genetic tumour risk syndromes.

An overview on a selection of the tangible outcome of EU-funded research and innovation activities, highlighting the practical application and the direct impact of research on patients’ lives is available [here](#).

The interim evaluation of Horizon 2020 concluded that Societal Challenge 1 ‘Health, demographic change and wellbeing’ (SC1) was on track to deliver on its objectives. The biggest share of the funding, 43%, had been allocated to ‘Treating and managing disease’, followed by ‘Active ageing and self-management of health’ (13.5 %), ‘Understanding health, wellbeing and disease’ (10.5%), ‘Preventing disease’ (9.5%), ‘Methods and data’ (7%) and ‘Health care provision and integrated care’ (3.5%). The final evaluation of Horizon 2020 will be carried out once the programming period is over, and all projects are closed.
**Cancer research activities and funding under Horizon Europe**

Legislation putting in place the next framework research programme, Horizon Europe (2021-2027) is not yet finalised as the Multiannual Financial Framework for that programming period is still under negotiation. When presenting the legislative proposal in 2018, the Commission proposed a gradual increase of the research budget: the 94.1 billion EUR-budget would have been repatriated amongst three pillars of the programme, ‘open science’, ‘global challenges and industrial competition’ and ‘open innovation’. The second pillar, ‘global challenges’ would have more than half of the budget (57.2 billion EUR); this is where health-related research belongs as one of the five clusters of the pillar. In its first reading position, Parliament proposed to substantially increase the budget of the programme to 120 billion EUR, allocating 55.48% to the second pillar, and 8.16%, i.e. 9.79 billion EUR for the health cluster.

Following a political agreement on large parts of the draft legislation in spring 2019, the Commission, together with Member States and all concerned stakeholders, launched a co-design process to prepare for the first work programmes. Part of this preparation concerns the definition of the desired impacts and funding priorities. The result of the process will be set out in a multiannual Strategic Plan to prepare the content in the work programmes for the first four years of Horizon Europe, which will be published in the first quarter of 2021.

The COVID-19 pandemic and the ensuing economic and health crises shifted the priorities of the EU’s long-term budget. According to the deal made by the European Council in July 2020, the financial envelope for the implementation of the Horizon Europe programme for the period 2021-2027 would be 75.9 billion EUR. In the final stage of the negotiations, Parliament still insists that programmes in areas such as health and research should receive extra funding; while the German Presidency says that it is willing to

**The need for a paediatric and rare cancer research agenda**

Pursuant to the incidence-based definition of rare cancers by the RARECARE project, rare cancers are considered as the ones with less than 6 new cases out of 100,000 people per year in the European population. Though they are individually rare, they affect many patients: one quarter of all cancers diagnosed each year are rare cancers, and altogether approximately 5.1 million patients are suffering from rare cancers all over Europe. Given their uncommon nature, they pose specific challenges concerning clinical research, healthcare organisation and clinical decision-making. Research in rare cancers is hindered by the shortage of biological samples from patients, the challenging organisation of clinical trials, and the lack of clinical expertise and suboptimal quality of care.

Cancer is the main cause of death in children of older than one year, and incidence rates have been increasing continuously over the last decades. Paediatric cancers develop early in life and over a much shorter period, opposed to adult cancers which result from long-term processes. Cancers in adolescents and young adults also require special attention, as their biological characteristics are different both from early childhood cancers and from cancers in adults. Among children, several types of rare cancers occur, which have specific epidemiological, biological and clinical characteristics. For these reasons, understanding how cancers in children, adolescents and young adults start and develop is crucial for better prevention and developing more efficient treatment options. As an indicator of the current state of play, it is worth mentioning that more than 150 cancer medicines were developed in the last decade, and only nine of them, i.e. 6% were approved for children.

*Source: Study ‘Strengthening Europe in the fight against cancer’, Chapter 4; Cancer Mission outline, Recommendation 11*

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208 Legislative procedure 2018/0224(COD)
find 10 billion EUR for the programmes, they also caution that any structural changes to a deal reached by leaders in July are unacceptable.

What did not change with the pandemic is the importance of cancer-related research, which will be one of the ‘missions’ of Horizon Europe. According to the draft legislation, missions are bold and inspirational research activities, sparking activity across disciplines, sectors and actors, and have a wide societal or economic relevance; they aim to deliver solutions to some of the greatest challenges of our times.

The Cancer Mission has a Mission Board, composed of experts in the field of cancer research, public health policy, healthcare provision and practice, and patient advocacy, whose task is to identify the details of the mission. Following an initial report and public consultation, they presented their report this September, outlining ambitious targets by 2030.

**Recommendations for the Cancer Mission, according to the September 2020 Mission outline**

<table>
<thead>
<tr>
<th>Understand cancer, its risk factors and impact</th>
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<tbody>
<tr>
<td><strong>Recommendation 1:</strong> Launch UNCAN.eu – a European Initiative to Understand Cancer</td>
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<td><strong>Recommendation 2:</strong> Develop an EU-wide research programme to identify (poly-)genic risk scores</td>
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<th>Prevent what is preventable</th>
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<tr>
<td><strong>Recommendation 3:</strong> Support the development and implementation of effective cancer prevention strategies and policies within Member States and the EU</td>
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<td><strong>Recommendation 4:</strong> Optimise existing screening programmes and develop novel approaches for screening and early detection</td>
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<tr>
<th>Optimise diagnostics and treatment</th>
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<td><strong>Recommendation 5:</strong> Advance and implement personalised medicine approaches for all cancer patients in Europe</td>
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<td><strong>Recommendation 6:</strong> Develop an EU-wide research programme on early diagnostic and minimally invasive treatment technologies</td>
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<th>Support quality of life</th>
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<tr>
<td><strong>Recommendation 7:</strong> Develop an EU-wide research programme and policy support to improve the quality of life of cancer patients and survivors, family members and carers, and all persons with an increased risk of cancer</td>
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<tr>
<td><strong>Recommendation 8:</strong> Create a European Cancer Patient Digital Centre where 25 cancer patients and survivors can deposit and share their data for personalised care</td>
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<th>Ensure equitable access</th>
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<td><strong>Recommendation 9:</strong> Achieve Cancer Health Equity in the EU across the continuum of the disease</td>
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<td><strong>Recommendation 10:</strong> Set up a network of Comprehensive Cancer Infrastructures within and across all EU Member States to increase quality of research and care</td>
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<th>Cross-cutting recommendations</th>
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<tr>
<td><strong>Recommendation 11:</strong> Childhood cancers and cancers in adolescents and young adults: cure more and cure better</td>
</tr>
</tbody>
</table>
Recommendation 12: Accelerate innovation and implementation of new technologies and create Oncology-focused Living Labs to conquer cancer

Recommendation 13: Transform cancer culture, communication and capacity building

Source: Cancer Mission outline, September 2020

This Mission outline serves as a basis for defining and developing synergies with national cancer plans and other programmes of Member States, with other Horizon Europe Missions and research and investment programmes, and with other EU policies actions, in particular the Europe’s Beating Cancer Plan. The final Cancer Mission report, due in December 2020, will feed the work programmes of Horizon Europe.

Available expertise

✓ Cancer research

Chapter 3, point 3 (pp 108-117) of the study Strengthening Europe in the fight against cancer - Policy Department for Economic, Scientific and Quality of Life Policies, July 2020

✓ Rare cancers and childhood cancers

Chapter 4 of the study Strengthening Europe in the fight against cancer - Policy Department for Economic, Scientific and Quality of Life Policies, July 2020

✓ Horizon 2020

Scrutiny on Horizon 2020 focusing on the European Parliament’s priorities - Study - Policy Department for Economic, Scientific and Quality of Life Policies, July 2020

Interim evaluation of Horizon 2020 - Briefing - EPRS, March 2018

Assessment of the Horizon 2020 programme - Study - Policy Department on Budgetary Affairs, January 2016

✓ Horizon Europe

Horizon Europe: Framework programme for research and innovation 2021–2027 - Briefing - EPRS, May 2019
BACKGROUND NOTE ON LIFESTYLE-RELATED AND VACCINE-PREVENTABLE RISK FACTORS, AND PREVENTION STRATEGIES

I. Context

Nearly 3 million people are diagnosed with cancer every year in the EU, and it is estimated that in 2020 1.3 million will die of it. Around 40% of these cases are caused by modifiable risk factors and can be prevented, and screening and early diagnosis and access to proper and timely treatment can reduce mortality.

Cigarette smoking and other forms of tobacco use is responsible for 15-20% of all European cancer cases, that is the top avoidable risk factor. Other life-style related factors such as unhealthy diet, lack of physical activity, sedentary lifestyle, obesity and alcohol consumption, also take a prominent place. Infections by carcinogenic viruses or bacteria (HPV, HBV, HCV and Helicobacter pylori), environmental factors (UV and ionising radiation, pollution) and occupational factors (e.g. exposure to asbestos) also have a well-established causative link to cancer. Finally, other biological or internal factors such as no breastfeeding, postmenopausal hormonal replacement therapies and carcinogenic pharmaceutical drugs are also associated with cancer development. Avoiding, or limiting exposure, to these risk factors can prevent the development of cancer. Screening programmes are

In this note
- Tobacco: carcinogens, cancer, smoking patterns, prevention
- Alcohol: carcinogens, drinking patterns, cancer, prevention
- Nutrition and obesity: carcinogens in food, obesity, physical (in)activity, sedentary lifestyle, cancer types, prevention, colorectal cancer screening
- Infectious agents: cancer burden, HPV, H.pylori, HBV, HCV
- Sunlight and UV radiation
- National cancer control plans
- European Code against Cancer
crucial to detect cancer at pre-cancerous or at early stage, ensuring that can receive treatment before cancer spreads further.

### Modifiable risk factors and potential for primary cancer prevention

<table>
<thead>
<tr>
<th>By risk factor</th>
<th>By cancer type</th>
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<tbody>
<tr>
<td>Tobacco</td>
<td>Cervix</td>
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<tr>
<td>Obesity/Inactivity</td>
<td>Oral cavity</td>
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<td>Diet</td>
<td>Lung</td>
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<td>Alcohol</td>
<td>Ceesophagus</td>
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<td>Infections</td>
<td>Melanoma</td>
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<td>Radiations</td>
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<td>Occupation &amp; Environment</td>
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<tr>
<td>Not preventable:</td>
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<tr>
<td>Utilisation</td>
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</table>

Source: Cancer prevention - modifiable risk factors; proceedings from the workshop organised for the ENVI Committee, p.2

This note focuses mostly on lifestyle-related risk factors and infectious agents, which are subject to the upcoming BECA Committee hearing on 2 December 2020. It compiles publicly available, neutral and scientifically sound information, and relies mostly on publications by the International Agency for Research on Cancer\(^\text{209}\), the OECD and the European Commission\(^\text{211}\), the World Health Organisation’s Regional Office for Europe\(^\text{212}\), and the European Centre for Disease Prevention and Control\(^\text{213}\).

### II. Tobacco

Cigarettes are the predominant form of tobacco use, with non-cigarette products gaining popularity recently. The latter includes electronic nicotine delivery systems (ENDS, which heat a nicotine solution without producing a smoke), heated tobacco products (which heat tobacco instead of a nicotine solution), water pipes and cigars.

#### II.1. Carcinogens in tobacco

\(^\text{209}\) Cancer prevention - modifiable risk factors; proceedings from the workshop organised for the ENVI Committee; [https://www.europarl.europa.eu/cmsdata/206720/PE%20648.765.pdf](https://www.europarl.europa.eu/cmsdata/206720/PE%20648.765.pdf)


\(^\text{212}\) World Health Organisation, Regional Office for Europe; [https://www.euro.who.int/en/health-topics/disease-prevention](https://www.euro.who.int/en/health-topics/disease-prevention)

Cigarette smoke contains more than 8000 compounds, of which more than 70 are carcinogens. Some of those carcinogens are particularly important, including tobacco-specific nitrosamines, polycyclic aromatic hydrocarbons, and aromatic amines. Smoke from other combustible products exposes the smoker to many carcinogens that we find in cigarette smoke. Water pipe smoking also exposes the user to high levels of carcinogens, which remain present even when passing through water; and as water pipe users breathe very deeply when smoking, they inhale much smoke. The long-term impact of non-cigarette products is not yet fully understood; but it is known that even if exposure of users to toxic and carcinogenic compounds is lower, it can lead to nicotine addiction and can drive users to more traditional forms of tobacco use, incl. cigarettes.

**II.2. Smoking patterns**

Though some progress has been made over the last decade, according to 2018 data from the EU, more than 20% of adults still smoked daily. The proportion of adults who smoke daily is the lowest in Nordic countries, and three and half times higher in Greece, Bulgaria and Hungary. Concerning children and adolescents, tobacco smoking continues to decline in most EU countries, but many adolescents still smoke. According to 2018 data, on average across EU countries, 18% of 15-year-olds reported having smoked cigarettes at least once in the past month. Early smoking has immediate and long-term health consequences; it increases the risks of respiratory diseases in the short term, and the risks of cardiovascular diseases, respiratory illnesses and cancer in the long term.

The ‘[Special Eurobarometer 458](https://www.eurostat.ec.europa.eu)’ reveals citizens’ attitude towards tobacco and electronic cigarettes.

**II.3. Tobacco-related cancers**

There are at least 20 different types or subtypes of cancer known to be linked to cigarettes, with tracheal, bronchial and lung cancers affecting most of the patients. Worldwide, an estimated 2.4 million tobacco-related cancer deaths occur per year. 15-20% of cancer cases and 27% of cancer deaths are currently attributable to tobacco use in Europe. Second-hand smoke, i.e. the exposure of non-smokers to smoke exhaled by others is an established cause of lung cancer.

Putting cancer burden into context, it is of note that compared to the rest of the world, the WHO’s European Region has one of the highest proportions of deaths attributable to tobacco. In the European Region, an estimated 16% of all deaths among adults over 30 are due to tobacco use, compared to the global average of 12%. Around 50% of smokers die prematurely (on average 14 years earlier) which, from a health economies point of view is a significant drain to the economic wellbeing and poses excessive stress to the healthcare system.
Types of cancer caused by cigarette smoking

<table>
<thead>
<tr>
<th>Cancer site or type</th>
<th>Year formally classified by the United States Surgeon General</th>
<th>Year formally classified by the IARC Monographs</th>
<th>Relative risk for current versus never smoking</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lip, oral cavity, pharynx</td>
<td>1964/1971*</td>
<td>1985</td>
<td>5.7</td>
<td>5.6</td>
<td></td>
</tr>
<tr>
<td>Oesophagus</td>
<td>1902</td>
<td>1966</td>
<td>3.9</td>
<td>5.1</td>
<td></td>
</tr>
<tr>
<td>Stomach</td>
<td>2004</td>
<td>2004</td>
<td>1.9</td>
<td>1.7</td>
<td></td>
</tr>
<tr>
<td>Colon/rectum</td>
<td>2014</td>
<td>2012</td>
<td>1.4</td>
<td>1.6</td>
<td></td>
</tr>
<tr>
<td>Liver</td>
<td>2014</td>
<td>2004</td>
<td>2.3</td>
<td>1.6</td>
<td></td>
</tr>
<tr>
<td>Pancreas</td>
<td>1982</td>
<td>1986</td>
<td>1.6</td>
<td>1.9</td>
<td></td>
</tr>
<tr>
<td>Larynx</td>
<td>1964</td>
<td>1986</td>
<td>13.0</td>
<td>10.3</td>
<td></td>
</tr>
<tr>
<td>Trachea, lung, bronchus</td>
<td>1964/1966*</td>
<td>1986</td>
<td>25.3</td>
<td>22.9</td>
<td></td>
</tr>
<tr>
<td>Cervix</td>
<td>2004</td>
<td>2004</td>
<td>–</td>
<td>3.5</td>
<td></td>
</tr>
<tr>
<td>Bladder</td>
<td>1970</td>
<td>1986</td>
<td>3.9</td>
<td>3.9</td>
<td></td>
</tr>
<tr>
<td>Kidney, other urinary tract</td>
<td>1982</td>
<td>2004</td>
<td>1.8</td>
<td>1.2</td>
<td></td>
</tr>
<tr>
<td>Acute myeloid leukaemia</td>
<td>2004</td>
<td>2004</td>
<td>1.9</td>
<td>1.1</td>
<td></td>
</tr>
</tbody>
</table>

* Lip cancer was classified as causal in 1964 and other oropharyngeal cancers in 1971.
* Lung cancer was classified as causal in men in 1964 and in women in 1968.

Source: IARC, p. 54, table 2.1.1

II.4. Prevention of smoking and related cancers

Targeted policy actions and legislative measures have contributed to lowering smoking rates amongst adults and young people. The WHO Framework Convention on Tobacco Control (WHO FCTC) to which the EU and all Member States are parties, and the revised Tobacco Products Directive (TPD - 2014/40/EU) set the context into which national measures fit. The WHO FCTC, in force since 2005, is a real paradigm shift in the regulatory approach towards addictive substances; instead of simple control measures, it addresses demand reduction strategies and supply issues as well.

The revision of the 2001 TPD has adapted the EU’s rules to the changing market, scientific and international developments. The TPD mandates health warnings on packages of tobacco and related products, bans promotional and misleading elements on tobacco products, and tightens safety and quality requirements for e-cigarettes containing nicotine. The sale of cigarettes with characterising flavours, and in slim packaging, both mainly targeting adolescents and young age groups with limited spending power, are now banned. The Joint Action on Tobacco Control is a collaborative action between the Member States and the Commission, which pools knowledge and provides a platform for exchange of good practices, in order to support the implementation of the TPD, and the formulation of tobacco control policies.

Increasing taxes on tobacco is one of the most effective ways to reduce tobacco use and to encourage users to quit smoking. Council Directive 2011/64/EU requires Member States to levy excise duty on tobacco, and sets the harmonised minimum rates and the structure of the excise duty. Aa number of EU countries recently increased taxes on tobacco products.

Creating a smoke-free environment and protect non-smokers from second-hand smoke forms an integral part of prevention policies. The WHO FCTC calls for adopting measures which provides for protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places and, as appropriate, other public places. Council Recommendation 2009/C 296/02 elaborated
Regulating tobacco advertising is an important element of the policy mix. The Tobacco Advertising Directive (2003/33/EC) introduced an EU-wide ban on cross-border tobacco advertising and sponsorship in the print media, radio, internet and sponsorship of events involving several EU countries (e.g. Olympic Games and Formula One races). Tobacco advertising and sponsorship on television was prohibited already in 1989; the updated Audiovisual Media Services Directive (2010/13/EU) extended the application of this ban to all forms of audiovisual commercial communications, including product placement.

III. Alcohol

In 2016, at global level, almost 43% of the adult population consumed alcohol. In the same year, an estimated 376,200 cancer deaths, representing 4.2% of all cancer deaths, was due to alcohol. The worrying global trend shows that, resulting from population growth, ageing and the economic development of countries, the total number of alcohol-attributable cancer deaths worldwide increased from 8.1 million in 2010 to 9 million in 2016.

III.1. Carcinogens in alcohol

Numerous carcinogenic compounds can be found in alcoholic beverages, but it is ethanol that poses the biggest risk. Alcohol is linked to cancer in different parts of the digestive system (oral cavity, oropharynx, hypopharynx, oesophagus, colon, rectum, liver and intrahepatic bile duct, larynx), as well as in female breast. Cancer risk is clearly linked to the amount of alcohol consumed during lifetime; for female breast cancer the patterns of alcohol consumption, in particular episodic heavy drinking, may also have an important role.

III.2. Drinking patterns

Alcohol-related harm is a major public health issue in the EU. High alcohol consumption is associated with increased risk of heart diseases and stroke, liver cirrhosis, certain cancers and foetal alcohol disorders; even moderate alcohol consumption increases the long-term risk of developing such diseases. Alcohol also contributes to morbidity and mortality through accidents and injuries, violence, homicide and suicide. Over the past decade, alcohol consumption has decreased in most EU countries: measured through sales data, overall alcohol consumption was 10 litres of pure alcohol per adult in
2018, down from 11 litres in 2008. Drinking initiation and heavy drinking in adolescence are of particular concern, given their severe health, education and social consequences. Two-thirds of European adolescents report having drunk alcohol at least once in their life by age 15, and over 20% report repeated drunkenness, though the legal drinking age in most EU countries is 18. The overall trend, however, is positive, with the proportion of 15-year-olds reporting repeated drunkenness declining significantly in most EU countries over the past two decades (decreasing from 41% to 24% for boys, and from 29% to 20% for girls).

III.3. Cancer types and cancer burden

Alcohol-attributable cancer deaths, by gender and cancer site

<table>
<thead>
<tr>
<th>Outcome and cancer site</th>
<th>ICD-10 code</th>
<th>Number of alcohol-attributable deaths/100000 (95% uncertainty interval)</th>
<th>Percentage of deaths attributable to alcohol consumption (95% uncertainty interval)</th>
<th>Percentage of the total alcohol-attributable cancer deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>C00–C07</td>
<td>207.6 (246.9–346.1)</td>
<td>57.6 (48.8–66.8)</td>
<td>100.0</td>
</tr>
<tr>
<td>Lip and oral cavity</td>
<td>C09–C14</td>
<td>36.9 (39.4–46.0)</td>
<td>5.2 (3.6–7.3)</td>
<td>11.7</td>
</tr>
<tr>
<td>Other pharynx</td>
<td>C09–C14</td>
<td>31.7 (24.9–37.7)</td>
<td>2.1 (1.5–3.0)</td>
<td>9.0</td>
</tr>
<tr>
<td>Oesophagus</td>
<td>C15</td>
<td>56.9 (51.6–79.7)</td>
<td>5.6 (3.9–9.9)</td>
<td>19.3</td>
</tr>
<tr>
<td>Colorectum</td>
<td>C18–C21</td>
<td>75.9 (61.6–89.7)</td>
<td>13.8 (6.6–25.2)</td>
<td>23.9</td>
</tr>
<tr>
<td>Liver</td>
<td>C22</td>
<td>65.1 (51.5–102.5)</td>
<td>13.8 (9.5–34.4)</td>
<td>22.3</td>
</tr>
<tr>
<td>Larynx</td>
<td>C32</td>
<td>19.1 (14.8–23.1)</td>
<td>5.8 (3.9–10.0)</td>
<td>8.5</td>
</tr>
<tr>
<td>Breast</td>
<td>C50</td>
<td>–</td>
<td>5.0 (2.6–8.8)</td>
<td>5.3</td>
</tr>
<tr>
<td>All causes</td>
<td>A00–Z09</td>
<td>2307.3 (1926.7–2720.1)</td>
<td>681.0 (536.4–990.7)</td>
<td>–</td>
</tr>
</tbody>
</table>

Source: IARC, p. 73, table 2.3.1

Alcohol-attributable cancer deaths by 100 000 people, per region

Source: IARC, p. 74, table 2.3.6
III.4. **Prevention of drinking and related cancers**

Many European countries have implemented a range of policies to limit alcohol consumption. The EU’s 2006 alcohol strategy sets a framework, the Committee on National Alcohol Policy and Action plays a major role in coordination between the Member States, and the European Information System on Alcohol and Health, maintained through the cooperation of the Commission and the WHO, monitors trends and developments in alcohol consumption and alcohol-related harm.

Alcohol taxation is the main tool, used by all Member States, to influence alcohol prices. Similarly to tobacco, the obligation to levy an excise duty on alcoholic beverages, and its harmonised minimum level and structure are set out in a Council Directive (Council Directive 92/83/EEC). The directive has been recently revised, and the new rules will be applicable from the beginning of 2022.

Tax can be levied based on the alcohol content (specific taxation), the overall product volume (unitary taxation) or the price of the product (ad valorem taxation). From public health protection perspective, the best method is when the tax payable is directly proportional to the alcoholic content of the product; but practice shows that Member States apply a hybrid tax system where components of specific, unitary and ad valorem taxation are mixed; and where different types of alcoholic beverages are taxed at different rates.

Minimum unit pricing of alcohol also contributes to drinking less. It is not in force in any EU Member State (Scotland and Wales have it in place, and legislation passed in Ireland in 2018, but it is not yet in force) but is applied in a few countries of the WHO Europe Region. Evidence from those countries proves the effectiveness of the policy; its added value is that it effectively targets cheap and strong products and discourages their consumption; thus, it contributes to reducing health inequalities.\(^{214}\)

In the international scene, the WHO Global Alcohol Strategy recommends to regulate the content and the volume of alcohol marketing, while its European Action Plan proposes a total ban on alcohol advertising for Europe. At EU-level, the Audiovisual Media Services Directive (Directive 2010/13/EU) regulates alcohol advertising on television, and it imposes restrictions for the protection of minors and for promoting moderate, responsible consumption of alcohol. Sweden introduced a complete ban on alcohol marketing on TV, while the majority of Member States apply time-based or content-based restrictions.

Advertising on social media and the internet is now also regulated; restrictions on the content and/or the placement of advertising are the most common methods, though some countries have pushed further and put in place advertising bans on social media. About one-third of European countries have voluntary agreements on industry sponsorship of sport and youth events, while one-quarter have no such restrictions at all. Crucial for the reduction of alcohol drinking among adolescents are the restrictions on location and hours of sales, and the raising of the minimum legal age for drinking.

\(^{214}\) Alcohol pricing in the WHO European Region, [https://apps.who.int/iris/bitstream/handle/10665/336159/WHO-EURO-2020-1239-40989-55614-eng.pdf?sequence=1&isAllowed=y](https://apps.who.int/iris/bitstream/handle/10665/336159/WHO-EURO-2020-1239-40989-55614-eng.pdf?sequence=1&isAllowed=y)
The labels on alcoholic beverages allow consumers to know the alcohol content of the product, and guide them in making informed, conscious choices. According to the Food Information to Consumers Regulation (FIC - Regulation (EU) No 1169/2011), the alcoholic strength by volume is a mandatory element of the label for alcoholic beverages with more than 1.2% alcohol content. These alcoholic beverages are, however, exempted from indicating the list of ingredients and the nutrition declaration on the label. The regulation tasked the Commission to monitor the situation and presenting a report whether these labelling requirements should apply to alcoholic beverages as well. In the report, the Commission called on the industry to present self-regulatory proposals. Having done that, memorandums of understanding have already been signed with certain sectors.

Research shows that the majority of the general population is still unaware of the causal link between alcohol consumption and the development of cancer, therefore awareness raising campaigns and explanation by general practitioners remain crucial. Warning labels could be used to underline the link between alcohol and cancer; however, the effectiveness of these labels to reduce alcohol consumption is currently unknown.

All the above measures, designed to reduce alcohol consumption in general, are effective and cost-effective means for the prevention of alcohol-related cancers. Measures that target those risk factors that interact with alcohol consumption (either increase the risk of cancer, or directly affect the risk of alcohol-related cancers) such as tobacco smoking may have a spill-over effect and can reduce alcohol-attributable cancer risk.

IV. Nutrition and obesity

Diet can influence cancer risk many years before the diagnosis of cancer, already during childhood. Diets with ample intake of fruits and vegetables, whole grains instead of refined grains, and low intake of red meat and processed meat, sugar-sweetened beverages, and salt will reduce the risk not only of cancer, but also of cardiovascular disease, diabetes, and overall mortality. Recent evidence also supports that the same dietary pattern has benefits on cancer survival for at least some cancer types, although research on this subject is still limited.

IV.1. Carcinogens in food

The World Cancer Research Fund/American Institute for Cancer Research (WCRF/AICR) drew conclusions on the link between diet and cancer risk:

- In 2015, IARC classified the consumption of processed meat as carcinogenic to humans, and the consumption of red meat as probably carcinogenic to humans. For each 50 grams of processed meat consumed per day, the risk of colorectal cancer increases by approximately 16%, and the risk of colon cancer by 23%. For each 100 grams of red meat consumed per day, the risk of colorectal cancer increases by about 12%, and for colon cancer by 22%.

- A large study in France compared men and women with less than 12% of energy intake from ultra-processed foods with those who had more than 25% of energy intake from ultra-
processed foods. This latter group had a 23% higher risk of any cancer, a 23% higher risk of colorectal cancer, and a 38% higher risk of postmenopausal breast cancer. Excess sugar and energy, low dietary fibre and micronutrients, added preservatives and other ingredients, carcinogens formed during processing, and sedentary lifestyle (which is often linked to the consumption of fast food) may all relate to cancer risk.

- WCRF/AICR categorised as probable the evidence that consumption of whole grains decreases risk of colorectal cancer. WCRF/AICR also categorised as probable the evidence that consumption of dietary fibre is associated with lower risk of colorectal cancer, weight gain, overweight, and obesity.
- The effects of intake of dairy products and calcium on cancer risk are complex. WCRF/AICR categorised as probable the evidence that higher intake of calcium and dairy products decreases risk of colorectal cancer.
- WCRF/AICR concluded that greater consumption of non-starchy vegetables or fruits probably protects against several cancers of the aerodigestive tract.

Alternate Healthy Eating Index 2017

The scores range between 0 (worst) and 100 (best); dietary data was not available for white areas. Higher scores are given to lower amounts of red meat, sugar-sweetened beverages, salt, and trans fat, and higher amounts of fruits, vegetables, whole grains, nuts and legumes, omega-3 fatty acids, and omega-6 polyunsaturated fatty acids (alcohol is not included). Although scores vary widely across the globe, even those countries with the highest scores (60–65) have considerable room for improvement, because the ideal diet would score 100.

Source: IARC, p. 98, Figure B2.6.3

IV.2. Obesity

In Europe in 2018, 19% of 15-year-olds was either overweight or obese, up from 16% in 2010. Overweight and obesity rates among adolescents is the lowest in the Netherlands, and almost three times higher in Malta. As for adults, 17% of adults were obese in 2018, up from 11% in 2000. This increasing trend is due to a number of behavioural and environmental factors, such as urbanisation, increased sedentary behaviour, and the widespread availability and marketing of energy-dense foods. Obesity rates among adults vary more than two-fold in Europe, and differences show not only geographically but along the social divide as well.
IV.3. Physical (in)activity

The most recent WHO public health recommendations for physical activity are 150 minutes per week of moderate activity, or 75 minutes per week of vigorous activity; anything below that is considered as physical inactivity. The WCRF/AICR committee recommended this target for weekly physical activity as the minimum for cancer prevention.

IV.4. Sedentary lifestyle

Continued sedentary behaviour (sitting in the workplace, at home, during leisure activities and while travelling) has a potentially important role in cancer aetiology. It has not been determined yet what accumulation of daily sedentary behaviour is related to cancer risk, and it is also unclear whether there are specific periods in life when prolonged sedentary behaviour carries a particular risk for developing cancer. Therefore, currently there is not enough evidence to give specific recommendations about limiting daily sedentary time or including breaks from sitting into the day.

IV.5. Cancer types linked to physical inactivity, sedentary lifestyle and obesity

Based on the 2018 scientific report of the Physical Activity Guidelines Advisory Committee, PAGAC, (of the Office of Disease Prevention and Health Promotion, US) and a WCRF/AICR expert synthesis, physical inactivity, sedentary lifestyle and obesity are associated with cancer in numerous sites, as the table below shows.
Evidence on the relationships of physical activity, sedentary behaviour, and obesity to risk of cancer

<table>
<thead>
<tr>
<th>Cancer site</th>
<th>Physical activity</th>
<th>Sedentary behaviour</th>
<th>Obesity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectum</td>
<td>Strong evidence for decreased risk (color)</td>
<td>Limited evidence for increased risk (color)</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Endometrium</td>
<td>Strong evidence for decreased risk</td>
<td>Limited evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Breast (postmenopausal)</td>
<td>Strong evidence for decreased risk</td>
<td>Limited evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Breast (premenopausal)</td>
<td>Strong evidence for decreased risk</td>
<td>Limited evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Oesophageal adenocarcinoma</td>
<td>Strong evidence for decreased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Kidney</td>
<td>Strong evidence for decreased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Bladder</td>
<td>Strong evidence for decreased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Gastric cardia</td>
<td>Strong evidence for decreased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Liver</td>
<td>Limited evidence for decreased risk</td>
<td>Limited evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Lung</td>
<td>Limited evidence for decreased risk</td>
<td>Moderate evidence for increased risk (advanced)</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Prostate</td>
<td>Limited evidence for decreased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Ovary</td>
<td>Limited evidence for decreased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Pancreas</td>
<td>Limited evidence for decreased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Gall bladder</td>
<td>Strong evidence for increased risk</td>
<td>Moderate evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Mouth, pharynx, and larynx</td>
<td>Limited evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Cervix</td>
<td>Limited evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Thyroid</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Multiple myeloma</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Meningioma</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Diffuse large B-cell lymphoma</td>
<td>Moderate evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
<tr>
<td>Male breast</td>
<td>Moderate evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
<td>Strong evidence for increased risk</td>
</tr>
</tbody>
</table>

Source: IARC, p. 107, table 2.7.1

IV.6. Preventive actions

A wide range of policy options exist to tackle obesity, including food and menu labelling, public awareness campaigns, mobile apps, restrictions on food advertising targeting children, school and workplace programmes, and price policies. In general, policies to provide information and to increase the number of healthy options are common, while measures to modify the cost of health-related choices and to regulate promotion of unhealthy choices are less widely used.

In Europe, many countries take actions to improve diet, increase physical activity, and reduce obesity – among their population in general, and among children in particular. Actions at EU level, and the EU regulatory environment plays an important role.

The broader policy context is the EU’s strategy on nutrition, overweight, and obesity-related health issues, which goes back to 2007. The strategy clearly shows how important the partnership is between governments, the private sector, civil society, and the support and coordination by the Commission and the WHO. Specific actions, like the EU Action Plan on Childhood Obesity 2014-20, setting the goal to halt the rise in obesity in children and young people in the EU by 2020, complement the strategy. The EU Platform for Action on Diet, Physical Activity and Health, and the High Level
Group on Nutrition and Physical Activity reinforce the partnership between governments, private sector, the EU and the WHO, and the cooperation with food business operators (manufacturers, retailers, caterers, fast food restaurants), consumer organisations, public health NGOs, and scientific and professional associations.

The Food Information to Consumers Regulation (FIC Regulation (EU) No 1169/2011) mandates nutrition declaration on food labels, and opens the way for using graphical forms or symbols (in addition to the mandatory text) for presenting nutritional information. The French Institute of Public Health developed the Nutri-Score front-of-pack logo, which informs consumers about the nutritional quality of the food in a simplified design; it has been increasingly used by the food industry and retailers in France, and is under development in other European countries. The Nutritional and Health Claims Regulation (Regulation (EC) No 1924/2006) ensures that claims on food such as “low sugar”, “high fibre”, “essential for healthy growth of the children”, etc. are scientifically sound and not misleading. A publicly accessible register holds all permitted claims and their condition for use.

Concerning the composition of food, in 2015, the EU made agreements with food manufacturers, supermarkets and caterers to reduce the amount of added sugars in processed food by minimum 10% by 2020. The maximum limit of trans fat (other than trans fat naturally occurring in fat of animal origin) in food which is intended for the final consumer and in food intended for supply to retail is set by a Commission regulation. A pilot database on the nutritional characteristics of food products in the EU was commissioned in 2017 to help monitor whether food products have increasingly less (or increasingly more) salt, fat or sugars.

These EU-level legislations and actions contribute to making food healthier and accessible, and ensure that consumers make their food choices in a well-informed way, based on accurate and clear information.

Educating about dietary and health issues via mass media campaigns, enabling consumers to make informed choices and shaping consumer habits with the help of warning labels, and diverting consumers’ interest through pricing policies also feature among the measures that Member States apply. Restrictions on advertising food and drinks to children, school-based wellness and educational programmes, reducing the availability of unhealthy food options in schools, encouraging or enabling active transport to school, and family physical activity programmes target specifically children and their parents.

IV.7. Colorectal cancer screening

Recommendations at EU-level on cancer screening and early detection are in place since 2003 (2003/878/EC). The recommendations proposes population-based cervical, female breast and faecal occult blood for colorectal cancer screening programmes. The 2017 report by the Commission on the implementation of the recommendations found that substantial progress were made in colorectal cancer (faecal occult blood) screening in the EU countries. Population-based screening programmes are implemented nationally or regionally in 20 Member States. Non population-based programmes are ongoing in 3 Member States. Immuno-chemical fecal occult blood test (iFOBT or FIT) are the most common screening test in the EU because of its higher sensitivity and logistic advantages.
Endoscopy as a screening test is also being adopted in some Member States. Most of the countries with population-based approach to colorectal screening also have high levels of programme organization.

V. **Infectious agents**

The IARC Monographs programme classified 11 infectious agents, or groups of related agents, as carcinogenic:

- one bacterium, *Helicobacter pylori*;
- seven viruses: 13 carcinogenic subtypes of human papillomaviruses (HPVs), hepatitis B virus (HBV), hepatitis C virus (HCV), Epstein–Barr virus (EBV), Kaposi sarcoma-associated herpesvirus (KSHV), human T-cell lymphotropic virus type 1 (HTLV-1), and HIV-1; and
- three macroparasites: *Schistosoma haematobium*, *Opisthorchis viverrini*, and *Clonorchis sinensis*.

V.1. **Cancer burden**

It is estimated that globally, in 2018, about 13% of new cancer cases (2.2 million) were caused by infection. Four from these infectious agents were responsible for 90% of the new cases; these are HPV, *H. pylori*, HBV and HCV. Through vaccination or treatment, many of those four infections are preventable, curable, or can be kept other control.

The proportion of cancer cases caused by infection varies significantly by geographical region and World Bank income group; in many high-income countries in Australasia, Europe, and North America, fewer than 5% of cancer cases are attributable to infections.
New cancer cases in 2018, attributable to infectious agents (global data)

<table>
<thead>
<tr>
<th>Infectious agent</th>
<th>Cancer types for which there is sufficient evidence of causality</th>
<th>Number of new cancer cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helicobacter pylori</td>
<td>Non-cardia gastric carcinoma, low-grade B-cell mucosa-associated lymphoid tissue (MALT) gastric lymphoma</td>
<td>810 000</td>
</tr>
<tr>
<td>Human papillomavirus</td>
<td>Carcinomas of the cervix, vulva, vagina, penis, anus, oral cavity, oropharynx, and tonsil</td>
<td>690 000</td>
</tr>
<tr>
<td>Hepatitis B virus (chronic infection)</td>
<td>Hepatocellular carcinoma</td>
<td>360 000</td>
</tr>
<tr>
<td>Hepatitis C virus</td>
<td>Hepatocellular carcinoma, non-Hodgkin lymphoma</td>
<td>160 000</td>
</tr>
<tr>
<td>Epstein–Barr virus</td>
<td>Nasopharyngeal carcinoma, Burkitt lymphoma, immunosupression-related non-Hodgkin lymphoma, extranodal NK/T-cell lymphoma (nasal type), Hodgkin lymphoma</td>
<td>160 000</td>
</tr>
<tr>
<td>Kaposi sarcoma-associated herpesvirus</td>
<td>Kaposi sarcoma, primary effusion lymphoma</td>
<td>42 000</td>
</tr>
<tr>
<td>Human T-cell lymphotropic virus type 1</td>
<td>Adult T-cell leukaemia/lymphoma</td>
<td>3 600</td>
</tr>
<tr>
<td>HIV-1</td>
<td>Kaposi sarcoma, non-Hodgkin lymphoma, Hodgkin lymphoma, cervical cancer, anal cancer, conjunctival cancer</td>
<td>—</td>
</tr>
<tr>
<td>Schistosoma haematobium</td>
<td>Bladder cancer</td>
<td>6 000</td>
</tr>
<tr>
<td>Opisthorthis viverrini Clonorchis sinensis</td>
<td>Cholangiocarcinoma</td>
<td>3 600</td>
</tr>
</tbody>
</table>

* Cancers attributable to HIV are included with the underlying causal infections.

Source: IARC, Table 2.2.1, p. 62

V.2. **Human papilloma virus**

V.2.1. **Cancer burden due to HPV infection**

The global cancer burden due to HPV is 570 000, and the death toll is 120 000. Out of the more than 100 types of HPV, at least 14 types are classified as ‘high risk’ that can cause cervical cancer in women, and are also associated with other ano-genital cancers and head and neck cancers in both men and women.

In Europe, cervical cancer is the second most common cancer that affect women in the 15-44 age group; each year, there are around 33 000 new cases of cervical cancer diagnosed, and 15 000 lives are lost. The primary cause of cervical cancer is a persistent infection of the genital tract caused by some highly carcinogenic types of Human Papilloma Virus. HPV 16 and HPV 18 are the most common ‘high-risk’ types, causing about 70 %of all cases of cervical cancer.

Website of the European Centre for Disease Prevention and Control, HPV section

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V.2.2. Prevention of HPV-associated cancers

HPV-associated cancer risk can be reduced by safe sexual practices, male circumcision and a reduction or stop of tobacco use, which is an important co-factor in cervical cancer and head and neck cancers. Over the past 10-15 years, HPV vaccination programmes were successfully deployed in 80 countries. Unfortunately, low-income and lower-middle-income countries, where infection rate and cancer burden is the highest, cannot provide for a vaccination scheme. Therefore cervical screening programmes, in particular those that use HPV-based testing, continue to play an important role in the early detection of the infection or pre-cancerous lesions.

V.2.3. HPV vaccination in the EU/EEA and the UK

Three types of HPV vaccines were granted marketing authorisation in the EU, a bivalent, a quadrivalent and a nine-valent vaccine. All of the licensed vaccines provide protection against HPV types 16 and 18, and are shown to prevent more than 90% of precancerous lesions in the cervix. The nine-valent vaccine additionally prevents more than 90% of precancerous lesions associated with HPV 31, 33, 45, 52 and 58 types. HPV vaccines are given in a two-dose regimen over a six-month period for 9 to 15 years’ old, and in three doses to individuals aged 16 years or older.

The ECDC vaccine guidance\textsuperscript{216} explains that immunising pre-adolescents provides greater benefit and protection, since HPV vaccination is more efficacious when given to subjects who have not been exposed to the virus yet, and the immunogenic response is stronger in pre-adolescents than in adults.

It also underlines that universal, gender-neutral vaccination strategy, though more costly and resource-demanding, would provide more resilient herd protection at lower levels of vaccine uptake. It would also halt the prevalence and circulation of the virus, and could more effectively protect all risk groups. If vaccination uptake is lower in specific population subgroups (in terms of geographical region, ethnicity, socioeconomic status and religion), it would be advisable to re-allocate resources to increasing uptake among these under-vaccinated groups.

V.2.4. Cervical cancer screening in the EU

Recommendations at EU-level on cancer screening and early detection are in place since 2003 (2003/878/EC). The recommendations proposes population-based cervical, female breast and colorectal cancer screening programmes. The 2017 report by the Commission found considerable differences in the approach of Member States to the implementation of cervical cancer screening.

Population-based cervical cancer screening programmes exist in 22 Member States either nationally or regionally. Following the European guidelines, most countries have stopped cervical screening prior to 25 years of age, and have raised the screening intervals to 3-5 years. Gradual introduction of the HPV test as the primary screening modality are offered within organized screening in six Member States. HPV-based programmes in general start at a later age, and the test is performed at 5 years interval (though the 3 years interval is retained for the women below 50 years of age in some countries).

Organised screening programmes have some essential components such as written invitation to all eligible persons with pre-fixed appointments, linking the screening registry to the cancer registry, periodic audit of the incident cancer cases. Most Member States integrated these components into their programmes.

V.3.  *Helicobacter pylori*

*H. pylori* is a highly adapted bacterium, which can survive and live in the acidic environment of the stomach. It causes chronic inflammation, which may slowly lead to fibrosis, atrophy, and ultimately cancer in a small proportion of infected individuals, usually after several decades. Infection often occurs during childhood, and without treatment, it lasts lifelong.

In high-income countries, the prevalence of *H. pylori* infection has been declining together with the occurrence of the diseases it causes, and is now rare in children and young adults. But as gastric cancer tends to occur at an advanced age, given the global population growth and ageing, the total number of *H. pylori*-related gastric cancer cases is not expected to decrease for decades.

Current treatment comprises of the combination of antimicrobial drugs and a protonpump inhibitor, and is used widely in symptomatic individuals. Mass treatment of ill patients also works as a means of cancer prevention. Vaccine would provide a cheaper and more effective way to reduce disease risk and the related cancer burden, but all of the vaccines currently under development are at an early stage, and there appears to be little, if any, investment from large pharmaceutical companies (without which progress is likely to be limited.)

V.4.  *Hepatitis B virus*

V.4.1.  **Global HBV infection and cancer burden**

Globally, more than 260 million people are estimated to be chronic carriers of HBV, more than 90% are even not aware of their status. In the EU, EEA and the UK, there are an estimated 4.7 million cases of chronic hepatitis B. The infection disproportionately affects migrants, people in prison settings, men who have sex with men, people living with HIV, healthcare workers, haemodialysis patients, sexual partners and household contacts of HBsAg positive persons, people who inject drugs, sex workers and patients with chronic liver disease.
Each year, 1-2% of those infected will progress to liver disease. In 2018, chronic HBV infection led to about 360 000 cases of hepatocellular carcinoma worldwide, which was 55% of all cases of hepatocellular carcinoma diagnosed that year.

The virus transmits vertically (from mother to child), parenterally (via other routes than the digestive tract), or via sexual contact. Infection is now preventable, thanks to the vaccine that has been available since 1982, and large-scale vaccination programmes. Treatment, in the form of antiviral drugs is available for adults with a chronic infection and evidence of liver damage; and prevention of mother-to-child transmission can be improved by routine antenatal screening, antiviral drugs during pregnancy, and HBV vaccination of the baby at birth.

V.4.2. State of play in the EU/EEA and the UK

In the EU/EEA and the UK, 27 out of 31 countries recommend universal childhood vaccination against HBV; 2017 data on vaccine coverage (available from 24 countries) show that seven countries have already reached the 2020 target of 95% coverage.

Countries implement different strategies to prevent vertical transmission; those include universal vaccination of newborns, and antenatal screening combined with post-exposure prophylaxis. There are only five EU/EEA countries that provide universal birth dose of HBV vaccine; four (80%) of these countries have reached the 2020 target of 90% coverage.

All EU/EEA countries and the UK have haemovigilance systems in place to test donations for, among others, HBV and HCV infections, and ensure the safety of the blood transfusion chain. The prevalence of HBV and HCV infections among first time blood donors is low, as is the number of transfusion-associated HBV and HCV infections reported by EU/EEA countries.

People who inject drugs are overrepresented among HBV and HCV carriers due to the sharing of injecting equipment and drug paraphernalia. Data show a high prevalence of both infections, but especially HCV, and ongoing transmission in this group. Data on coverage of prevention programmes targeting people who inject drugs (syringe distribution) are lacking from half of the countries in the EU/EEA and the UK.\textsuperscript{217}

V.5. Hepatitis C virus

Approximately 200 million people worldwide are infected with HCV. In the EU, EEA and the UK, there are an estimated 3.9 million cases of chronic hepatitis C. Infection is the highest among people who inject drugs, people in prison settings, men who have sex with men, and people living with HIV.

About 75–85% of the infections become chronic, and approximately half of the chronic carriers will die of liver disease without treatment. Chronic HCV infection led to about 160 000 new cancer cases worldwide in 2018, mostly of hepatocellular carcinoma but also of non-Hodgkin lymphoma.

\textsuperscript{217} ECDC technical report: Prevention of hepatitis B and C in the EU/EEA and the UK, November 2020
Transmission is mainly parenteral, although it can occur via sex and from mother to child (though this latter is rare).

HCV is highly variable, with many different genotypes, which complicates vaccine development. Direct-acting antiviral agents were introduced in 2014, which cure now more than 90% of the treated patients. The downside is that the complexity of HCV testing and the high cost of treatment make the treatment currently unavailable to most of the people who would benefit, even in high-income countries. Prevention efforts are most critically needed for people who inject drugs, including in harm reduction settings and prisons.

VI. Sunlight and UV radiation

Solar ultraviolet radiation has beneficial biological effects, such as enabling vitamin D synthesis, but its adverse effects include sunburn and the development of solar lentigines ("liver spots"), immunosuppression, and skin cancers. Ultraviolet radiation directly and indirectly induces DNA lesions, which cause mutations and trigger inflammation and immunosuppression, which then mediate tumour growth.

People with certain conditions are at a higher risk of photocarcinogenesis, e.g. those living with the heritable disease xeroderma pigmentosum, which causes an extreme sensitivity to sunlight and a greatly increased risk of developing skin cancers at sunexposed areas. Immunosuppressants or some other kinds of medication are also associated with increased risk of skin cancer.

Skin cancer incidence has a sharp rise over recent decades, particularly amongst fair-skinned populations. According to estimates for 2018, about 103 000 new cases of cutaneous melanoma and about 17 000 deaths from it occurred in Europe; in total, UV radiation is thought to account for around 3-4% of the European cancer burden.

The most effective way to reduce skin cancer incidence is to avoid unnecessary exposure to sun and adopt personal preventive measures (like wearing protective clothing and hat, applying sunscreen, and using shade.) Avoiding tanning devices (sunbeds) and minimizing the time spent outdoors during the period when the intensity of sunlight is the strongest, also reduces the risk. The public should be aware that the strength of UV radiation does not correlate with the temperature.

VII. National cancer control plans

As health care, including cancer prevention and treatment, is essentially the competence of the Member States, it is also their responsibility to put together comprehensive cancer control plans. Named as programmes, plans or strategies, they include primary prevention (health promotion and environmental protection), secondary prevention (screening and early detection), integrated care and organization of services, and palliative care as main elements. They serve as a framework for the
development of their policies on cancer control, with the ultimate goal of reducing cancer morbidity and mortality, and improving quality of life.

A comprehensive analysis of the national cancer control plans concluded that all Member States are facing similar challenges in terms of the cancer burden and the need to formulate sustainable, effective and responsive policies for patients and citizens. However, national programmes are heterogeneous, and their mechanism depends on various contextual factors such as resource availability, health systems capacity, organization of services, geography, epidemiology and past experience in cancer policy. In the same way as there is an objective heterogeneity in cancer incidence, prevalence and mortality across the EU, there are differences in the approach to primary and secondary prevention programmes as well.

VIII. European Code against Cancer

The European Code against Cancer informs people about actions they can take for themselves or their families to prevent the development of cancer, to reduce their risk of cancer. It consists of recommendations that most people can follow and integrate into their life without any special skills or advice.

The first edition of the Code was published in 1987, and since then it is subject to continuous review and updates. The current, fourth edition, was prepared in 2012–2013 by cancer specialists, scientists, and other experts from the EU, in a project coordinated by the IARC, with financial support from the EU Health Programme. The recommendations were drafted in collaboration with experts in behavioural research and communication, aiming at clear and simple presentation, and taking into account the fact that the target population is the general public.
BACKGROUND NOTE ON ENVIRONMENTAL AND OCCUPATIONAL RISK FACTORS, AND PREVENTION STRATEGIES

This note provides technical background information for the upcoming BECA Committee hearing on environmental and occupational risk factors, taking place on 11 December 2020. It relies on publicly available, scientifically sound and impartial information, mostly the IARC ‘World Cancer Report 2020’, the OECD/European Commission ‘Health at a Glance: Europe 2020’, as well as information and documents published on the website of the European Commission (environment and health sections), EFSA, ECHA, and EU-OSHA.

I. ENVIRONMENTAL RISK FACTORS

I.1. CONTEXT

People are involuntarily exposed to a wide range of pollutants that are established or suspected carcinogens, at home and in the general environment. The most significant risk comes from breathing polluted air that contains known human carcinogens; contamination of water and of food chain, due to both naturally occurring carcinogens and anthropogenic pollutants, is less extensively studied.

Environmental exposures to carcinogens
- are widespread such as air pollution, which affects billions of people worldwide;
- frequently occur at low doses, e.g. endocrine disrupters in foods and products;
- frequently occur in mixtures, like the hundreds of chemicals in drinking water;
- occur throughout the lifetime, as exposure may begin in utero and continue in childhood and adult life;
- may concern single agents and routes, e.g. dioxins from incomplete combustion of waste, which is ingested through contaminated food; or may concern mixtures of chemicals from multiple sources and routes, e.g. heavy metals, gaseous pollutants, particulate matter, and dioxins from complex industrial settings.

High-income countries often use regulatory action to control and prevent environmental exposure. Its adverse effect, however, is that it can lead to relocating certain industrial processes to low-income countries, exposing the local population to carcinogenic products or waste.

**Environmental pollutants as carcinogenic hazard to humans, the main associated cancer sites or types, and the level of evidence**

<table>
<thead>
<tr>
<th>Agent</th>
<th>Cancer site or type</th>
<th>IARC Monographs classification*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outdoor air pollution</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outdoor air pollution, particulate matter in outdoor air pollution</td>
<td>Lung</td>
<td>Group 1</td>
</tr>
<tr>
<td>Outdoor air pollutants, other*</td>
<td>Lung, leukaemia</td>
<td>Group 1</td>
</tr>
<tr>
<td>Diesel engine exhaust, silica dust, benzene</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indoor air pollution</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indoor emissions from household combustion of coal</td>
<td>Lung</td>
<td>Group 1</td>
</tr>
<tr>
<td>Indoor emissions from household combustion of biomass fuel (primarily wood)</td>
<td>Lung</td>
<td>Group 2A</td>
</tr>
<tr>
<td>Second-hand tobacco smoke</td>
<td>Lung</td>
<td>Group 1</td>
</tr>
<tr>
<td>Indoor air pollutants, other*</td>
<td>Lung, leukaemias, lymphoma, nasopharynx, and others</td>
<td>Group 1</td>
</tr>
<tr>
<td>Benzene, 1,3-butadiene, diesel engine exhaust, ethylene oxide, formaldehyde, polychlorinated biphenyls</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asbestos and other fibres</td>
<td>Lung, mesothelioma, larynx, ovary</td>
<td>Group 1</td>
</tr>
<tr>
<td>Carbon black, diamond dust</td>
<td>Lung, mesothelioma</td>
<td>Group 1</td>
</tr>
<tr>
<td>Chrysotile, fluoro-edenite</td>
<td>Mesothelioma</td>
<td>Group 1</td>
</tr>
<tr>
<td>Drinking water contaminants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arsenic</td>
<td>Lung, skin, bladder</td>
<td>Group 1</td>
</tr>
<tr>
<td>Disinfection by-products</td>
<td>Bladder</td>
<td>Group 2B and Group 3</td>
</tr>
<tr>
<td>Nitrates</td>
<td>Stomach</td>
<td>Group 2A</td>
</tr>
<tr>
<td>Contaminants of soil and food, including pesticides</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dioxin (2,3,7,8-tetrachlorodibenzo-p-dioxin)</td>
<td>All neoplasms</td>
<td>Group 1</td>
</tr>
<tr>
<td>Polychlorinated biphenyls</td>
<td>Skin, melanoma</td>
<td>Group 1</td>
</tr>
<tr>
<td>Lindane</td>
<td>Lymphomas</td>
<td>Group 1</td>
</tr>
<tr>
<td>Several other pesticides</td>
<td>Mostly leukaemia and lymphoma</td>
<td>Group 2A</td>
</tr>
<tr>
<td>Metals in water and soil</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cadmium, lead, chromium(VI)</td>
<td>Lung</td>
<td>Group 1</td>
</tr>
<tr>
<td>Endocrine disruptors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food, cosmetics, and other products</td>
<td>Breast, testis</td>
<td>Specific: Group 1 carcinogens (e.g. 2,3,7,8-tetrachlorodibenzo-p-dioxin) are endocrine disrupters</td>
</tr>
<tr>
<td>Irradiating and ultraviolet radiation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radon-222 and its decay products (indoor air)</td>
<td>Lung</td>
<td>Group 1</td>
</tr>
<tr>
<td>Solar radiation</td>
<td>Skin, malignant melanoma</td>
<td>Group 1</td>
</tr>
<tr>
<td>Tanning devices that emit ultraviolet radiation</td>
<td>Cutaneous malignant melanoma, ocular melanoma</td>
<td>Group 1</td>
</tr>
<tr>
<td>Non-ionizing radiation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extremely low frequency magnetic fields</td>
<td>Childhood leukaemia</td>
<td>Group 2B</td>
</tr>
<tr>
<td>Radiofrequency electromagnetic fields</td>
<td>Brain</td>
<td>Group 2B</td>
</tr>
</tbody>
</table>

Group 1: carcinogenic to humans; Group 2A: probably carcinogenic to humans; Group 2B: possibly carcinogenic to humans; Group 3: not classifiable as to its carcinogenicity to humans.
I.2. AIR POLLUTION

Air pollution remains the main environmental risk factor for health in Europe and around the world; it is one of the major political concerns since the late 1970s.

I.2.1. Air pollutants and their impact on health

Air pollutants are categorised as primary or secondary. Primary pollutants are directly emitted to the atmosphere, whereas secondary pollutants are formed in the atmosphere from precursor pollutants through chemical reactions and microphysical processes.

<table>
<thead>
<tr>
<th>Air pollutants</th>
<th>Key primary air pollutants</th>
<th>Key secondary air pollutants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>particulate matter (PM)</td>
<td>ozone (O&lt;sub&gt;3&lt;/sub&gt;)</td>
</tr>
<tr>
<td></td>
<td>black carbon (BC)</td>
<td>NO&lt;sub&gt;2&lt;/sub&gt;</td>
</tr>
<tr>
<td></td>
<td>sulphur oxides (SO&lt;sub&gt;4&lt;/sub&gt;)</td>
<td>several oxidised volatile organic compounds (VOCs)</td>
</tr>
<tr>
<td></td>
<td>nitrogen oxides (NO&lt;sub&gt;x&lt;/sub&gt;) (including both nitrogen monoxide, NO, and nitrogen dioxide, NO&lt;sub&gt;2&lt;/sub&gt;)</td>
<td>particulate matter formed in the atmosphere (PM)</td>
</tr>
<tr>
<td></td>
<td>ammonia (NH&lt;sub&gt;3&lt;/sub&gt;)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>carbon monoxide (CO)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>methane (CH&lt;sub&gt;4&lt;/sub&gt;)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>non-methane volatile organic compounds (NMVOCs), including benzene (C&lt;sub&gt;6&lt;/sub&gt;H&lt;sub&gt;6&lt;/sub&gt;), and certain metals</td>
<td></td>
</tr>
<tr>
<td></td>
<td>polycyclic aromatic hydrocarbons (PAHs), including benzo[a]pyrene (BaP)</td>
<td></td>
</tr>
</tbody>
</table>

Main sectors contributing to emissions of air pollutants in Europe

- transport (split into road and non-road, i.e. air, rail, sea and inland water transport; note that emissions from aviation cruise and international maritime navigation are not considered in the total emissions because of the reporting regulation);
- residential, commercial and institutional
- energy supply, which includes fuel production and processing and energy production
- manufacturing and extractive industry, which includes heavy and light industry
- agriculture
- waste, which includes waste water management

Different air pollutants attack different organs, and it is exposure to particulate matter, in particular to fine particulate matter (PM<sub>2.5</sub>) which causes the greatest health damage by increasing the risk of heart diseases, stroke, lung cancer and many respiratory diseases.
Main air pollutants with adverse effects on health

Particulate matter (including PM_{10} and PM_{2.5}) are particles that are suspended in the air. Primary PM emissions result from the combustion of fuels, such as for power generation, domestic heating and in vehicle engines. Chronic exposure to particles contributes to the risk of developing cardiovascular and respiratory diseases, irritates eyes, nose and throat, causes disorders in the reproductive and central nervous systems, as well as increases the risk of lung cancer. Small particulates of less than 10 microns in diameter (PM_{10}) are capable of penetrating deep into the respiratory tract and causing significant health damage. Fine particulates smaller than 2.5 microns in diameter (PM_{2.5}) cause even more severe health effects because they penetrate deeper into the respiratory tract and are potentially more toxic.

Nitrogen dioxide (NO_{2}) is formed primarily from vehicle exhausts, especially from diesel vehicles, power plants and combustion in industry. In addition to being a primary pollutant, it contributes to the formation of particulate matter and ozone. NO_{2} can cause bronchitis and asthma, lead to irritations of eyes, nose and throat, cause respiratory infections and reduced lung function, and impact on liver, spleen and blood.

Ozone (O_{3}) at ground level, is formed by chemical reactions (triggered by sunlight) involving pollutants emitted into the air, including those by transport, natural gas extraction, landfills and household chemicals. Excessive ozone in the air can cause cardiovascular diseases as well as lead to breathing problems, irritations of eyes, nose and throat, trigger asthma and reduce lung function.

Sulphur dioxide (SO_{2}) is emitted mainly from the burning of fossil fuels such as coal and oil, and the smelting of mineral ores that contain sulphur. Sulphur dioxide can affect the respiratory system, central nervous system and lung function, and can cause headaches, anxiety and eye irritation. It can also aggravate bronchitis and asthma, and be a cause of cardiovascular diseases.

Benz(a)pyrene (BaP) originates from incomplete combustion of fuels. Main sources include wood and waste burning, coke and steel production and vehicle engines. BaP can affect the respiratory system, and irritates eyes, nose and throat.

Source: OECD/European Union: Health at glance - Europe 2020; p. 85

Various methods exist for calculating mortality due to air pollution, resulting in diverging figures. Depending on the method applied, in 2018, in the EU, 168 000 to 346 000 premature deaths were caused by exposure to outdoor air pollution in the form of fine particles (PM_{2.5}) alone, counting for 4% to 7% of all deaths in the given year. Mortality and morbidity, i.e. lower quality of life due to ill-health, caused by air pollution is the main concern; but increased health spending care costs to treat related conditions, and reduced labour productivity arising from greater absences from work due to illness, are also to note as they generate substantial welfare loss.

Lung cancer remains the most common cause of death from cancer among men, and the second most common cause among women; in 2020, over 257 000 people are expected to die from lung cancer in the EU. The main risk factors for lung cancer are tobacco smoking and environmental factors such as air pollution but there is no data available on the share of these two risk factors. The survival rate after a diagnosis for lung cancer remains fairly low, despite improvement in the past decade, and varies greatly across the Member States, suggesting differences in timely diagnosis and access to pharmaceuticals and other treatments. Between 2000-2004 and 2010-2014, five-year net survival following diagnosis of lung cancer increased from 11% to 15% on average across EU countries.

I.2.2. Air quality standards, legal and policy context

The EU has been working now for decades with the Member States and international organisations to improve air quality by controlling the emissions of air pollutants and integrating environmental protection requirements into the energy, transport, industrial and agricultural sectors. A series of directives and international conventions set the legislative framework, and air quality policy forms an integral part of the European Green Deal and the ‘zero pollution ambition for a toxic free environment’.
The Air Quality Directive (Directive 2008/50/EC), setting objectives for fine particulate matter (PM2.5), together with the fourth so-called daughter directive (Directive 2004/107/EC) relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air, provides the current framework for the control of ambient concentrations of air pollution in the EU. In addition to the limits set by the EU directives, the WHO Air Quality Guidelines also set recommended limit values.

<table>
<thead>
<tr>
<th>Pollutant</th>
<th>Averaging period</th>
<th>Standard type and concentration</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>PM$_{2.5}$</td>
<td>1 clay</td>
<td>EU limit value: 50 µg/m$^3$</td>
<td>Not to be exceeded on more than 35 days per year</td>
</tr>
<tr>
<td>Calendar year</td>
<td>WHO AQG: 50 µg/m$^3$</td>
<td>99th percentile (3 days per year)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Limit value: 40 µg/m$^3$</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>WHO AQG: 20 µg/m$^3$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PM$_{10}$</td>
<td>1 clay</td>
<td>WHO AQG: 25 µg/m$^3$</td>
<td>99th percentile (3 days per year)</td>
</tr>
<tr>
<td>Calendar year</td>
<td>EU limit value: 25 µg/m$^3$</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>WHO AQG: 10 µg/m$^3$</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


The Clean Air Programme for Europe (COM(2013)0918) re-confirmed the objective to achieve full compliance with existing air quality standards across the EU. It set objectives for 2020 and 2030, with the aim to reduce the health impact of air pollution by half by 2030 compared with 2005.

The Directive on national emission ceilings (NEC - Directive (EU) 2016/2284) is the main legislative instrument to achieve the 2030 objectives of the Clean Air Programme. It transposes the 2020 reduction commitments to which the EU and the Member States agreed under the under the UN Convention on Long-range Transboundary Air Pollution (LRTAP Convention) and its Gothenburg Protocol; sets national emission reduction commitments for each Member State for the period of 2020-2029; and sets more ambitious targets from 2030 onwards. The pollutants responsible for serious health and environmental damages targeted by the directive are nitrogen oxides (NOx), non-methane volatile organic compounds (NMVOCs), sulphur dioxide (SO2), ammonia (NH3) and fine particulate matter (PM$_{2.5}$). The directive also requires Member States to draw up National Air Pollution Control Programmes that should contribute to the successful implementation of air quality plans established under the Air Quality Directive.

In the international context, the UNECE Convention on Long-Range Transboundary Air Pollution (the Air Convention), already mentioned above, is the main instrument, recognising that air pollution does not respect national borders. Reducing air pollution and its negative impact is also part of the UN Sustainable Development Goals (SDG), notably under Goal 3 (Good health and well-being) that calls for substantial reductions in the number of deaths from air pollution, under Goal 11 (Sustainable cities and communities) that aims to reduce the negative environmental impact of cities, and under Goal 13 (Combat climate change) that calls for urgent actions to combat climate change.
1.2.3. **Air quality trends**

Authentic and complete data on air quality are available on the [European Air Quality Portal](https://www.eea.europa.eu), which is managed by the European Environment Agency. The Agency's annual report *Air Quality in Europe* analyses the data and its implications.

Pursuant to the EEA’s analysis, emissions for all primary and precursor pollutants contributing to ambient air concentrations of PM, O\(_3\) and NO\(_2\), as well as arsenic (As), cadmium (Cd), nickel (Ni), lead (Pb), mercury (Hg) and BaP (16), decreased between 2000 and 2018 in the EU. SO\(_x\) emissions show the largest reductions (79\%) since 2000, and NH\(_3\) emissions show the smallest reductions (10\%; however, NH\(_3\) emissions have been increasing since 2015 for the Member States, mainly driven by the agriculture sector). Anthropogenic emissions (i.e. emissions originating in human activities) of As, Cd, Ni and Pb were reduced by 35\%, 42\%, 59\% and 68\%, respectively, from 2000 to 2018.

With regard to PM\(_{2.5}\) which is particularly relevant given the established link with lung cancer, emissions of PM\(_{2.5}\) were reduced by more than 25\% between 2005 and 2017. Such significant reduction could be achieved as combustion processes in both industry and residential heating improved, the use of coal in the energy mix decreased and transport-related emissions lowered.

According to the first implementation report by the Commission on the NEC Directive ([COM(2020)0266](https://eur-lex.europa.eu/LexUriLite/EnLexUriLite?uri=COM:2020:0266:FIN:en:XML:Full)), published at the end of June 2020, 10 Member States are projected to fulfill all of their 2020 emission reduction commitments under current measures, while only 4 would meet the 2030 commitments. Regarding primary PM\(_{2.5}\) emissions specifically, 23 Member States are to meet their 2020 emission reduction commitments, but only 13 would achieve the 2030 commitments. Other Member States will need to put in place additional measures to fulfil their emission reduction commitments.

**Projected compliance as reported by Member States in 2019 under existing policies and measures against emission reduction commitments for 2020-2029 and 2030-onwards**
The contrast between a reduction in air pollutant emissions and an increase in EU-28 GDP during the period 2000-2018 clearly indicates that there are now fewer emissions for each unit of GDP produced per year. The greatest decoupling has been for $SO_X$, followed by NMVOCs, CO, NO$_X$, BC and certain metals (Ni, Pb, Cd, Hg) and organic species (BaP). Decoupling may be due to a combination of factors, including achievements within the EU such as increased regulation and policy implementation, fuel switching, technological improvements and improvements in energy or process efficiencies; as well as the increase in the consumption of goods, which are produced in industries outside the EU.

Regulating industrial emissions is pivotal, as the largest industrial installations account for a fair share of total emissions of key atmospheric pollutants, and have other important environmental impacts.
such as emissions to water and soil, generation of waste and the use of energy. Environmental impacts of industrial installations have therefore been subject to complex EU-wide legislation for some time. The following main pieces of legislation currently apply:

- Directive on industrial emissions (IED - Directive 2010/75/EU);
- Directive on medium combustion plants (MCPD - Directive (EU) 2015/2193);
- Directive 1994/63/EC and Directive 2009/126/EC on petrol storage & distribution; and
- Regulation 166/2006 on the European Pollutant Release and Transfer Register.

I.2.4. Prevention

Compliance with air quality standards, transition towards a greener economy and green recovery from the coronavirus-induced economic crises are pivotal in preventing the harmful impacts of air pollution. Full implementation of the European Green Deal, whose initiatives would deliver important co-benefits for more efficient and quicker implementation of the NEC Directive, and scaled-up support from the Just Transition Fund and relevant Union funding programmes would facilitate the achievement of the NEC objectives. The EU recovery plan from the COVID-19 crisis, approved by the European Council in July 2020, integrates environmental considerations into the recovery process and promotes a green recovery; this plan should also promote the achievement of national emission reduction commitments. The upcoming zero-pollution action plan for air, water and soil, that is expected from the Commission in 2021, will also play a key role in streamlining policy actions and incentives.

Concerning lung cancer, trends in lung cancer mortality rates follow trends in incidence rates. This is partly due to the absence of any large-scale screening programme for lung cancer in the Member States, particularly for high-risk populations, which impedes the detection and treatment of lung cancer at an early stage. Effective treatment of lung cancer also remains difficult. Therefore, the most promising approach to reducing lung cancer incidence and mortality with currently available means is to strengthen primary prevention through tobacco control policies and policies to reduce air pollution. The establishment of lung cancer screening programmes is an option to consider. Risk prediction models should serve to identify participants for screening, and determine the intensity and duration of screening, to make the programme (cost-)effective. However, inequalities in lung cancer diagnosis and care could become greater if screening is recommended, but introduced unequally across Europe.\textsuperscript{218}

I.3. WATER CONTAMINATION

I.3.1. Contaminants in water and their impact on health

\textsuperscript{218} Official statement of the European Society of Radiology (ESR) and the European Respiratory Society (ERS), published in the European Respiratory Journal [DOI: 10.1183/13993003.00506-2019].
Drinking water, and water used for agricultural or recreational activities, can be polluted by naturally occurring carcinogenic contaminants or by anthropogenic pollutants (those deriving from human activity).

The link between arsenic in drinking water and the risk of lung cancer, skin cancer, and bladder cancer is established in areas with naturally occurring very high arsenic content. These are territories outside Europe, such as Argentina, Bangladesh, northern Chile, West Bengal in India, and Taiwan, China. Exposure to low levels of arsenic is widespread. The link between low to moderate level exposure to arsenic and risk of bladder cancer in Europe and the US is supported by evidence mostly from studies, and less consistent.

Chlorination of drinking water is used for disinfection. During the process, chlorine reacts with organic matter in water and produces a mixture of by-products, several of which are carcinogenic. Chlorination by-products in drinking water are associated with risk of bladder cancer.

Nitrates and organic nitrogen compounds from fertilizer and manure applied in agriculture enter groundwater through leaching and reach surface water through runoff. Nitrate is therefore a widespread contaminant in drinking water. Though it is established that in the body nitrates are transformed in nitrite and can prevent the normal transport of oxygen by the blood to the tissues; evidence is not consistent on linking nitrate uptake from water to (stomach) cancer.

Water can also be the medium through which infectious agents enter the body, as is the case with a parasite, Schistosoma haematobium, that can cause squamous cell carcinoma of the bladder.

I.3.2. The EU legal framework

The Drinking Water Directive (Council Directive 98/83/EC) lays down the essential quality standards at EU level. The WHO guidelines for drinking water, and the opinion of the Commission’s Scientific Advisory Committee are used as the scientific basis for setting the quality standards. The directive requires the regular testing and monitoring of 48 microbiological, chemical and indicator parameters; it establishes a minimum harmonised level of human health protection, allowing Member States to set higher standards or include additional requirements (e.g. regulate additional substances that are relevant within their territory).

The Directive is currently going through a review (2017/0332 (COD)), with the ENVI Committee just having confirmed the deal reached with the Council in trilogue negotiations. The new rules will improve the quality of tap water by tightening the maximum limits for certain pollutants such as lead and harmful bacteria. By strengthening consumers’ confidence in the quality of drinking water and encouraging the use of tap water, the legislation also contributes to cutting plastic litter.

The Nitrate Directive (Council Directive 91/676/EEC) requires Member States to monitor the quality of the waters, and to identify areas that are polluted or at risk of pollution i.e. waters that due to agricultural activities are eutrophic or contain or that could contain a concentration of more than 50
mg/l of nitrates. Member States action programmes under the Nitrates Directive are accessible in the NAPINFO database; implementation is monitored by the Commission.

The regulation of industrial emissions is pivotal from water quality point of view as well, as mentioned above in the section on air pollution.

Implementation and the monitoring of implementation of these directives is key for cancer prevention.

I.4. SOIL CONTAMINATION

I.4.1. Contaminants in soil, and their impact on health

Contamination of the soil may be a risk factor for cancer. Carcinogenic agents present in the soil, either naturally or as a result of human activities, may be (i) inhaled (asbestos or other mineral fibres), (ii) accidentally ingested (children playing in direct contact with the ground), or (iii) absorbed through the food chain as a consequence of their release from soil into groundwater and surface water.

According to a report by the European Joint Research Centre, there are 342,000 sites in the EU where soil is contaminated, and only 15% of those sites have been subject to remediation interventions. Two-thirds of the overall contamination is due to industrial activities, including industrial waste disposal and treatment. The main contaminants are heavy metals, mineral oils, and aromatic hydrocarbons.

Estimates of cancer risk for people living near contaminated sites are available in a few countries only. For example, in Italy an epidemiological surveillance project of 44 contaminated sites found links with 23 cancer types or cancer sites. The cancer incidence on these contamination sites were 9% higher for men and 7% higher for women. A higher occurrence of mesothelioma was also demonstrated, with an ascertained role of environmental, non-occupational exposure to asbestos.

Both in the USA and in Europe, hazardous waste is present on a large proportion of contaminated sites; such waste has been dumped, burned, or otherwise improperly managed. The WHO extensively investigated the potential adverse health effects associated with waste management practices, but has not reached firm conclusions on the causative link with cancer risk; only limited evidence was identified with cancer of the liver, breast, testis, and bladder, and for non-Hodgkin lymphoma.

I.4.2. The EU and international legal framework

To date, soil has not been subject to a specific protection policy at EU level. The Commission presented a legislative proposal for soil protection in 2006 (2006/0086 (COD). The draft directive proposed to establish a common strategy for the protection of soil, by integrating soil concerns into other sectoral policies; preventing threats to soil and mitigating their effects; identifying and remediying contaminated sites; and raising awareness, reporting and exchanging information. The Parliament adopted its first reading in position, but the file got blocked in the Council. While some
delegations supported the proposal for an EU-level instrument so as to fill a gap in EU environmental legislation and put soil on par with water or air in terms of protection, others opposed to it on the grounds of subsidiarity, administrative burden and cost-effectiveness-related concerns. Finally, in 2014, the Commission decided that the proposal became obsolete and withdrew it.

In the absence of a dedicated legislative framework, EU soil protection policy is shaped by the EU Soil Thematic Strategy ([COM(2006)0231](https://ec.europa.eu/environment/soils/strategy/index_en.htm)) and a number of other policy instruments, such as the Industrial Emissions Directive, the Environmental Liability Directive, the EU Biodiversity Strategy, the EU Forest Strategy and the Common Agricultural Policy.

As land degradation and desertification are issues of both global and EU concern, they are in the focus of international action as well. Promoting sustainable land management is therefore a Sustainable Development Goal (SDG) Accelerator, and the target of ‘striving to achieve a land-degradation neutral world by 2030 (SDG 15.3) forms part of the Agenda 2030. The United Nations Food and Agriculture Organization (FAO) in 2012 established the Global Soil Partnership as a voluntary partnership. This partnership is open to the governments of FAO Member States, regional organisations, institutions, universities, research organisations, civil institutions, soil science societies, industry and companies, and other stakeholders at various levels. Its key objective is to promote Sustainable Soil Management (SSM) and improve soil governance, so as to guarantee healthy and productive soils. In addition, the GSP established Regional Soil Partnerships to provide guidance on goals and priorities within specific regions and to develop relevant activities within each region; the European Soil Partnership is one of them.

### 1.5. CONTAMINANTS IN FOOD

Contaminants are chemical substances that have not been intentionally added to food, and may pose a risk to animal and human health. Contaminants can enter the food chain at various stages: during primary production, processing, transport and distribution; they also might result from environmental contamination.

Food safety is regulated extensively at EU level. Measures controlling food contaminants are part of the EU’s overarching policy to ensure the safety of food in the entire agri food chain, and feature as part of the ‘sustainable food production’ and ‘sustainable food processing and distribution’ legs of the new ‘From farm to Fork Strategy’ ([COM(2020)381](https://ec.europa.eu/info/publications/2020-from-farm-to-fork-strategy_en)).

[Council Regulation (EEC) No 315/93](https://eur-lex.europa.eu/eli/reg/1993/315/oj) lays down procedures for contaminants in food, based on the following principles:

- Food containing a contaminant to an amount that is unacceptable from the public health viewpoint, and in particular at a toxicological level, shall not be placed on the market;
- Contaminant levels shall be kept as low as can reasonably be achieved following recommended good working practices; and
- Maximum levels must be set for certain contaminants in order to protect public health. The maximum levels of contaminants are strict, based on the risk related to the consumption of the food, but in the same time are reasonably achievable via good agricultural, fishery and manufacturing practices.
Aflatoxins, polycyclic aromatic hydrocarbons (PAHs), benzo(a)pyrene as marker for the occurrence and effect of carcinogenic PAH in food, and benzo(c)fluorene are considered as carcinogens; based on the opinion of the Scientific Committee on Food, the Commission regulates their maximum levels in Commission Regulation (EC) No 1881/2006.

The Panel on Contaminants in the Food Chain of EFSA, the European Food Safety Authority, carries out risk assessments on a wide range of chemicals that can be present in food.

I.6. **IONISING RADIATION AND RADIOFREQUENCY ELECTROMAGNETIC FIELD**

Electromagnetic fields (EMFs) are a combination of invisible electric and magnetic fields of force, generated by natural phenomena, but also by human activities, mainly through the use of electricity. One of the main characteristics which defines an electromagnetic field is its frequency or wavelength, according to which EMFs are grouped into two categories: mid to high-frequency ionising radiation, and low-frequency non-ionising radiation.

I.6.1. **Non-ionising radiation**

I.6.1.1. *The impact of non-ionising radiation*

Exposure to electromagnetic fields is not a new phenomenon but during the 20th-21st century, environmental exposure to man-made electromagnetic fields has been increasing. Due to growing electricity demand, advancing technologies and changes in social behaviour, nowadays everyone is exposed to a complex mix of low-frequency radiation both at home and at work. At low frequencies, external electric and magnetic fields induce small circulating currents within the body; the levels of induced currents inside the body are too small to produce obvious effects.

Responding to growing public health concerns over possible health effects, in 1996 the WHO launched a large-scale, multidisciplinary research project. Based on a recent in-depth review of the scientific literature (it is of note that in the area of biological effects and medical applications of non-ionizing radiation, approximately 25 000 articles were published over the past 30 years), the WHO has concluded that current evidence does not confirm the existence of any health consequences from exposure to low-level electromagnetic fields.

I.6.1.2. *Radiofrequency electromagnetic fields*

Radiofrequency electromagnetic fields (RF-EMF) are emitted from various sources, the most relevant in daily life are wireless communication devices and transmitters.

Wireless phones and other devices that are used close to the body produce near-field exposure, which is characterized by the specific absorption rate; while transmitters that are further away (e.g. base stations for mobile and cordless phones, other people’s mobile phones) are far-field sources, and the most common exposure metric is the incident electric field.
Because RF-EMF belong to the non-ionising part of the electromagnetic spectrum, the photon energy is too weak to ionise molecules and cause direct DNA damage. Though absorption of RF-EMF is known to heat biological tissue, a minimal temperature increase below the regulatory limits is not expected to increase the risk of cancer. Research so far has not consistently identified mechanisms relevant for carcinogenesis.\(^\text{219}\)

In 2011 the WHO/International Agency for Research on Cancer (IARC) classified radiofrequency electromagnetic fields as possibly carcinogenic to humans, based on an increased risk for glioma, a malignant type of brain cancer, associated with wireless phone use.

The IARC Monograph Working Group, composed of 31 experts from 14 countries, evaluated the available literature on occupational exposures to radar and to microwaves; environmental exposures associated with transmission of signals for radio, television and wireless telecommunication; and personal exposures associated with the use of wireless telephones.

The evidence was reviewed critically, and was evaluated as being limited among users of wireless telephones for glioma and acoustic neuroma, and inadequate to draw conclusions for other types of cancers. The evidence from the occupational and environmental exposures mentioned above was similarly judged inadequate.

**I.6.1.3. EU legislation**

Exposure limits recommended by scientific committees of experts, such as the International Commission on Non-Ionising Radiation Protection (ICNIRP), constitute the basis for the regulation in the European Union. Council Recommendation 1999/519/EC deals with radio waves, electric and magnetic fields of extremely low frequencies and static electric and magnetic fields. This recommendation relates to the exposure of the general population to the electromagnetic radiation that originates from installations such as transmission towers and high-voltage lines and from products such as mobile telephones and microwave ovens.

**I.6.2. Ionising radiation**

**I.6.2.1. The health impact and cancer risk of ionising radiation**

Ionising radiation is made up of electromagnetic waves on the high-energy end of the electromagnetic spectrum. Biological effects of ionising radiation are determined by the amount of energy absorbed by the exposed organ or tissue. Radiation produces carcinogenic changes through mutations, alterations in the structure of genes or chromosomes, and changes in gene expression. The carcinogenic impact of radiation is complex, and many uncertainties still remain, especially at low doses. The latency between exposure to ionising radiation and occurrence of an excess risk of cancer varies from several years to several decades, and host factors such as age at exposure, attained age, and gender modify the dose-risk relationship.

People have always been exposed to ionising radiation from natural sources. Natural radiation exposure comes from four main sources: cosmic radiation (which is higher at high altitudes), terrestrial radiation, ingestion of radionuclides present in the soil and ground (which varies from place

\(^{219}\) Mobile phones and health: Where do we stand? Briefing by the European Parliamentary Research Service
to place according to geology), and inhalation of radon. Radon is a gas that forms during the decay of natural uranium in the soil; exposure varies depending on the geology, building construction, and household lifestyle. Inhalation of radon is the single highest source of exposure (41%). On average, natural sources account for 80% of the average total dose of ionising radiation in the population.

The remaining 20% originates from artificial sources that have developed over the past century. Environmental exposures include fallout from weapons testing, nuclear power plant accidents and routine releases from nuclear installations. Exposures to medical radiation arise from some diagnostic procedures, such as radiography, nuclear medicine and CT, or as a consequence of treatment (most commonly radiotherapy for cancer).

The increasing use of CT scans in paediatric populations raised the question of a possible health impact of radiation exposure because of the much higher doses of radiation compared to conventional radiology. Research so far has shown dose–response relationship between the dose to the red bone marrow due to CT examinations and the risk of leukaemia, and between the dose to the brain and the risk of brain tumours. The European EPI-CT project, involving more than 1 million children, will provide new results on cancer risks associated with paediatric CT scans.

The nuclear accident at the Chernobyl nuclear plant in Ukraine on 26 April 1986 was the largest one ever happened. It caused a large release of radionuclides, which were deposited over a very wide area; the greatest deposits were in Belarus and Ukraine. Exposure to iodine-131 among children caused an excess risk of thyroid cancer: about 25% of thyroid cancer cases in the contaminated area among people who were children or adolescents at the time of the accident are linked to this exposure. The Fukushima Daiichi nuclear accident in Japan on 11 March 2011 resulted in a much lower release of radionuclides, which were deposited over a small territory, in some parts of the Fukushima Prefecture. Thanks to the handling of the accident and preventive measures taken (evacuation and food restrictions), the resident populations were much less exposed than after the Chernobyl accident. The estimated doses are low and are limited to a small population, and no observable radiation-induced excess risk of cancer is expected.

### I.6.2.2. Regulation at EU-level

Radiation protection at EU level is regulated extensively.

The Euratom Community drew up a set of basic safety standards ([Council Directive 2013/59/Euratom](https://eur-lex.europa.eu/oj/dat/2013/C_0292_R_20130204.pdf)) to protect workers, members of the public, and patients against the dangers from ionising radiation. These standards also include emergency procedures, which were further strengthened after the Fukushima nuclear accident.

The Euratom Drinking Water Directive ([Council Directive 2013/51/Euratom](https://eur-lex.europa.eu/oj/dat/2013/C_0292_R_20130204.pdf)) provides a framework for controlling radioactivity in drinking water and the radiation dose received from the consumption of different forms of drinking water. The Directive lays down values for radon, tritium, and the so-
called ‘indicative dose’, which covers many other radionuclides. The values have an indicative function, they are not limits.

All Member States produce radioactive waste, originated from either facilities like nuclear power plants and research reactors, or though activities like radioisotope applications in medicine, industry, agriculture, research and education. The shipment of radioactive waste and spent fuel, through import, export and transit are common practices in the EU that occur regularly. Council Directive 2006/117/Euratom establishes a system of prior authorisation for such shipments in Europe.

Before the operation of a new nuclear plant is authorised, the Commission must evaluate the potential health impact that the release of gaseous and liquid radioactive substances from the plant could have on the population of another Member State. Therefore, the Member State where the new nuclear power plant would operate, must provide the Commission with a comprehensive and detailed file on the new project, in compliance with the Commission Recommendation 2010/635/Euratom.

Member States continuously monitor their environmental radioactivity, levels of radioactivity in air, water, soil and foodstuffs, and communicate data to the Commission. Based on this data and in cooperation with its Joint Research Centre, the Commission publishes reports on environmental radioactivity in the EU.

I.7. CHEMICALS

I.7.1. Carcinogenicity and endocrine disruptor property of chemicals

Knowledge about the carcinogenicity of chemicals dates back to the late 1700s when an English physician noted that cancer of the scrotum was common amongst chimney sweeps due to exposure to soot, which contains polycyclic aromatic hydrocarbons. Since then, a large number of chemicals have been identified as known or suspected causes of cancer.

EU legislation defines carcinogenicity as “the induction of cancer or an increase in the incidence of cancer occurring after exposure to a substance or mixture. Substances and mixtures which have induced benign and malignant tumours in well performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumour formation is not relevant for humans. Classification of a substance or mixture as posing a carcinogenic hazard is based on its intrinsic properties and does not provide information on the level of the human cancer risk which the use of the substance or mixture may represent.”

The EU strategy on endocrine disruptors (EDs) defines them as “exogenous substances or mixtures that alter function(s) of the endocrine system and consequently cause adverse health effects in an intact organism, or its progeny, or (sub)populations”. Many chronic health disorders, including reproductive cancers, have been clearly linked endocrine disruptors. As these substances are present in food, food contact materials, cosmetics, consumer goods (incl. furnishings, cleaning products),
toys, and drinking water, the EU population is widely exposed to known and suspected endocrine disruptors.

Scientific consensus now exists for (1) the definition of endocrine disruptors; (2) the presence of suspected or recognized EDs in the environment and in humans in the EU; (3) EDs as a serious concern for the health of current and future generations and the environment; (4) the limitations of current regulatory approaches used to identify so-called safe thresholds and (5) the lack of consideration of cumulative effects of combined exposures in regulations.220

I.7.2. EU legislative and policy framework

I.7.2.1. Sustainable Chemical Strategy

In October 2020 the Commission presented its Sustainable Chemical Strategy (COM(2020)667), a piece contributing to the ‘zero pollution ambition’ under the European Green Deal.

The new strategy makes the use of the ‘generic approach to risk management’ more widespread. The generic approach means that carcinogenic substances are generally banned, only limited exemptions are allowed under conditions clearly defined in law.

Currently, the vast majority of chemicals in the EU is regulated on a case-by-case basis, for each specific use. The generic approach to risk management now becomes the default option for the most harmful chemicals, in particular as regards their use in consumer products. That means the most harmful chemicals in consumer products will be banned, and their use will be allowed only where essential. The cocktail effect of chemicals will also have to be taken into consideration in the future when assessing risks from chemicals.

The new strategy aims at ensuring, among others, that consumer products (food contact materials, toys, childcare articles, cosmetics, detergents, furniture and textiles, etc.) do not contain chemicals that cause cancers; it also wants to strengthen information requirements on the carcinogenicity of substances and on other critical hazards at all production levels.

I.7.2.2. A comprehensive legal framework: REACH and CLP

Two flagship regulations spearhead the legal framework, REACH - Regulation (EC) No 1907/2006 on the registration, evaluation, authorisation and restriction of chemicals; and CLP - Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures.

In the past, a large number of chemicals were manufactured and placed on the market in Europe, sometimes in very high amounts, and yet there was insufficient information on the hazards that they pose to human health and the environment. There was a need to fill these gaps. REACH entered into force in 2007, with the aim to improve the protection of human health and the environment through

220 Barbara Demeneix, Rémy Slama: Endocrine Disruptors: from Scientific Evidence to Human Health Protection. Study for the PETI Committee
the better and earlier identification of the intrinsic properties of chemical substances. The regulation applies to all chemical substances; not only those used in industrial processes but also in daily life.

By applying the rule "no data, no market", REACH places the burden of proof on companies. To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. They have to demonstrate to ECHA how the substance can be safely used, and they must communicate the risk management measures to the users. If the risks cannot be managed, authorities can restrict the use of substances in different ways. In the long run, the most hazardous substances ("substances of very high concern") should be substituted with less dangerous ones.

The European Chemicals Agency (ECHA) manages the databases necessary to operate the system, co-ordinates the in-depth evaluation of suspicious chemicals and builds a public database in which consumers and professionals can find hazard information. Pursuant to the latest information published by ECHA, as of 2 November 2020, over 101 000 registration have already been granted for more than 23 200 substances.

CLP categorizes carcinogens according to the hazard they pose:

<table>
<thead>
<tr>
<th>Hazard categories for carcinogens as per Annex I, section 3.6.2 of the CLP Regulation and the IARC nomenclature</th>
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</thead>
<tbody>
<tr>
<td>Categories</td>
</tr>
<tr>
<td>---------------------------------</td>
</tr>
<tr>
<td>CATEGORY 1</td>
</tr>
<tr>
<td>Category 1A (IARC Group 1)</td>
</tr>
<tr>
<td>Category 1B (IARC Group 2A)</td>
</tr>
</tbody>
</table>

The classification in Category 1A and 1B is based on strength of evidence together with additional considerations set out in Annex I., section 3.6.2.2. Such evidence may be derived from human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen); or animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen). In addition, on a case-by-case basis, scientific judgement may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals.

<table>
<thead>
<tr>
<th>CATEGORY 2 (IARC Group 2B)</th>
<th>Suspected human carcinogens</th>
</tr>
</thead>
<tbody>
<tr>
<td>The placing of a substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or 1B, based on strength of evidence together with additional considerations. Such evidence may be derived either from limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies.</td>
<td></td>
</tr>
</tbody>
</table>

Of note, the IARC nomenclature also includes Group 3 as not classifiable as to their carcinogenicity to humans, largely due to inadequate evidence in humans.
I.7.3. Specific legislation for pesticides

Unlike many other chemical agents, pesticides are designed for being released into the environment. Exposure to pesticides can be occupational, but it can also be environmental bystander exposure, and can occur through ingestion of foods containing pesticides or pesticides residues. In 2016, according to the data compiled by the UN Food and Agriculture Organisation, the EU used 368 588 tonnes of pesticides which accounts for 11.8% of the global consumption. The FAO also noted that the use of pesticides in the EU was on an upward trend since 2009, but the trend differs across Member States, ranging from a sharp increase in some of them to a steep fall in others. The total volume of pesticide active substances sold in 16 EU Member States increased by 1.6% from 2011 to 2016;

Biocidal products are used to control unwanted organisms that are harmful to human or animal health or to the environment, or that cause damage to human activities. This product group includes insecticides (except those used for plant protection purposes, which are regulated separately), insect repellents, disinfectants, preservatives for materials such as wood, plastics and fibres, and anti-fouling paints for the protection of ship hulls.

Given their intrinsic properties, biocidal products can pose risks to humans, animals and the environment. For this reason an EU-wide framework was introduced by Regulation (EU) No 528/2012.

Before an active substance can be used in biocidal product, it needs to be assessed and approved at EU level. The assessment is carried out by the national authority of a Member State, followed by a peer review within the Biocidal Products Committee under the coordination of ECHA. ECHA delivers an opinion to the Commission as to whether or not an active substance can be approved. On the basis of its conclusions, the Commission decides whether or not to approve the use of the active substance in biocidal products.

Substances of very high concern, including, among others, substances that are classified as known or presumed human carcinogens (category 1A or 1B) under the CLP Regulation, are to be phased out gradually for better alternatives.

The final product also must be shown to be safe for human health, animal health and the environment.

Plant-protection products (PPPs) are a specific product group within pesticides that protect plants or plant products against pests/diseases, before or after harvest; influence the life processes of plants; preserve plant products; or destroy or prevent growth of undesired plants or parts of plants. They are primarily used in the agricultural sector but also in forestry, horticulture, amenity areas and in home gardens. At EU-level they are regulated by Regulation (EC) No 1107/2009.

The active substances, i.e. the component against pests/plant diseases, are evaluated by the Commission for their safety. In its evaluation the Commission bases itself on a report by Member States authorities, conclusions by EFSA, and the opinion of the Standing Committee for Food Chain and Animal Health. Only after approval can the active substance be used in a product. The products are authorised by Member States for their territory who must ensure compliance with EU rules.
The perhaps most well-known, and most widely used active substance is glyphosate, a systemic, broad-spectrum herbicide. Triggered by controversies over the safety of glyphosate, in 2018 the European Parliament set up a special committee looking into how pesticides are authorised at Union-level. Based on the report of the special committee, the plenary adopted a resolution on 16 January 2019 (P8_TA(2019)0023).

IARC classified glyphosate as probably carcinogenic to humans (Group 2A of IARC nomenclature, which is the equivalent to category 1B under the CLP Regulation); while EFSA and ECHA, the European agencies responsible for providing scientific assessments, which form the basis for EU risk management decisions, concluded that no classification of glyphosate as carcinogenic was warranted. In 2017 EFSA carried out a comparison of 54 pesticides that had been assessed under both the EU and IARC systems, and found that in 14 cases the EU classification was more conservative (and thus stricter) than IARC; in 11 cases (glyphosate and 10 other active substances) less strict; and in 29 cases equivalent. Several other competent authorities around the world, including those of the US, Canada, New Zealand, Australia and Japan, had subsequently finalised new assessments of glyphosate and concluded that it was not carcinogenic. Concerns, however, keep rising over the opinions by EFSA and ECHA concerning their favourable opinion on glyphosate. Controversies about the safety of glyphosate thus remained unresolved; nevertheless, the Parliament in its final resolution adopted over 100 recommendations on making the EU authorisation procedure even more stringent.

Concerning endocrine disruptors, a legal definition of EDs only exists for pesticides. The guidance documents for biocides and plant protection products are thorough and, if correctly used, can help identifying EDs. But even for pesticides, the regulation incomplete: though a definition and a management logic exist (i.e. zero exposure to EDs in pesticides), without ED tests covering all ED endpoints being compulsory in application dossiers, making ED identification very difficult in practice. This lack of efficient consideration of EDs is more pronounced in other sectors where human ED exposure is also very likely, such as food additives and food contact materials, cosmetics, toys, consumer goods and workers’ protection.221

II. OCCUPATIONAL EXPOSURE TO CARCINOGENS

II.1. Occupational risk factors

Occupational exposure refers to the exposure of workers to carcinogens in the context of work. Under EU legislation, ‘worker’ refers to those who are employed in an employment relationship, in all sectors of activity, both public and private. The European Agency for Health and Safety at Work (EU-OSHA) lists and assesses these risk factors.

- Chemicals, pesticides, pharmaceuticals, infectious agents, physical factors (incl. radiation), and the combination of these factors are established causes of occupational cancer. Air pollution and fine particulate matters, and endocrine disruptive substances are amongst the emerging factors. Many of the carcinogens to which workers are the most frequently exposed

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221 Barbara Demeneix, Rémy Slama: Endocrine Disruptors: from Scientific Evidence to Human Health Protection. Refer to reference in footnote 3.
are generated by the work processes; carcinogens may also be present in raw materials, intermediates, products or by-products.

- Other risk factors relate to work organisation (shift work with circadian disruption, and sedentary work) and work-related stress. Stress may indirectly lead to cancers, in case the coping strategies involve smoking, drinking, drug consumption or excessive, unbalanced eating.
- When cancer-causing factors and working conditions are classified as carcinogenic by scientists and by scientific panels, that is just the first step. The knowledge gained from research needs to be translated into prevention measures and legal requirements by regulators, which can be an equally lengthy process.
- Occupational exposure is rarely about a single factor; rather, it involves a combination of factors, which makes the assessment and classification harder. In this regard, there is scientific consensus that the current understanding of the relationship between occupational exposures and cancer is far from complete, as only a limited number of individual factors are established occupational carcinogens.
- An additional complication is that in many cases there is considerable evidence of increased risks associated with particular industries and occupations, but no specific agents can be identified with causative link to cancer.

According to latest available data published by EU-OSHA, in 2015 work-related cancer accounted for an estimated 53 % of all work-related deaths in the EU and other developed countries. According to the Roadmap on Carcinogens in 2016, about 120,000 work-related cancer cases occurred annually as a result of exposure to carcinogens at work in the EU, leading to approximately 80,000 fatalities each year. The IARC World Cancer Report 2020 noted that some of the most frequent occupational cancer types are lung cancer, bladder cancer, and skin cancer.

II.2. Prevention of occupational cancer risk factors

The designation of an agent as carcinogenic is an important public health and scientific statement, but this is just the starting point. It has to be followed by engineering and/or industrial hygiene measures to reduce or eliminate occupational exposure. Measures designed to control workplace exposures to carcinogens are summarised in the table below.

**Measures to control workplace exposures to occupational carcinogens**

<table>
<thead>
<tr>
<th>Control method</th>
<th>Examples of good practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elimination</td>
<td>Remove the hazard from the workplace, for example change a process so that the chemicals, materials, or equipment are no longer required.</td>
</tr>
<tr>
<td>Substitution</td>
<td>Replace a hazardous material or piece of equipment with a less-hazardous one.</td>
</tr>
<tr>
<td>Engineering controls</td>
<td>Redesign the equipment or process so that the hazard is controlled at its source, for example through a physical barrier.</td>
</tr>
<tr>
<td>Worker education</td>
<td>Provide information and training on all workplace carcinogens and the use of appropriate control methods. Use information media (e.g. posters, leaflets, data sheets) imaginatively and strategically.</td>
</tr>
<tr>
<td>Administrative controls</td>
<td>Design and operate effective and reliable processes and activities to minimize exposure. Provide safe storage, handling, and transportation, and disposal facilities.</td>
</tr>
<tr>
<td>Personal protective equipment</td>
<td>Use suitable personal protective equipment, for example gloves, coveralls, respirators, hard hats, safety glasses, high-visibility clothing, and safety footwear.</td>
</tr>
</tbody>
</table>

Source: IARC World Cancer Report 2020, p. 135
The global trend shows that reduction strategies, such as improvement of compliance with current occupational exposure limits, and targeting small- and medium-sized industries, work effectively in high-income countries. The problem is more acute in low- and middle-income countries; an important factor contributing to the devastating situation in low-income countries is that some particularly dirty and dangerous industrial work is now ‘outsourced’ and being performed there.

II.3. Preventive and protection measures taken at EU-level

The so-called ‘OSH Framework Directive’, Council Directive 89/391/EEC lays down the main principles to encourage improvements in the safety and health of workers at work. It guarantees minimum safety and health requirements in the Union, while Member States are allowed to maintain or establish more stringent measures. Further directives focusing on specific aspects of safety and health at work accompany the Framework Directive; this legislative package forms the fundamentals of European safety and health legislation.

Two from these specific directives are of particular relevance for work-related cancers:

- **Directive 2004/37/EC** of the European Parliament and of the Council (to so-called Sixth Individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) protects workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. The directive provides binding occupational exposure limit values. The minimum requirements included in the directive protect workers at Union level, while allow Member States to set more stringent binding occupational exposure limit values or other protective measures at national level.

  The directive applies to chemical agents that may cause cancer or are suspected of causing cancer, according to the CLP Regulation; and to the substances, mixtures and processes referred to the annex of the CMD. It sets minimum requirements to eliminate or reduce exposure to carcinogens and mutagens, and establishes occupational exposure limit values. Identifying and assessing exposure-associated risks for workers, and preventing exposure, are the responsibility of the employer. Where technically possible, the process or chemical agent must be substituted with safer alternative; where substitution is not possible, chemical carcinogens/mutagens must be used in a closed system, or worker exposure must be reduced, while respecting the occupational exposure values.

  The Commission has just presented its proposal for the fourth update of the directive (‘CMD4’) ([COM(2020)571; 2020/0261(COD)]).

- **Directive 2009/148/EC** on asbestos. Even though it has not yet been possible to identify the exposure threshold below which asbestos does not involve a cancer risk, occupational exposure of workers to asbestos should be reduced to a minimum. The directive applies to activities in which workers are, or may be, exposed during their work to dust arising from asbestos or materials containing asbestos. The directive sets out the minimum requirements

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222 Limits on exposure to carcinogens and mutagens at work: Fourth proposal. [Briefing](https://www.europarl.europa.eu) by the European Parliamentary Research Service
concerning the protection of workers from the risks related to exposure to asbestos at work, both in the form of dust arising from asbestos, or materials containing asbestos.

Strategic policy documents complement the legislative package:

- Commission paper on (COM(2017)0012) modernising the EU Occupational Safety and Health Legislation and Policy, which proposes key actions in specific OSH priority areas; and

- Strategic Framework on Health and Safety at Work 2014-2020 (COM(2014)0332), which identifies key challenges and strategic objectives for health and safety at work, presents key actions and describes instruments to address these.
4. Background note for the Public Hearing "Beating Cancer: Empowering patients and their caregivers" - 11 January 2021

BACKGROUND NOTE ON PATIENTS AND CAREGIVERS

I. Patients
   
I.1. Cancer patients’ rights

General framework of patients’ rights

The origin of patients’ rights are the fundamental human rights of integrity and self-determination. These individual rights have been complemented by the “social” patients’ rights, i.e. the rights to become a patient which address issues of coverage, access and entitlements; and more recently, by “consumer” patients’ rights, which are more focused on issues of information, quality and choice. The broadening of patients’ rights is accompanied by the recognition of the importance of patient empowerment, including the trends of involving patients or patient organisations more closely in policy-making.
Though patient empowerment is essentially determined at national level, the international legal framework enshrining human rights is equally important. The **Charter of Fundamental Rights of the European Union** brings together all the personal, civic, political, economic and social rights that people within the EU enjoy. It includes all rights found in the case law of the Court of Justice of the EU, the rights and freedoms protected by the European Convention on Human Rights, and other rights and principles originated in the common constitutional traditions of the Member States and other international instruments. These rights are inalienable and universal, rise above citizenship and are attached to a person as such. With the entry into force of the Treaty of Lisbon, in December 2009, the Charter became legally binding in the EU. It means that these fundamental rights, including patient’s rights are not only officially reaffirmed and recognised as part of the universal values shared by the Union and all Member States, but they must be observed in the development and application of EU law.

The first calls for a more explicit endorsement of patient’s rights in the EU date back to the ‘80s. Already in 1984, the European Parliament called on the Commission to submit a proposal for a European charter on the rights of patients. In 2002, the **Active Citizenship Network** promoted the idea of a European charter of patients’ rights in the context of increasing citizen and patient mobility and the enlargement of the EU.

Further developments in EU consumer policy, and the increased attention to patient safety and medical liability put patients’ rights into the focus again. Personalised medicine and other innovation in the fields of medicine, and the development and wider uptake of e-health have created new implications and challenges for patients’ rights, especially with regard to privacy issues.

**Directive 2011/24/EU** on the application of patients’ rights in cross-border healthcare also represents an important milestone; however, it essentially focuses on the social and consumer patients’ rights in the context of cross-border health care. With the exception of the right to reimbursement of cross-border care, it does not specify particular rights for patients but rather ensures that procedures and structures are in place in Member States to guarantee common operating principles.

Emerging common challenges across the EU, such as the growing complexity of healthcare interventions and the rise in ethical questions, ageing population, the rise of chronic conditions, the prioritisation of quality and safety of health care, the empowerment of citizens and the increased attention of cultural preferences require Member States to develop a coherent strategy around

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citizens’ and patients’ rights in health care. A comprehensive overview and a comparative analysis of the situation in the Member States can be found in “Patients’ rights in the European Union. Mapping eXercise: final report”.

The rights of cancer patients

Created in partnership between the European Cancer Concord (ECC) and the European Cancer Patient Coalition, launched on World Cancer Day at the European Parliament in 2014, and endorsed by the then Health Commissioner, Tonio Borg, the European Cancer Patient’s Bill of Rights rests on three key patient-centred initiative:

### European Cancer Patient’s Bill of Rights

**Article 1:** The right of every European citizen to receive the most accurate information and to be proactively involved in his/her care.

**Article 2:** The right of every European citizen to optimal and timely access to diagnosis and to appropriate specialised care, underpinned by research and innovation.

**Article 3:** The right of every European citizen to receive care in health systems that ensure the best possible cancer prevention, the earliest possible diagnosis of their cancer, improved outcomes, patient rehabilitation, best quality of life and affordable health care.

Built on the Bill of Rights, and co-produced by a team of cancer patients, patient advocates and cancer professionals, the European Code of Cancer Practice is a citizen- and patient-centred declaration of the core requirements for good clinical cancer practice, which has the ambition to improve outcomes for all of Europe’s cancer patients.

The Code sets out ten key overarching rights, and indicates what patients should expect from their healthcare system throughout their cancer journey. Each right links to three questions that a patient might want to ask their healthcare professionals; and each right is supported by a short explanation. The rights are based on the best available medical evidence, which is summarised in a supporting document, the Medical Literature and Evidence. Essentially, the Code is an empowerment tool, which aims to ensure the delivery of best available care for European citizens and patients.
At Member State-level, National Cancer Control Programmes (NCCP) play a key role in the implementation of initiatives to improve cancer patients’ rights. The NCCPs are integrated plans, bringing together all efforts for cancer prevention and care at national level. With sufficient resources, and being conform to European guidelines and good international practices, NCCPs ensure the quality of care. NCCPs should develop patient-centred cancer services, taking into consideration the views and needs of patients and their families. Through access to information about the disease and its treatment and the available cancer care services, good communication with healthcare professionals and shared decision-making, patients are empowered to seek the best available and suitable care. Furthermore, NCCPs should develop a model based on cancer centres, cancer networks or multidisciplinary teams, addressing the entire cancer care continuum through a comprehensive and holistic approach. Sharing of best practices across European cancer healthcare systems, promoting
research and innovation and its translation to maximise its impact to improve outcomes, and improving access to new and established cancer care are also key in delivering on the Bill of Rights.  

I.2. Patients’ involvement and empowerment: towards a patient centered cancer care?

Service specifications and guidelines from international and national governmental and non-governmental organisations define good practices in clinical cancer care. These are tested practices, with robust data supporting the link between the applied practice and the achieved good outcomes.

The European Society for Medical Oncology produces comprehensive topic- and disease-specific clinical guidelines. The European Cancer Organisation has set out the Essential Requirements for Quality Cancer Care (EROCC) for a number of cancers and primary care, and work is underway to complete requirements for several other cancers; these are organisational requirements, not clinical guidelines.

The EU has been supporting partnerships for more than a decade, and each project builds on the results of the previous ones. The European Partnership for Action against Cancer (EPAAC) delivered documents on a broad range of topics, including the European Guide for Quality National Cancer Control Programmes. The main deliverable of the Joint Action on Comprehensive Cancer Control (CANCON) was the European Guide on Quality Improvement in Comprehensive Cancer Control in 2017, the result of the work of hundreds of cancer experts, in 25 countries and 126 partner organisations. CANCON and it also published policy papers and briefs; please refer to the Annex of this note for a summary of the CANCON Guide chapter on policy recommendations for quality improvement in cancer survivorship and rehabilitation.

The Innovative Partnership for Action against Cancer (iPAAC), the current Joint Action brings together 24 associated partners and 20 affiliated entities across Europe whose main objectives are to build upon deliverables of the CANCON Joint Action and to implement innovative approaches to cancer control. Its main product will be a Roadmap on Implementation and Sustainability of Cancer Control Actions; an impressive set of work package documents is already available.

All international and national specifications and guidelines emphasise the importance of patient-centred cancer care, whose pivotal element is patient empowerment. Patient-centred cancer care rests on two pillars: (i) it requires a properly organised health care system and accessible and affordable cancer care, where various oncology healthcare professionals work together to provide seamless care;

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224 M. Lawler, I. Banks, K. Law, et al: The European Cancer Patient’s Bill of Rights, update and implementation; ESMO Open. https://esmoopen.bmj.com/content/1/6/e000127
and (ii) it needs healthcare professionals who commit themselves to properly inform the patient about the diagnosis, treatment options and prognosis, and encourage patients and their families to take part in the discussion about the treatment plan. Clarity for the patients about what is happening to them during the treatment, why, how and when; and trust that they know whom to turn if they have questions, doubts or difficulties, are of key importance.

Patient-centred cancer care and patient empowerment improve the quality of care and patient outcomes such as improved quality of life and well-being; helps to better adapt to the long-term effects of treatments; and creates greater independence from healthcare providers and carers. As active patients may comply with, and manage care better, it may increase the efficacy of the treatment, which then contributes to making healthcare systems more effective and sustainable.

The European Patients Forum launched the Patients’ Charter on Patient Empowerment in 2015. It defines the fundamental principles of patient empowerment from the patients’ perspective.

The Patients’ Charter on Patient Empowerment

1. I am more than my health condition.
2. I am empowered to the extent I wish to be.
3. I am an equal partner in all decisions related to my health.
4. I have the information I need in an easily understandable format, including my own health records.
5. My health professionals and our health system actively promote health literacy for all.
6. I have the ongoing support I need to manage my own care.
7. My experience is a vital measure of healthcare quality.
8. I can participate in evaluating and co-designing healthcare services so they work better for everyone.
9. Through patient organisations, my voice becomes part of a bigger, united voice.
10. Equity and empowerment go hand-in-hand - I want a fair deal for all patients.

Source: Charter on Patient Empowerment; EuropeanPatientsForum

I.3. Direct and indirect economic consequences of cancer: Financial toxicity

Thanks to scientific advances in oncology, more treatment options are available to an expanded number of cancer patients; but healthcare systems clearly feel the impact of rising treatment costs and longer treatment duration, and economic side-effects also become obvious at the patient level. The individual financial effects include not only the quantifiable, objective financial burden such as out-of-pocket expenses; the subjective financial impact, i.e. the consequence of cost concerns on the individual patient, is also an important component, which came to the spotlight only in recent years.

Research shows that anxiety and stress about cancer therapy costs are linked to adverse physical and mental health outcomes. It affects patients’ satisfaction of cancer care, leads to delay or give up cancer care, bankruptcy, poor quality of life and poor survival; in short, it becomes a clinical issue.

There are various definitions of financial toxicity in the literature. One defines it as the damaging effects of the financial pressure caused by the diagnosis and treatment of cancer on the well-being of patients, their families and the society. Another one describes it as the possible outcome of perceived ‘subjective financial distress’ resulting from ‘objective financial burden’. Here ‘objective financial burden’ refers to direct and indirect cancer-related costs, a concept well established in health economic analysis. There are also opinions questioning the use of the word ‘toxicity’ and the analogy between the ‘financial toxicity’ and treatment-related side-effects, as financial difficulties are not always fateful but the consequence of social or private circumstances in the past.

![Framework of financial toxicity and related aspects of subjective financial distress](image)

Financial toxicity is linked, on the one hand, to certain sociodemographic characteristics. Younger patients and those with lower household income will more likely face a greater financial burden; and the type of insurance, race, marital status, education, geographic location and comorbidity play a role, according to studies. On the other hand, cancer drug prices and rising cost of health insurance, as well as increased non-drug expenditure such as travel and lodging cost, hospital costs and supportive care also play a significant role.

Financial toxicity has, until now, been studied most in the United States; studies from countries with social insurance-based health care systems are still rare, and indicate the need for further investigation.

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227 See footnote 3
228 See footnote 4
methodological research. There is no consensus yet about how to measure financial toxicity; and while different methods exist, the only validated tool so far is the “Comprehensive Score for Financial Toxicity (COST)”, assessing financial toxicity in US cancer patients. Due to different socio-political conditions, however, it might not fit for use in Europe, and currently there is no consensus on a standardised instrument in Europe. Authors of the study referred to in footnote 4 note that there is a need to join efforts to develop a common understanding of the concept of financial toxicity and related subjective financial distress. They encourage using the following six domains to further develop survey instruments and adjust them to different health systems: (i) active financial spending, (ii) use of passive financial resources, (iii) psychosocial responses, (iv) support seeking, (v) coping with care or (vi) coping with one’s lifestyle. They propose to have the discussion on item domains and taxonomy coordinated by the European Organisation for Research and Treatment of Cancer (EORTC) group. In addition, they suggest initiating discussions with the European Society of Medical Oncology on whether questions on the subjective financial distress should also be included in their Magnitude of Clinical Benefit Scale (ESMO-MCBS), to enable a better understanding of new treatment options and their relative financial implications to patients.

II. Survivors

Cancer survivorship increases progressively, by 3% on a yearly basis; in 2018 more than 12 million cancer survivors were estimated in Europe. After successful treatment, social and professional reintegration is key in restoring “normality” in the patient’s life; it is so important that it even contributes to the patient’s remission. Returning to normal life has many components, but reintegration to work and access to financial services are central to that.

II.1. Reintegration to work
Though cancer management improved largely and the number of cancer survivors is increasing, many cancer survivors face long-term symptoms and deficiencies after their treatment ends, making it more difficult for them to remain in, or re-enter, the job market.

These include fatigue, exhaustion and emotional strain; diminished mental health, including depression and anxiety; diminished physical functioning and symptoms such as pain; and diminished cognitive capacities, including attention and memory problems. In the world of work, these symptoms and impairments translate into diminished work productivity, work ability impairments and reduced functioning at work. Workers treated for cancer are likely to have to take sick leave, and they might no longer carry out their usual tasks. These implications can occur early in the treatment process or can last years after diagnosis.

Not returning to work leads to financial loss for not only the worker but the employer and the society as well; little is reported though about the overall financial loss, and the results are no consistent. What is known is that the total economic loss to the EU, due to lost working days as a result of cancer, was estimated at EUR 9.5 billion in 2009, but this is not all related to unsuccessful return to work. The overall risk of unemployment among cancer survivors is 1.4 times higher than the general population of similar age amongst cancer survivors with follow-up times of 0–5 years post-diagnosis. Cancer survivors have an increased risk for long-term unemployment among very long-term survivors, mainly among patients diagnosed with CNS malignancies and lymphoma. Improving rehabilitation and return to work of workers affected by cancer is important to improve the well-being of this vulnerable group, and reduce the societal and financial impacts of the disease.

At EU-level, given the lack of specific instruments for the reintegration into work of cancer patients and patients of other non-communicable diseases (NCDs), employment activation is implemented through non-discrimination policies and the policy framework for the employment of persons with disabilities. It includes

- the European Disability Strategy 2010-2020 (COM(2010)636); the post-2020 strategy is in preparation;
- Council Recommendation on the integration of the long-term unemployed into the labour market (2016/C 67/01); and
- Commission Recommendation on the active inclusion of people excluded from the labour market (2008/867/EC).

Furthermore, policy provisions focusing on the professional (re-)integration of persons with NCDs are also often part of broader policy frameworks such as the Europe 2020 Strategy, and the EU

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229 Y. Rottenberg, A.G.E.M. de Boer: Risk for unemployment at 10 years following cancer diagnosis among very long-term survivors: a population based study; Journal of Cancer Survivorship

Strategic Framework on Health and Safety at Work 2014-2020 (COM(2014)332) and 2021-2027 (in preparation). This Health and Safety at Work Strategic Framework refers to supports in recruitment and return to work of people with, among others, a chronic or rare disease, and the use of integrated employment measures such as individualised support, counselling, guidance, access to general and vocational education and training.

In addition, a number of EU actions specifically target chronic diseases or particularly cancer such as the ‘Reflection Process on Chronic diseases’ and its final report; the Joint Action on Chronic Diseases (CHRODIS); and the Joint Action on Cancer Control 2014-2017 (CANCON) and the Innovative Partnership for the Action Against Cancer 2018-2021 (iPAAC).

CANCON as a joint action was co-funded by the past EU Health Programme. Its final deliverable is the comprehensive European Guide on Quality Improvement in Comprehensive Cancer Control, giving policy recommendations on cancer screening; comprehensive cancer control networks; community-level cancer care; and cancer survivorship and rehabilitation. Concerning rehabilitation and return to work, the guide calls for

- integrating social and return-to-work issues early into the cancer care pathway. Adaptation of working conditions for any patient returning to his/her previous work should be assessed at early stages.
- developing and implementing public policies to support cancer patients from diagnosis to return to work, including a) financial aspects such as access to loan, mortgages, life insurances; b) implementation of a pan-European strategy to tackle the differences between workers with cancer in different countries and to prevent discrimination; and c) generation of more evidence to better understand the living conditions of cancer survivors who return to work.
- implementing a person-centred approach to a) access a multidimensional physical and psychosocial rehabilitation plan focusing on the skills of cancer survivors; b) safeguard cancer survivors’ working lives; their employability, competencies and capacity to work, as well as their motivation to work; offer new skills to self-employed workers to help them to achieve balance between health needs and work; c) involve peers, patient organizations and trade unions to help patients and survivors; and d) negotiate a patients’ bill of rights, including the right to work with special conditions (e.g. reduced hours of work or adapted working conditions).
- implementing a work-centred approach with a better involvement of employers in survivors’ return-to-work process, to a) explore possibilities of changes in job function for cancer survivors and to encourage them to acquire new skills; b) facilitate the implementation of flexible working hours and options (remote working, part time work); and c) offer economic benefits to employers who agree to adapt the workplace to the needs of cancer survivors and to help self-employed workers to adapt their workplace and business to address health needs.

Policy approaches at European level are reflected in national-level polices. Due to budgetary constraints and changing trends, integration-oriented policies are expanding and compensation-oriented policies are less widely used in most of the Member States. Despite the similar general approach, divergences across the EU exist due to the different cultural, historical and economic backgrounds, differences in institutional and social settings, in approaches to chronic diseases and disabilities, etc.
The PATHWAYS Project (Participation to Healthy Workplaces and Inclusive Strategies in the Work Sector) was a three-year project, funded by the previous EU Health Programme, which aimed to develop innovative approaches to promote the professional integration of people with chronic diseases, and improve their employability. Its final report, ‘Comparison of available strategies for professional integration and reintegration of persons with chronic diseases and mental health issues’, addressed this specific need. The project mapped the strategies for professional (re-)integration of persons with NCDs in ten selected countries, based on five categories of social welfare models in Europe, and concluded that NCD patients are treated as part of a group of persons with disabilities, including persons with reduced work capacity due to illnesses. In many cases, persons with chronic health problems are eligible for specialised support in employment only when their condition is recognised as a disability (with a certain eligible degree of disability) or has a negative impact on their work ability, depending on national and regional regulations.

The report by the European Agency for Safety and Health at Work on ‘Rehabilitation and return to work after cancer - instruments and practices’ identifies 78 instruments, practices, policies and interventions addressing rehabilitation and return to work of cancer survivors, collected from 13 Member States, the USA and Australia. It singles out seven innovative good practice examples. All of these good practices include a range of information resources, training materials and guidance for employers; employment advice in the form of information and helpline for employees affected by cancer, carers, and specific advice for the self-employed; and resources for health and social care professionals. Several programmes involve different stakeholders, such as the hospital, the employer, a job consultant and the employee. Some programmes start early, allowing occupational health physicians to be part of the in-hospital rehabilitation team.

II.2. The right to be forgotten

Bankers and insurers have difficulties to assess the risks associated with cancer and the risk of relapse; therefore, they tend to take a precautionary approach for the protection of their business and require cancer survivors to meet additional conditions for accessing loans, mortgages and insurance policies. Moreover, risk assessments used by financial service providers are often based on outdated data or models and do not follow therapeutic progress and improvements in prognosis. All this falls back on the customer, i.e. the cancer survivor, who faces various obstacles when applying for loans and mortgages, or taking out insurance policies. Hurdles range from direct denial by the bank to the need to contract a life insurance to ensure the loan/mortgage, and the charging of additional insurance premium or a warranty exclusion provision.

Directive 2014/17/EU on credit agreements for consumers relating to residential immovable property (Mortgage Credit Directive) stipulates that before concluding a credit agreement, the creditor makes a thorough assessment of the consumer’s creditworthiness. That assessment takes appropriate account of the factors which are relevant to verifying the prospect whether the consumer meet his obligations under the credit agreement. It is carried out on the basis of information on the consumer’s income.

and expenses and other financial and economic circumstances which are necessary, sufficient and proportionate.

It appears that the lack of uniformly applied specific criteria concerning cancer survivorship has contributed to a fragmented creditworthiness assessment practice, with no transparency and monitoring control. Recognising the problem, France, Belgium, Luxembourg and the Netherlands have passed legislation about the right to be forgotten for cancer survivors.

The provisions of the legislation in these Member States are very similar. They stipulate that the longest period for which medical information relating to cancer can be collected is ten years after the end of treatment if there is no relapse, and, for cancers occurring before the age of 18 (age of 21 in the Netherlands), five years after the end of treatment. A list of exceptions for cancers with an excellent prognosis complement the provisions, where a shorter timeline is applicable to exercise the right to be forgotten. The provisions are subject to regular review, in order to adjust them to scientific data and advancement in treatments.

Those legislative initiatives prove that where there is a will, there is a way to remedy discrimination practices and limit the margin of insurers and banks concerning creditworthiness assessment and risk assessment for insurance policies. Enacting an EU-wide ‘right to be forgotten’ would initiate a dialogue between lawmakers and medical science; would ensure that legislation is kept updated to medical progress; and, most importantly, would minimise discrimination, promote social equality and ensure equal access to financial services for all EU citizens who are cancer survivors.

In 2020, the European Cancer Patient Coalition started a legal research project to review the laws and practices of all Member States, and evaluate what discrimination cancer survivors face when attempting to obtain mortgages and loans, life insurances, and other financial services. The project also assesses the conditions for introducing European legislation on the right to be forgotten.

III. Caregivers

Healthcare and support for people with chronic illnesses, such as cancer, has traditionally been provided in hospitals and care institutions by trained health staff. With resources for in-hospital services having become limited, more services are now provided on an ambulatory basis. In this situation carers, typically family members or close friends of the patient, take responsibility for many of the home healthcare services.

The recently adopted Directive (EU) 2019/1158 on work-life balance for parents and carers defines carer as “a worker providing personal care or support to a relative, or to a person who lives in the

same household as the worker, and who is in need of significant care or support for a serious medical reason, as defined by each Member State”. Eurocarers, the EU network working with and for carers, approaches it from a different angle and includes into their definition those carers as well who are not workers: “persons of all ages who provide care (usually unpaid) to someone with a chronic illness, disability or other long-lasting health or care need, outside a professional or formal employment framework”.

Based on the broader definition of carers and the data collected through Eurofound’s European Quality of Life Survey, it is estimated that there are more than 100 million carers in the EU today. Caregiving represents an enormous cost saving to the health care and social security system: the economic value of unpaid informal care, expressed as a percentage of the overall cost of formal long-term care provision, ranges from 50 to 90% across the Member States.

Carers often need to reduce their working hours, cannot take certain working opportunities or have to give up their job. As two thirds of the 100 million European carers are women aged between 45 and 75 years, caring responsibilities contribute substantially to the gender pay gap (on average 16% in the EU) and gender pension gap (on average 40% in the EU), and make many women economically more dependent on their partners or the state. This results in a higher risk of exposure to poverty and social exclusion for women, and the negative impacts also affect their children and families. The direct costs of care, medical devices, home adaptations and payments for formal care which often fall on the carer or his/her family, further worsen the financial burden. 42% of non-working carers are in the lowest income percentile (compared to 24% of non-carers) and 59% of non-working carers have difficulty covering for their needs (compared to 46% for non-carers).

Recent developments such as lower birth rates and the trend towards smaller families, increasing mobility, the growing number of women in active employment and delayed retirement result in increased pressure on carers. Furthermore, in many countries, care provision is being decentralised and the health care system counts on society to step up to the challenge; which coincides with increasing shortages of formal caregivers.

Against this backdrop, it is not surprising that mental health problems (e.g. depressive disorders, anxiety, anger and hostility) among informal carers is 20% higher than in the rest of the population. Caring also has adverse effects on physical health, as carers are more likely not to meet their own health needs due to coping techniques resulting in harmful habits and lifestyles, and failure to take preventive health measures.

It is clear from the above that informal carers, and through them the whole system of caregiving, comes under pressure; and it is happening in the exact same time when cancer prevalence is rising.

The EU has been addressing these issues through policies related to ensuring gender equality in the labour market and the promotion of work-life balance. Legal provisions, the European Semester of policy coordination, and EU funding and policy guidance form the framework. Legislation has been modernised recently, with the adoption of Directive (EU) 2019/1158 on work-life balance for parents and carers, mentioned above, which has introduced specific provisions into EU law on carers’ rights:
The work-life balance directive has introduced carers’ leave, and set its minimum level at five working days per year.

Under the directive, carers have the right to request flexible working arrangements (remote working, flexible working schedules, or part-time working arrangements) for caring purposes. The directive ensures that employers must deal with these requests within a reasonable period of time, and provide reasons for refusing or postponing such arrangements.

Member States must ensure that rules are introduced into national legislation to protect workers from discrimination and dismissal on the grounds that they have applied for, or have taken, family-related leave or flexible working arrangements.

Member States have until August 2022 to transpose the provisions of the directive into national law.

In addition, in its communication COM(2017)0252, the Commission proposed non-legislative measures to address the lack of sufficient or adequate care services and tackle economic disincentives to work for second earners:

- Continuing to monitor the transposition of EU legislation, pursuing and launching infringement procedures when necessary, ensuring better implementation of legislation, and promoting compliance e.g. via EU funding;
- Continuing to monitor the design and the gender balanced take-up of family-related leaves and flexible working arrangements as part of the European Semester, and in the annual report on gender equality;
- Continuing to identify country-specific obstacles resulting from tax-benefit systems, and monitoring progress in addressing them;
- Improving the collection of EU-level data by Eurostat on the uptake of family-related leaves and flexible working arrangements by women and men; improving EU-level data collection on economic disincentives for second earners; and developing and using benchmarks at EU level on work disincentives for second earners created by tax-benefit systems in the context of the European Semester;
- Providing funding and ensuring that the European Social Fund Plus and other funds are supporting adequately work-life balance measures; and
- Sharing best practices with social partners and Member States.
Annex: The CANCON guide on Cancer survivorship and rehabilitation

This is a summary of the key points of the chapter of the CANCON Guide dedicated to policy recommendations for quality improvement in cancer survivorship and rehabilitation, reflecting on all issues covered in Section I of this background note.

CANCON guide on Cancer survivorship and rehabilitation
- Summary of the chapter on policy recommendations for EU Member States for quality improvement in cancer survivorship and rehabilitation -

Medical follow-up: focus on late effects and tertiary prevention

- Systematically planned, early and personalised follow-up programmes should be put in place, addressing the survivors’ individual risk of multidimensional late effects of treatment and respective rehabilitation needs; socially disadvantaged people should be supported to be able to fully engage in follow-up programmes.

- Adequate and updated information on medium and long-term effects of treatments should be available to survivors and their relatives, and to care providers involved in the follow-up (in particular primary care professionals) for better prevention and care.

- Identification and management of late effects of cancer treatment should be integrated in the professional training and continuous medical education of clinicians (including GPs).

- In tertiary prevention, self-management should be emphasized, particularly on lifestyle recommendations.

- Physical activity should be integrated early in the care pathway for all cancer survivors.

- Evaluation of physical and psychosocial rehabilitation needs should be screened already prior to the start of any cancer-specific treatment; both physical and psychosocial screening should be carried out simultaneously by using simple algorithms; and after the first screening, regular updates should be performed on individual basis.

Needs for a person-centred approach in psychosocial rehabilitation, supportive and palliative care

- Periodic screening of psychological distress and psychosocial needs should be conducted during the entire cancer pathway and integrated in routine cancer care; and screening should be followed by adequate provision of psychosocial care.

- For the diagnosis of psychological conditions a specific assessment should be carried out by a psychological care professional, anticipating the specific needs of populations at high risk, including young populations (e.g. children, adolescents, young adults) and relatives.

- A step-wise or tiered model of psychological care is recommended depending on the level of distress, psychological condition and morbidity of each patient. The interventions range include a) information and psycho-education by primary oncology team to peer support; b) e-health platforms for psychosocial support and self-management programmes; c) Psychological interventions by professionals trained in psycho-oncology (e.g. psychologists, social workers, psychiatrists); d) complementary spiritual support by chaplains and others; and e) psychotropic treatments by trained physicians (e.g. psychiatrists, oncologists).
Psychosocial interventions in individual or group format should be delivered by appropriately trained professionals with specific expertise in psychosocial oncology. Increased investment in training in psychosocial oncology and communication skills for primary oncology staff is highly recommended. Existing clinical practice guidelines for psychosocial support of patients with cancer could be recommended for the provision of evidence-based psychosocial care.

Social and return-to-work issues should be integrated early into the cancer care pathway. Adaptation of working conditions for any patient returning to his/her previous work should be assessed at early stages.

Public policies should be developed and implemented to support cancer patients from diagnosis to return to work, including a) financial aspects such as access to loan, mortgages, life insurances; b) implementation of a pan-European strategy to tackle the differences between workers with cancer in different countries and to prevent discrimination; and c) generation of more evidence to better understand the living conditions of cancer survivors who return to work.

A person-centred approach should be implemented, to a) access a multidimensional physical and psychosocial rehabilitation plan focusing on the skills of cancer survivors; b) safeguard cancer survivors’ working lives; their employability, competencies and capacity to work, as well as their motivation to work; offer new skills to self-employed workers to help them to achieve balance between health needs and work; c) involve peers, patient organizations and trade unions to help patients and survivors; and d) negotiate a patients’ bill of rights, including the right to work with special conditions (e.g. reduced hours of work or adapted working conditions).

A work-centred approach should be implemented with a better involvement of employers in survivors’ return-to-work process, to a) explore possibilities of changes in job function for cancer survivors and to encourage them to acquire new skills; b) facilitate the implementation of flexible working hours and options (remote working, part-time work); and c) offer economic benefits to employers who agree to adapt the workplace to the needs of cancer survivors and to help self-employed workers to adapt their workplace and business to address health needs.

Somatic and psychological symptoms as well as social challenges should be addressed in all phases of the cancer disease trajectory early, systematically and regularly. Treatment should be according to the best scientific evidence available.

Formal education in palliative care should be a compulsory component of the professional curriculum for specialists in medical oncology, for GPs and community clinicians. Basic training should be mandatory in medical and nursing schools; and specialized palliative care skills and services should be accessible to patients with advanced incurable disease and part of multidisciplinary tumour boards.

Best achievable quality of life for the individual patient and the relatives should be part of a survivorship care plan for patients with late side-effects from cancer and antineoplastic treatments.

Multidisciplinary approach in survivorship care: coordination of providers and empowerment of survivors

Psychosocial care, rehabilitation and palliative care should be integrated into the entire cancer pathway including the survivorship and rehabilitation period. Psychosocial, rehabilitation and palliative care specialists should be members of (or associated with) the medical team in hospitals and in community care.

After the completion of the acute treatment phase, the follow-up period should begin with the elaboration of a survivorship care plan.
The role of GPs and other primary care professionals should be actively supported to help them to manage all the care plan challenges. Their role should be clearly defined and tailored to the patient and the care plan needs; and this role could evolve during the follow-up period.

Communication between primary health care providers and health care specialists needs to be improved, via electronic patient records systems that should be accessible to all health care providers treating the patients. Communication between patients and health care providers should also be improved. Communication skills should be integrated into the training of health care professionals.

A key health care professional assuming a case management role should be assigned to each patient in accordance with medical and/or psychosocial specific requirements. This health care professional could play a main role in reducing the vulnerability of the patient, for example with the management of adverse drug effects.

Empowerment of patients and their relatives should be enhanced to increase their participation in self-management, rehabilitation and back to work programmes. Online programmes would facilitate this process.

Education and self-management programmes should be developed and evaluated.

**Childhood, adolescent and young adults issues in cancer survivorship care**

Transition of care from paediatric oncology to adult medicine, including a survivorship passport for each patient, should be organized to guarantee adequate long-term follow-up and setting up appropriate intervention.

It is necessary to aim for a more efficient survivorship care planning and coordination to respond to the challenges of the prevalence of chronic conditions, health status deteriorations, treatment and complex prevention.

Rehabilitation and supportive care should be specifically offered to children, adolescent and young adults as cancer survivors, in particular adapted physical activity. A routine yearly psychosocial assessment with attention to social, psychological, and behavioural issues, educational and/or vocational progress should be provided to this population.

End-of-life care and palliative care for children and adolescents should be improved across Europe.

**Perspectives in survivorship and rehabilitation cancer research**

An information and data collection system focused on late adverse effects (physical, psychological, cognitive, social, sexual), coupled to the surveillance of patients and involving primary care professionals, should be set up. More patient-reported outcome measures and their routine use are needed.

Through the use of cancer registries for collecting data on survivors, lifestyle, quality-of-life or socioeconomic information could be used to better identify the causes of inequalities in survivorship; registries should be expanded to include additional factors that influence the quality of life (e.g. rehabilitation and employment issues); and patient reported outcomes could also be a way to collect appropriate information.

Clinical research should evaluate the feasibility, the efficacy and the cost-effectiveness of non-drug-related interventions such as self-management and e-health programmes.
Future research is needed to establish a multidimensional rehabilitation model focused on the quality of life and the coordination of complex care to better address the management of late effects across the whole survivorship trajectory. More research would also be required to maximize the long-term follow-up and care of childhood cancer survivors and to identify the genetic risks associated with late effects and second cancers.

More solid methodological randomized controlled trials and cohort studies are needed in order to reduce the intensity of cancer treatments while maintaining their efficacy and thus reducing the probability of late effects, especially in childhood cancer survivors.

Source: CANCON Guide
BACKGROUND NOTE ON ACCESS TO CANCER TREATMENT

After diagnosis, cancer patients require medical treatment and specialised care for months, or often years. Their treatment is tailor-made, reflecting the individuality of the patient and their cancer. Surgery, radiotherapy and chemotherapy are the most common treatments; other systematic and non-systematic options are also relevant for certain types of cancer or as complementary treatment. After successful treatment, the patient may need rehabilitation and specialised care; and when the treatment cannot cure the disease, supportive and palliative care are essential, helping to maintain the highest possible quality of life. Palliative care and rehabilitation include a range of medical services going beyond oncology.

I. No two cancers are the same: Modalities of cancer treatment

I.1. Surgery

Surgery is a key component of cancer treatment, which can cure most solid tumours. An estimated 80% of new cancer cases require surgery, some even several times. Though surgery was available for many years, surgical oncology as a speciality has emerged recently, together with the development of radiotherapy and chemotherapy as separate modalities. The advancement of operating techniques such as laparoscopy or fibre optic endoscopy makes surgery less invasive; and given the high technical demands of such surgery, surgeons specialise further in organ-based sub-groupings.

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Surgery aims at controlling the tumour locally. Thanks to the rapid development of diagnostics and technical advancement of operating techniques, surgery has become less mutilating and more conservative/organ sparing (as long as organ sparing remains compatible with an adequate resection of the tumour). Surgery can be performed not only to cure tumours, but also to prevent the onset of the disease; one of the most well-known example is mastectomy in patients with BRCA gene mutation and family history of breast cancer. It also plays a role in palliative cancer care, though it is now less widely used with the rise of endoscopic and radiological technology.

I.2. Radiation therapy

Radiation therapy uses ionising radiation, mostly high-energy X-rays or gamma rays. X-rays used for treatment are up to one hundred times more penetrating than those used for diagnosis. Tight beams deliver the radiation therapy to well defined areas in the body, in order to minimise damage to the surrounding healthy tissues. 50% of all cancer patients worldwide benefit from radiotherapy at some stage of their illness, either as part of curative therapy or as palliation for pain or other symptoms.

The provision of radiotherapy requires advance planning from the national health care systems: it needs facilities, equipment, and most importantly a specialised, well-trained oncology workforce including doctors, physicists, nurses and technicians. It is of note that this is a comparatively low-cost treatment; even if radiotherapy is an often applied treatment so the number of treatments represent a major component in cancer care, its share of the annual cancer budget is low. (According to a recent survey, annual expenses for radiotherapy, including capital investment, represent on average 7.8% of the cancer care budget.)

I.3. Chemotherapy

Chemotherapy is a systematic cancer treatment, as anticancer drugs circulate in the whole body via the bloodstream. Most of the currently used anticancer drugs inhibit DNA synthesis or cell division in cancerous cells, inducing cell deaths (apoptosis). Chemotherapy may be used prior to surgery or radiotherapy (neo-adjuvant treatment) to shrink the tumour or prevent metastasis; or after surgery or radiation (adjuvant treatment) to reduce the risk of relapse by eliminating cancer cells that have broken away from the tumour before operation. It can also be used as the principal treatment for haematological tumours such as leukaemia, or for metastatic cancers. Chemotherapy is also valuable in improving patients’ quality of life by soothing symptoms and pain, even in cases when the patient’s survival cannot be expected.

<table>
<thead>
<tr>
<th>Categorization of cancer by effectiveness of chemotherapy</th>
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<tr>
<td><strong>Responsiveness (in decreasing order of efficacy)</strong></td>
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<tr>
<td>Category 1</td>
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<td>Category 2</td>
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<td>Category 3</td>
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<td>Category 4</td>
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<tr>
<td>Category 5</td>
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Source: [IARC](footnote 1) - Table 6.7, p. 284
How efficient chemotherapy can be depends on the type of cancer. Currently, cancers can be split into five categories according to the relative usefulness of chemotherapy:

- **Category 1**: The use of a single drug or a combination of drugs, alone or in multimodal therapy, will cure the cancer (normal life span or prolongation of survival);
- **Category 2**: The average survival is prolonged when chemotherapy is used as an adjuvant treatment, i.e. after surgery or radiotherapy, in the early stages of disease;
- **Category 3**: A single drug or a combination of drugs will produce clinically useful responses in more than 20% of patients. The survival is prolonged for most responding patients, but may be of short duration;
- **Category 4**: Using chemotherapy before, during or after surgery and radiotherapy may improve the local control of the tumour;
- **Category 5**: Cancers for which there are currently no effective drugs. Cancer responds to chemotherapy in less than 20% of patients, and there is no evidence of survival benefit in randomised controlled trials compared to best supportive care.

Most of the world’s most common cancers fall into category 3.

**I.4. Other systematic and non-systematic treatment options**

In addition to the most common treatments mentioned above, other treatment options include:

**(a) systematic treatments:**

- **Immunotherapy**: As part of its normal functioning, the immune system detects and destroys abnormal cells, and most likely prevents or stops the growth of many cancers. However, cancer cells are protecting themselves and have ways to avoid destruction by the immune system. Immunotherapy therefore revs up the immune system and helps it to better act against cancer;
- **Nuclear therapy**: This therapy uses radioactive molecules as a drug. The drug is injected intravenously; it circulates in the body via the blood stream, recognises tumour cells, sticks to them and delivers radiation directly, which causes them to die. As over time radioactivity fades away, the therapy needs to be repeated multiple times to achieve the most benefit;
- **Targeted therapy**: It is the foundation of precision medicine (see below). The therapy targets proteins that control the growth, division and spread of cancer cells;
- **Hormone therapy**: This therapy works for those cancers that use hormones to grow such as breast and prostate cancer. The therapy either blocks the body’s ability to produce hormones or interferes with how hormones behave in the body. It can be administered as neo-adjuvant or adjuvant treatment, in combination with surgery or radiotherapy;

**(b) non-systematic treatments:**

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235 N. Couspel & others: ‘Strengthening Europe in the fight against cancer’ - study for the ENVI Committee; 2020 

236 See footnote 1
- **Interventional radiology/oncology**: It is a medical sub-specialty where minimally invasive procedures are performed under image guidance (X-ray, ultrasound, CT, MRI). It allows for direct delivery of treatment to the tumour site, and can also be used for diagnostic purposes. In the future it can also be used to locally deliver immune therapies;

- **Stem cell transplant**: In patients who have had their stem cells destroyed due to high doses of chemotherapy or radiotherapy, stem cell transplant helps restore those blood-forming cells;

- **Precision medicine or personalised medicine**: Based on the understanding of the genetic changes in the patients’ tumour, patients receives personalised treatment that works the best for them. It spares patients from undergoing treatment (and suffering from its side effects) which are not likely to help.

It is worth emphasising again that **cancer treatment is multimodal and multidisciplinary**, and the management of cancer cases requires that a team of oncology medical professions work together for the best results.

### II. From ideas to patients: Cancer drug development, authorisation and provision of medicines

#### II.1. Research and preclinical tests

Developing a new cancer medicine starts with understanding (more) about the given cancer and how to influence its behaviour, and identifying a molecule or compound that might have the potential to become a medicine. Tens of thousands of substances are investigated every year by pharmaceutical and biotechnology companies, doctors and academics as potentially promising treatments, and only a few of them will become a medicine.

That molecule or compound is tested first in preclinical settings to determine its safety, i.e. whether it is safe to test in people. These preclinical tests are performed either *in silico* (in computer models), *in vitro* (in a testing tube, in a controlled environment outside a living organism), or *in vivo* (in a living organism, in animal tests). Only after that, it can be tested on human subjects.

#### II.2. Clinical trials

Tests on human subjects are conducted in clinical trials, where well-elaborated and strict protocols guarantee the safety of trial subjects, the adherence to ethical norms, and the transparency of data of trial successes and fails. The trial can start only after the trial protocol has been authorised, and the trial has been registered in the publicly available database. Clinical trials start with a small trial in healthy volunteers (Phase I), and then move to increasingly large trials (Phases II and III). These latter phases are often multi-centre trials and may involve thousands of patients in several countries, in order to test the safety and efficacy of the drug on the broadest possible population group.

Clinical trials in the EU are currently conducted according to Directive 2001/20/EC and the national laws transposing the directive; the new clinical trials regulation (Regulation (EU) No 536/2014).
harmonising the conduct of clinical trials according to the highest standards all over the EU, is expected to enter into force soon. Trials must also meet the requirements of Good Clinical Practice (GCP) guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH); and the investigational medicinal product, i.e. the medicine used in the trial must be produced in compliance with the Good Manufacturing Practice (GMP) guidelines.

In a trial, participants are separated into two groups on a randomised basis, ensuring that the patient selection does not influence the outcome of the trial. One group is given the investigational medicine or treatment procedure, and the other group (the control group) the best existing therapy or a placebo. Most of the trials are blinded, i.e. participants do not know what treatment they receive. In double blinded trials the healthcare professionals assisting in the trial do not know either which patient is in which group and receives which treatment.

II.3. Authorisation procedure

Once the trial has been completed, the information and results from all the preclinical and clinical studies, together with a description of the medicine's manufacturing process, are compiled and submitted to the regulatory authority for authorisation. The authorisation procedure can be national or centralised. For certain medicines such as medicines with new active substances for the treatment of cancer, the centralised authorisation procedure is compulsory. Regulation (EC) No 726/2004 lays down the rules for the centralised procedure; the European Medicines Agency and its Committee for Medicinal products for Human Use (CHMP) assesses the application and submits its recommendation to the European Commission. The EU-wide marketing authorisation is granted by the Commission.

The EU pharmaceutical legislation allows for facilitating early access to new medicines via regulatory tools:

- Accelerated assessment: For medicines of major public health interest, in particular medicines for unmet medical needs, the timeframe for reviewing the application for marketing authorisation is reduced. The standard assessment time is 210 days; under accelerated assessment it can be down to 150 days or less;
- Conditional marketing authorisation: For new medicines for seriously debilitating or life-threatening diseases, including orphan medicines and medicines for emergencies, marketing authorisation is granted before complete data are available. Comprehensive data needs to be generated after marketing authorisation, within the agreed timeframe;
- Compassionate use: The use of an unauthorised medicine is allowed for patients or a group of patients with chronically, seriously debilitating or life-threatening diseases, with no satisfactory treatment authorised in the EU. The criteria and conditions of use, distribution and the target population are set in the recommendation of the CHMP; the decision on making the medicine available in their territory rests with the Member States.

In addition to these tools, in 2016 EMA launched the PRIME scheme promoting accelerated assessment. ‘PRIME’ stands for priority medicines, i.e. medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients with no treatment options. Through early dialogue and scientific advice, the scheme thrives to strengthen the design of clinical trials so that the
trials will generate high quality data. It works together with the regulatory tools mentioned above, so a PRIME medicine can benefit from accelerated assessment at the time of an application for marketing authorisation. Oncology medicines lead the PRIME chart both in terms of applications submitted and requests granted.

II.4. **Pricing and reimbursement**

Pricing and the rules on reimbursement of the medicines are set by the Member States. To determine the price, Member States use similar tools across the EU:

- External price referencing (EPR) is one of the most frequently applied pricing policies, when the price of a medicine in one country is based on the price of the same medicine in other countries;
- Public purchasers and payers conclude individual arrangements, so-called Managed Entry Agreements (MEAs) with manufacturers to manage the adoption and funding of those new medicines that have uncertain effectiveness, unfavourable cost-effectiveness and/or high budget impact at the time of market entry;
- Health technology assessment (HTA) is also a widely used tool; see the details below.
- Horizon scanning can help countries prepare for the pricing and reimbursement of medicines that have not yet been launched;
- Some Member States establish specific funds for cases when the expense of some high-priced medicines cannot be borne within general public reimbursement. For example, in 2017 Italy introduced two so-called “funds for innovation”, one for cancer medicines and one for non-oncology medicines, with 500 million EUR each from the national budget to support the regions, which normally procure and pay for medicines.

The efficacy, safety, and value of medical innovations are assessed in many countries through a formal **health technology assessment (HTA) system**. HTA measures the added value of a new health technology (medicinal products, medical equipment, diagnostic and treatment methods, rehabilitation, and prevention methods) compared to existing ones, whether it works better, equally well, or worse than existing alternatives. In addition to medical issues, the process also focuses on economic, organisational, social and ethical questions related to the use of a health technology such as its cost implications for the patient and its impact on the organisation of healthcare systems in the administration of treatment.

The assessment is carried out by **national authorities or designated HTA bodies**. Though HTA bodies have been cooperating since 2007, it was Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare that established formally a voluntary cooperation and a network of those authorities and bodies. The network is supported at technical and scientific level by the EUnetHTA Joint Action (2016-2021) under the third EU Health Programme.

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237 WHO Policy Brief 30 ‘Ensuring access to medicines: How to redesign pricing, reimbursement and procurement?’, 2018

[https://www.euro.who.int/__data/assets/pdf_file/0009/379710/PolicyBrief_AUSTRIA_PB30_web_13082018.pdf](https://www.euro.who.int/__data/assets/pdf_file/0009/379710/PolicyBrief_AUSTRIA_PB30_web_13082018.pdf)
To reinforce further the cooperation of Member States on HTA, in 2018 the Commission presented a legislative proposal (COM(2018)051). Greater transparency empowering patients by ensuring access to information on the added clinical value of new technology; more assessments leading to effective, innovative health tools that reach patients faster; more robust evidence on which national authorities can formulate policies for their health systems; and the advantage for manufacturers that they would no longer have to adapt to different national procedures are amongst the key objectives of the proposal. The European Parliament adopted its first reading position on the proposal back in February 2019 (P8_TA(2019)0120), while the Council’s position is not yet established. During her hearing as Commissioner-designate in 2019, Commissioner Kyriakides pledged for advancing on the proposal.

The pricing of cancer drugs balances on several factors: there must be incentives for the pharmaceutical companies to innovate and invest, and prices must be profitable; while the cost of pharmaceutical industry-led R&D should be transparent, and the drug must remain accessible to patients. In its 2016 conclusions the Council noted that new medicinal products pose new challenges to patients and public health systems, in particular with regard to the assessment of their added value, the consequences for pricing and reimbursement, the financial sustainability of health systems, their post-market surveillance and patient access and affordability.

Pricing and reimbursement rules are in the exclusive competence of the Member States. As price negotiations with the national payers, and the possible discounts and conditions agreed in these negotiations are kept confidential, the price of the same cancer drug might vary considerably across the EU. In the same conclusions as referred to above, the Council underlined that any possible cooperation amongst the Member States on pricing and reimbursement must remain Member State-driven.

II.5. Continued monitoring: pharmacovigilance; medicine shortages

Once on the market, strict monitoring of the medicine in the context of pharmacovigilance continues to detect any potential safety or quality issues. The basic pharmaceutical legislation, Directive 2001/83/EC and Regulation (EC) No 726/2004 were amended in 2010 for this purpose. The details of pharmacovigilance are set out in a Commission implementing regulation and the guidelines on Good Pharmacovigilance Practices (GVP).
**Medicine shortages** can occur for many reasons, due to manufacturing difficulties or problems affecting the quality of medicines that can affect patient care. National competent authorities in the Member States monitor the supply, take preventive measures, and deal with shortages. Regulatory authorities are increasingly working together, e.g. via the European medicines regulatory network, to prevent shortages and to limit their impact when they occur. EMA can be involved in certain situations, for example when a medicine shortage is linked to a safety concern or affects several Member States. Furthermore, since 2016, EMA publishes a public catalogue for shortages assessed by its Committee for Medicinal Products for Human Use (CHMP) and/or the Pharmacovigilance Risk Assessment Committee (PRAC), and provides information and if needed, recommendations to patients, healthcare professionals and other stakeholders.

### III. Mind the gap: Inequalities in accessing cancer treatment

#### III.1. Trends in cancer care spending

To produce benefits, innovations in cancer treatment must reach patients in clinical practice, which requires the Member States to invest into health care, to increase their spending. In Europe between 1995 and 2018, the health expenditure spent on cancer care doubled from 52 bn EUR to 103 bn EUR (in 2018 prices and exchange rates), and the per-capita health spending on cancer increased by 86% from 105 EUR to 195 EUR. However, the direct costs of cancer per capita differ greatly between countries: Austria, Germany, Switzerland, the Benelux countries, and France spend the most on cancer care; while countries along the Eastern border of the EU (except Finland)

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spend the least on cancer care, in line with their lower overall spending on health care per capita. It is of note though that differences in per-capita health spending on cancer are decreasing over time as poorer countries are spending more.

During this ten-year period, three main trends can be observed in the development of the direct costs of cancer:

- Direct costs have been growing in line with total health expenditure, and the share of cancer spending remains stable, around 4-7% of total health expenditure. The increase in direct costs is due to the rising number of cancer patients, more intensive care and increased costs per patient.
- Cancer care has shifted from inpatient (comparatively expensive) to ambulatory (comparatively cheaper) setting. New treatment modalities, including new cancer medicines and the more widespread use of oral medicines, has driven, at least partially, this change. Some countries are believed to have reached already the maximum possible cuts of hospital beds.
- Expenditures on cancer medicines have been rising: The total expenditure doubled from 14.6 bn EUR to 32.0 bn EUR (in 2018 prices and exchange rates), and per-capita spending on medicines increased from 28 EUR to 61 EUR. The share of costs in cancer medicines within the overall direct cancer costs has also increased from 17% to 31%. Increasing number of cancer patients, increasing number of new cancer medicines leading to increased usage, and higher prices of new medicines are behind the increase in cancer medicine spending.

### III.2. Patients’ access to cancer medicines

During the ten-year period of 2008 and 2018, the general pattern is the stronger uptake of the newest cancer medicines in wealthier countries. (Country differences in uptake of mature medicines with a large patient population were comparatively smaller than in newer medicines.)

- Measured in value, countries which spent the most on new cancer medicines in 2018 were Austria, Germany, and Switzerland with around 92-108 EUR per capita. Czechia, Latvia, and Poland spent the least, around 3-16 EUR per capita; higher rebates on medicines in might exaggerate these differences.
- Measured in volume, less wealthy countries used around 30-50% of the level of the five big countries (France, Germany, Italy, Spain, the UK) and other wealthier countries in a selection of cancer medicines.

A study focusing on data from the clinicaltrials.gov website on phase I-III clinical trials between 2009 and 2019 in Europe has found that the number of clinical trials varies greatly among European regions, resulting in potential asymmetries in patients’ access to clinical trials. Based on 18 454 trial entries, the number of trials per country varied from 2.48/100 000 inhabitants in Central and Eastern Europe to 5.33/100 000 inhabitants in Northern Europe. The proportion of phase I-II trials was higher in the Southern and Western regions (13-15%) compared to Central and Eastern and Northern regions.

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(4-9%). The number of trial-entries/100 000 inhabitants/country ranged from 0.14 (Albania) to 10.7 (Belgium). The study also noted that between 2010 and 2018, the total number of trials per country in Europe increased by 33%. Five countries dominated in terms of an increase in the absolute number of total trial-entries in both early- and late-phase trials: Spain (90/40), France (45/16), UK (45/13), Italy (38/19) and Belgium (35/12).

In addition, a recent study conducted by the European Society for Medical Oncology in 49 European countries concluded that there are substantial differences in the formulary availability, out-of-pocket costs and actual availability of many anticancer medicines. The survey also concluded that for cancer medicines on the WHO model list of essential medicines the differences across countries are not so striking, but even those medicines are not always available due to shortages. Shortages of cancer medicines are caused by disruptions in the manufacturing or supply chain, and parallel trade is also a contributing factor.

The report by the Swedish Institute for Health Economics (see footnote 5) notes that a challenge for access to new medicines is how to strike a balance between early access and evidence on value to patients. In their view, many cancer medicines lack evidence of additional clinical benefits/value to patients (such as in terms of overall survival) at the time of EMA approval. This creates a demand for follow-up studies of patient outcomes in clinical practice, and mechanisms for adjusting pricing and payments based on the results of such studies. Another challenge is the need to balance adequate reimbursement for value against affordability. A large share of European cancer patients, especially in Eastern Europe, cannot gain access to effective and potentially cost-effective medicines due to affordability-related reasons. The use of generics and biosimilars is an important way to support cost-effective spending on medicines and to create financial scope for investing into innovative and cost-effective medicines that previously seemed unaffordable. The study concludes that health care systems need to weigh the costs from investing in different areas of cancer care against the potential improvements in patient outcomes.

The New Pharmaceutical Strategy for Europe (COM(2020)761), proposed by the Commission in late 2020, has the objective to address some of these inequalities and challenges: the affordability, access and shortages of medicines, and the need to support the EU pharmaceutical industry to innovate, and be economically and environmentally sustainable.

### III.3. Patients’ access to other treatment options


241 Parallel trade allows wholesalers to buy medicinal products in one Member State (typically where prices of medicines are lower too), and sell into other Member States (where prices are higher).

242 Branded drugs can be synthetic, made from a chemical process, or biological, made from living sources. After the expiry of the 10-year exclusivity period for the original medicine, more affordable “replicas” can be placed on the market. Synthetic drugs can be exactly replicated generics, and biological medicines into biosimilars.
The recent study by the European Cancer Organisation, prepared for the ENVI Committee, underlines that cancer treatment must be understood to be multimodal. Key modalities of cancer treatment include non-systemic treatments, such as radiation therapy and surgery, and systemic treatments through pharmaceutical agents. There is a need to address inequalities in access to all forms of cancer treatment:

- Despite the increasing cancer incidence and consequent increasing need for surgery, at global level only 25% of the patients will receive safe, timely, affordable, and high-quality surgical care. In the EU, **access to appropriate surgical interventions and the quality of surgery** varies greatly across the Member States and even within a given Member State, depending on the surgeons’ workload, their training and practice in subspecialties, and the hospital setting. Multiple studies have indeed evidenced that “high volume” cancer centres and surgical specialists have better outcomes for treating complex or advanced cancers. It has also been shown that specialised surgeons have better outcomes for cancer surgery than their non-specialised colleagues. Recognising surgical oncology as a specialist discipline and facilitating patients’ access to “high volume” centres for cancer surgery could go a long way to addressing these differences.

- As mentioned above, **radiation therapy** is recommended for more than half of cancer patients. Unfortunately, according to studies, at least a quarter of those patients who would need the treatment will not receive it. As cancer cases rise, the demand for radiation therapy is expected to increase by 16% by 2025. The current capacity is insufficient to meet the demand, and building up the capacity (facilities, equipment, trained healthcare staff) takes more time. In the EU, access to radiation therapy equipment varies 6–7 fold across the Member States, and there is a 3–5 fold variation in available healthcare staff and their workload. Promotion and recognition of harmonised education and training standards across Europe, and stronger investment of EU and national research and innovation funds to support radiation therapy research are amongst the chief requests to advance this field of treatment in all countries.

- **Interventional oncology** requires a unique skillset, and is still a relatively young discipline so its use is not so widespread. Access to such treatment is therefore rather limited.

### III.3. Patients’ access to paediatric and rare cancer treatments

In EU legislation and regulatory decisions, rare diseases are considered as those affecting less than 5 in 10 000 people. The EU-funded Surveillance of Rare Cancers in Europe (RARECARE) project proposed to define rare diseases based on incidence (i.e. on the basis of new cases each year); according to this approach, rare diseases are those which appear in less than 6 out of 100 000 people per year in the European population.

Though there are many different rare cancers, they have one thing in common: their rarity, due to which they share **similar problems concerning therapies and care**. On the patients’ side it is translated into the difficulty to access timely and accurate diagnosis, highly specialised care and

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243 N. Couespel, R. Price: ‘Strengthening Europe in the fight against cancer’ - study by the European Cancer Organisation for the ENVI Committee

244 Study by the European Cancer Organisation for the ENVI Committee, see footnote 10
adequate treatments; and on the side of the health care system, it manifests in poor research opportunities, difficulties in clinical trials and lack of therapies. Paediatric cancers are all rare therefore, the same difficulties are present for them as for rare cancers; but given their age-related, biological, clinical and organisational specificities, they require to be addressed distinctively.

**Diagnosis for rare and paediatric cancers can be delayed** due to (i) the presence of perhaps only negligible symptoms, (ii) for paediatric cancers the fact that in early stages symptoms can be mistaken for symptoms of childhood diseases, (iii) the lack of associated risk factors, and (iv) the fact that patients developing rare cancers are not from the usual population groups considered as “at risk of cancer”.

After diagnosis, rare and paediatric cancer patients have the best chance if they receive treatment in **centres of expertise**. Well trained, specialised oncology workforce; multidisciplinary approach to care; adequate equipment and medicines; and the possibility for the patients and their company to travel for receiving the treatment and receiving reimbursement are among the key conditions for the success of treatment.

The centres of expertise follow a multidisciplinary approach to care, in order to address the complex and diverse conditions. The Council in its recommendation of 2009 encouraged Member States to identify or create such centres for rare diseases. Ten years later the Parliament in its resolution of 2019 underlined the importance of EU-wide cooperation to tackle rare and chronic diseases, including rare cancers; and encouraged the Commission to support the setting up of specialised centres for rare diseases in the EU, which should be fully integrated into the European Reference Networks. **Comprehensive training for rare cancer specialists and paediatric oncologists** is lacking in many Member States; so those training programmes should be worked out and the qualifications should be recognised via mutual recognition schemes.

**The availability of medicines and other treatments** is also problematic. The difficulty to organise clinical trials due to small patient populations, lack of available quality epidemiological and clinical data, shortages of dedicated public funding, and low attractiveness of private research and investment hinders the development of, and through that the access to, rare cancer medicines and other treatments.

The EU plays a central role in improving collaboration across countries in respect to rare and paediatric cancers. Launched in 2017 in connection to the EU's Cross-Border Healthcare Directive, several European Reference Networks were constructed and have been operational since then. ERNs are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. Like this, the ERNs are opening new possibilities for improving rare cancer treatment and care via sharing clinical cases; rationalisation of patient referral; and, improved rare cancer management in small countries. Four of the newly established networks are specifically devoted to rare cancers:

- **EURACAN**: European Reference Networks on rare adult solid cancer;
- **EuroBloodNet**: European Reference Networks on Rare Haematological Diseases;
- **ERN PaedCan**: European Reference Networks on paediatric cancers; and
III.4. **Social inequalities**

**Geographical inequalities**, across Europe and within countries, exist in relation to cancer incidence, prevention, care, survival, and rehabilitation. The situation is particularly challenging in Eastern Europe, with survival for many cancers below the European average. Western and Northern European countries also show inequalities in cancer care; this is reflected in lower survival from lung, colorectal and ovarian cancers in the UK and Denmark when compared to Norway and Sweden.

**Social inequalities** in cancer, having their origin in social circumstances, also occur within European countries. Privileged social groups have better outcomes because they have fewer lifestyle-related and environmental cancer risk factors, have easier access to health services including new interventions and screening programmes, and can minimise the social and financial consequences of cancer when it occurs.

**Lower socio-economic groups and socially vulnerable groups** participate at lower rates in cancer screening programmes, have more difficult access to health care services and their cancer diagnosis and treatment is therefore more likely to be delayed. In addition, social inequalities in cancer can have their origin in childhood, when social conditions can influence longer-lasting exposures that may lead to increased risk of developing cancer in later life; and behavioural risk factors can also be transferred from parents to children (unhealthy lifestyle habits and coping mechanisms). In particular, disadvantaged groups are at greater risk for cancers of the lung, stomach, upper aero-digestive tract, and cervix due to poor diet, unhealthy lifestyle habits or coping mechanisms, and difficult access to screening programmes.

Furthermore, a significant number of European citizens have inadequate access to surgery, radiotherapy and systemic therapies; as well as to innovative treatments, including personalised medicine. Social inequalities also affect survivorship and access to rehabilitation services, causing more difficulties with returning to work and deepening further the social divide. Social inequalities in cancer outcomes also have significant financial consequences for individuals and major economic consequences for Member States and the European Union but this goes beyond the scope of this background note.

The CanCon paper concludes that social inequalities in cancer are not only financially intolerable but unethical; the EU thus has a responsibility to patients and the wider population to take measures to address these inequalities. As social inequalities in cancer have common roots, both across Europe and among different social groups within the population, they should be addressed at the European level, through strengthened collaboration with the Member States such as e.g. the European Partnership for Action Against Cancer (EPAAC), the Equity Action Joint Action, the Cancer Control Joint Action (CanCon), and the Innovative Partnership for Action against Cancer (iPAAC).

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BACKGROUND NOTE ON THE IMPACT OF THE COVID-19 PANDEMIC
AND OTHER THREATS ON CANCER CARE

Though COVID-19 is an unprecedented global health crisis of the post-WWII era, it might not be the last one. It has made apparent the weaknesses of health systems; and made clear that without structural changes, future pandemics caused by emerging or already known pathogens or other looming crises could cause repeated public health shocks.

The pandemic has affected certain groups more severely, globally and across Europe as well. Those living in poorer countries with less efficient and less resilient healthcare systems; those in lower socio-economic groups, exposed to environmental risk factors or leading unhealthy lifestyles; those who are elderly and those with chronic health conditions have been more at risk since the beginning of the outbreak. Cancer patients are amongst the more vulnerable population groups, and cancer care has also suffered from the impact of the pandemic on the functioning of the healthcare systems.

In this note:
I. The impact of the COVID-19 pandemic on cancer care:
   Disruption in cancer care; shortages of medicines and PPE; impact on the cancer workforce and working methods

II. The potential of mRNA vaccines in cancer treatment

III. Antimicrobial resistance and its impact on cancer patients and cancer care

IV. Learning from the public health crises:
    Assessing the resilience of health care systems: building a European Health Union
I. The impact of the COVID-19 pandemic on cancer care

I.1. Disruption in cancer care

The COVID-19 pandemic has deeply affected cancer patients and the whole cancer pathway, and the impacts will be long-lasting. Reports and studies about the first wave of the pandemic in spring 2020 show that prevention programmes, including Hepatitis B virus and Human Papillomavirus vaccination, and population-based cancer screening and early detection services, were suspended in many countries, and there are concerns about whether/how it is possible to deal with the backlog. Patients with potential cancer symptoms did not seek, or sought late medical advice, resulting in missed or delayed diagnosis of cancer in the first round, and an increase of advanced cases and poorer prognosis in the second round. Cancer treatment and follow-up to treatments was often delayed or discontinued. Regular hospital infrastructure, like postsurgical recovery units or the operating rooms were converted into intensive care stations or isolation rooms, which often put on hold regular surgery programmes, including oncology surgery, and led many hospitals to close some or all of their regular wards. Recruitment to clinical trials and the conduct of trials were also severely affected, despite efforts by the Commission to simplify the management of trials. The pandemic also put cancer patients, their families, partners and carers under emotional stress due to isolation, family disruption, the restrictions on visits to homes and hospitals, the limitations on attending funerals, and occupational and financial challenges.

A coalition of Cancer Patient Organizations conducted a survey and concluded that in 67% of countries included in the survey, screening programmes were cancelled; in 59% a drop in urgent referrals for suspected cancers was observed; and in 69% a drop in the number of people seeking help for potential cancer symptoms was reported. The European Society of Medical Oncology held a survey and reported 44% cancellation of cancer surgery, and 10% of patients that missed at least one cycle of chemotherapy. The European Society of Radiation Oncology also did a survey in their Society, describing that 60% of departments saw a decline in patient volume; while the European Breast Cancer Research Association of Surgical Trialist reported an increase in time between diagnosis and treatment in 20% of 377 responding breast cancer centres.

https://www.europeancancer.org/component/attachments/?task=download&id=375

https://journals.lww.com/ejop/Fulltext/2021/03000/The_effect_of_COVID_19_on_oncology_pharmacy.1.aspx#T3
1.2. **Shortages of medicines and personal protective equipment**

Shortages of medicines, products and equipment badly affected cancer care. The Union’s dependency on third country import for essential medicines and active ingredients for pharmaceutical products is a known phenomenon, which has been recognised some time ago already as a potential threat to the EU’s strategic autonomy; but the pandemic worsened the situation. Apart from medicines used in intensive care units (ICU) and over-the-counter painkillers, the supply of certain cancer drugs was also cut short. During the peak of the first wave of the pandemic, half of oncology pharmacists in Europe experienced shortages of essential anticancer medicines, affecting more than ten different medicines in some hospitals and regions. It was a particularly distressing situation as cancer medicines affected by shortages often have few or no proven effective alternatives. The shortage of cancer drugs led to delays and interruptions to chemotherapy, which can be detrimental to patients’ treatment and highly distressing for them, their families and carers.

Alongside the shortage of medicines, the dramatic shortages of personal protective equipment in hospitals contributed to disruptions in cancer care and to placing both patients and oncology staff at risk.

Ensuring the continuity of supply of medicines remains the primary responsibility of pharmaceutical companies, and Member States continue to be responsible for regulatory oversight. The initial period of the COVID-19 outbreak was characterised by national protective measures and a lack of solidarity amongst the Member States. When it became clear that a more coordinated approach was needed at European level, the Commission and the European Medicines Agency played a key role in monitoring the situation, and used their power and competences to the maximum possible extent in this regard:

- EMA and the Commission brought together key figures in an executive steering group to tackle shortages. Established in March 2020, the EU Executive Steering Group on Shortages of Medicines Caused by Major Events provides strategic leadership for urgent and coordinated action to prevent and mitigate supply disruption during the pandemic. EMA also stepped up its cooperation with the national competent authorities and the pharmaceutical industry via the “Single Point of Contact” (SPOC) network and the “industry Single Point of Contact” system (i-SPOC).

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248 Medicine shortage in the EU during the novel coronavirus outbreak  Briefing for the ENVI Committee by the Policy Department on Economic, Scientific and Quality of Life Policies, 2020
Though these forms of cooperation focus primarily on medicines used in ICU settings and the treatment of COVID-19 patients, the lessons learnt are valuable for managing and ensuring the supply of other medicines as well, including anticancer drugs.

The New Pharmaceutical Strategy for Europe (COM(2020)761), proposed by the Commission in late 2020, includes an objective to reduce the medicine dependency of the Union, and tackle issues related to the access to and shortages of medicines, and the need to support the EU pharmaceutical industry to innovate, and be economically and environmentally sustainable.

I.3. Impact of the pandemic on the oncology workforce and working methods

The drastic rise of COVID-19 cases and high hospitalisation and ICU admission rates in the first wave of the pandemic put all healthcare workers under extreme pressure. As it was not possible to train additional ICU doctors and nurses at such short notice, oncology staff members who had already worked with sedation and ventilation were urgently redirected to COVID-19 cases. Hospital pharmacists and pharmacy technicians were also mobilised to prepare and deliver ready-to-administer drugs; their increased workload undermined their availability to perform other tasks, including cancer care-related ones such as dispensing of drugs for clinical trials, or chemotherapy compounding.

Already existing shortages in the cancer workforce, in areas such as pathology, cancer nursing and hospital pharmacy technicians, have been deepened. The consequences of the brain drain experienced by Central and Eastern European Member States, where oncology specialists leaving the country for better working conditions, higher salaries and better opportunities, has become more apparent in these countries.

All these resulted in a significantly increased workload for the oncology workforce during the pandemic, affecting their job performance and wellbeing, leading to stress, exhaustion and burnout. Cases of COVID-19 infection among frontline workers increased in particular in the beginning of the pandemic when personal protective equipment was not available, but later as well when equipment was already provided, adding to their stress and the pressure on the whole healthcare system.

One positive point during the spring wave was the deployment of telemedicine to support cancer care across Europe. It included the use of video, telephone, and other electronic communication, including software for virtual tumour boards. It increased the number of cases managed by primary healthcare professionals, helped to ensure continuity to the extent possible of care and research in cancer in spite of limited patient mobility. More discussion is needed though on how to make telemedicine in cancer care a sustainable solution; and the impact of telemedicine on diagnosis, access to multidisciplinary care and the digital divide must be assessed in order to ensure that a broader uptake of telemedicine does not widen disparities in access to cancer care.

Another positive point was the roll-out of other innovative solutions, helping to enhance cancer control at a time of increased needs and decreased resources. These include:

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249 See footnote 1
Drive-through vaccination centres for provision of HPV vaccination;
Self and home delivery of cancer screening and diagnostic examinations, such as self-HPV DNA sampling and testing for cervical cancer screening, Faecal Immunochemical Testing (FIT) for colorectal cancer screening;
The prioritisation of higher risk cancer patients, according to cancer type, tumour type or tumour stage;
Using community pharmacies and general practitioners as local diagnostic and monitoring hubs, thus minimising longer travels of patients to hospitals (but adding to the workload of these healthcare professionals);
Prioritisation of the provision of minimally invasive treatment modalities;
Self and home delivery of anticancer drugs, through oral chemotherapy or home infusion, as well as of blood tests; and
Provision of assisted home care and of online forms of support and therapy, in particular in the field of psychosocial interventions.

II. The potential of mRNA vaccines in cancer treatment

Disease-causing organisms, such as a virus or bacteria, produce proteins, and vaccines work by training the body to recognise and respond to those proteins:

- Traditional vaccines are prepared from small or inactivated doses of the whole disease-causing organism, or the proteins that it produces; it is then introduced into the body to provoke an immune response;
- mRNA, or messenger ribonucleic acid, is the molecule that essentially puts DNA instructions into action. Inside a cell, mRNA is used as a template to build a protein. mRNA vaccines work in a way that they trick the body into producing some of the proteins of the disease-causing organism itself, which then provokes the immune response.

For the COVID-19 vaccines, the mRNA in the vaccine has instructions for making the spike protein. This is a protein on the surface of the SARS-CoV-2 virus with which the virus enters the body’s cells. After vaccination, the cells of the vaccinated patient will read the mRNA instructions and temporarily produce the spike protein. The immune system then detects these viral proteins as an intruder, and starts to produce a defensive response to them. When later the vaccinated person comes into contact with SARS-CoV-2 virus, their immune system will recognise it and be ready to defend the body.
against it. The mRNA from the vaccine does not stay in the body; it is broken down shortly after vaccination.

Before the COVID-19 pandemic, most of the research into using mRNA to provoke an immune response focused on cancer. Cancer is able to make itself invisible to the immune system; the vaccine aims at removing that shield of invisibility by using tumour mRNA to train the immune system to recognise tumour cells as a target. As every tumour is different, it would allow for patient-specific mRNA therapeutic vaccines to be developed.

Moderna and BioNTech are currently conducting clinical trials of therapies that use mRNA technology to treat cancer. The preliminary results are promising: a BioNTech cancer vaccine shrank tumours in people with advanced melanoma, and a Moderna cancer vaccine, used in combination with a checkpoint inhibitor produced by Merck, shrank tumours in 50% of people with advanced head and neck cancer.

III. **Antimicrobial resistance and its impact on cancer patients and cancer care**

The group name “antimicrobials” include antibiotics, antivirals, antifungals and antiparasitics – these are medicines that are used to prevent or treat infections caused by bacteria, viruses, fungi and parasites respectively. Antimicrobial Resistance (AMR) occurs when pathogens change over time and become resistant to treatments. The more often the antimicrobials are used, the more the pathogens adapt to them to survive; the prudent use of these medicines, and avoiding their excessive or improper use is therefore crucial. AMR makes infections harder to treat and it increases the risk of disease spread, severe illness and death. AMR is responsible for an estimated 33 000 deaths annually in the EU; and it is also estimated that it costs the EU 1.5 bn EUR pear year in healthcare costs and productivity loss.

The emergence and spread of drug-resistant pathogens continue to threaten our ability to treat common infections. The rapid spread of multi-resistant bacteria, the so-called “superbugs” that cause infections that are not treatable with existing antibiotics, is particularly alarming. Antibiotics are becoming increasingly ineffective, and new ones need to be developed; however, if the way in which antibiotics are used does not change, even the new antibiotics will become ineffective.

Concerning cancer patients, they are more susceptible to infections due to the lowering of their immune defence, and therefore can suffer more severely from the consequences of AMR. One in every five cancer patients acquire an infection during their treatment; and even when in hospital, cancer patients are more susceptible to hospital-acquired infections. Pneumonia and sepsis are among the most frequent causes of admission to intensive care units for cancer patients, and an estimated 8.5% of cancer deaths are due to severe sepsis.
After surgery, many cancer patients require antibiotics to treat infected wounds. Radiation therapy and chemotherapy kill cancer cells, but also those cells that are part of the defence mechanism against infections. Patients who receive radiation or chemotherapy therefore often develop infections that require treatment with antibiotics. Transplantations and immunotherapy are also impossible to perform without antibiotics. Some cancer types, e.g. acute leukaemia and bone marrow cancer cannot be treated without antibiotics.

To tackle the problem at EU-level, in 2017 the Commission presented the EU One Health Action Plan against AMR (COM(2017)339). The key objectives of this plan are built on the three pillars of (i) making the EU a best practice region; (ii) boosting research, development and innovation; and (iii) shaping the global agenda. Later the Commission also adopted the first deliverables of the plan, for example the EU Guidelines on the prudent use of antimicrobials in human health, aiming to reduce inappropriate use and promote prudent use of antimicrobials in people.

Since the adoption of the action plan in 2017, several other flagship initiatives were presented and implemented, creating synergies between the fight against AMR and other policy goals. These include e.g. the new pharmaceutical strategy and the EU4Health programme; the forthcoming proposal on a new Health Emergency Response Authority, expected by the end of 2021, also fits into this line.

The Commission issues every half a year a progress report on the implementation of the AMR action plan; the latest one was published in December 2020. The report shows that a number of AMR initiatives have been continued or put in place in recent months, highlighting synergies mentioned above. E.g. the in the EU Farm to Fork Strategy the Commission adopted a target aiming to reduce by 50% the overall EU sales of antimicrobials for farmed animals and in aquaculture by 2030. This objective would be supported by the implementation of the recent regulations on Veterinary Medicinal Products and on Medicated Feed for which implemented and delegated acts are currently being drafted. The new Commission Implementing Decision (EU) 2020/1729 on the monitoring and reporting of AMR in zoonotic and commensal bacteria is also highly relevant. The recently adopted Pharmaceutical Strategy for Europe also flagged the fight against AMR as a key objective. The next progress report is planned to be published in mid-2021.

AMR is also high on the agenda of the European Centre for Disease Prevention and Control. Via EARS-Net (European Antimicrobial Resistance Surveillance Network) and ESAC-Net (European Surveillance of Antimicrobial Consumption Network), ECDC monitors AMR and the use of antibiotics.
In the international scene, countries are cooperating under the aegis of the WHO. The Global action plan on antimicrobial resistance, endorsed by the World Health Assembly in 2015, and the European strategic action plan on antibiotic resistance, adopted by WHO Member States in 2011, are the main policies in force. In addition to these, WHO/Europe supports the development of national action plans on AMR that are aligned with the objectives of the Global action plan.

IV. Learning from the public health crises

IV.1. Assessing the resilience of health care systems

Health system resilience is key to coping with catastrophic events, such as the economic crisis and the COVID-19 pandemic, but there is much confusion about what resilience means, how to strengthen it and how to assess it.

A recent briefing by the WHO European Observatory of Health Systems and Policies adopted the following definitions:

- Health system resilience is the ability to prepare for, manage (absorb, adapt and transform) and learn from shocks.
- Shock is a sudden and extreme change which impacts on a health system, and is thus different from the predictable and enduring health system stresses, such as population ageing. A shock cycle has four stages: preparedness; shock onset and alert; shock impact and management; and recovery and learning.

Based on the existing literature and emerging evidence from the ongoing COVID-19 pandemic, the authors identify strategies for enhancing resilience and map them on to the key health systems functions:

- **Governance**: effective and participatory leadership with strong vision and communication; coordination of activities across government and key stakeholders; an organisational learning culture that is responsive to crises; effective information systems and flows; and surveillance enabling timely detection of shocks and their impact.
- **Financing**: ensuring sufficient monetary resources in the system and flexibility to reallocate and inject extra funds; ensuring stability of health system funding through countercyclical health financing mechanisms and reserves; purchasing flexibility and reallocation of funding to meet changing needs; and comprehensive health coverage.
- **Resources**: appropriate level and distribution of human and physical resources; ability to increase capacity to cope with a sudden surge in demand; and motivated and well-supported workforce.
- **Service delivery**: alternative and flexible approaches to deliver care.

https://apps.who.int/iris/bitstream/handle/10665/332441/Policy-brief%2036-1997-8073-eng.pdf
Assessing these functions would allow the countries to identify the potential sources of vulnerability and plan for further action (to enhance resilience or the capacity to respond). Resilience can also be assessed after the crisis, evaluating crises management.

Assessment of health system resilience is crisis- and context-specific. Alongside the self-assessment in the given country, analysing experiences of other countries also provides useful lessons for policymakers to implement resilience-enhancing strategies. It would be particularly important to make the link between recovering from a shock and preparing for future shocks, which is an area often neglected once the health system returns to post-shock normality.

IV.2. Building a European Health Union

Drawing from the lessons learnt from the first wave of COVID-19 pandemic, in order to step up the fight against the pandemic and future health emergencies, in November 2020 the Commission put forward a set of proposals to strengthen the EU’s health security framework and reinforce the crisis preparedness and response role of key EU agencies. These proposals are first building blocks of a future European Health Union.

The first pillar is a proposal for a new regulation on serious cross-border threats to health (COM(2020)727), based on Article 168(5) of the Treaty on the Functioning of the European Union. The new framework aims at:

- Strengthening preparedness: EU health crisis and pandemic preparedness plan and recommendations will be developed, supporting the adoption of plans at national levels. ECDC and other EU agencies would support the preparation of national plans, and the Commission and EU agencies would audited and stress-test them;
- Reinforce surveillance: A strengthened, integrated surveillance system would be created at Union level, using artificial intelligence and other advanced technologies;
- Improve data reporting: Member States would have to step up their reporting of health systems indicators (e.g. hospital beds availability, specialised treatment and intensive care capacity, number of medically trained staff etc.); and
- Declaration of an EU emergency situation: The Commission could declare emergency at EU-level. It would trigger increased coordination and allow for the development, stockpiling and procurement of products relevant for the given crisis.

The second pillar is to strengthen and make the key EU agencies more operational.

The ECDC’s reinforced mandate (COM(2020)726) would allow the agency to support the Commission and Member States in the following areas:

- epidemiological surveillance via integrated systems enabling real-time surveillance;
- preparedness and response planning, reporting and auditing;
- provision of non-binding recommendations and options for risk management;
- capacity to mobilise and deploy EU Health Task Force to assist local response in Member States; and
- building a network of EU reference laboratories and a network for substances of human origin.

The EMA’s reinforced mandate (COM(2020)725) would allow the agency to facilitate a coordinated Union-level response to health crises by:

- monitoring and mitigating the risk of shortages of critical medicines and medical devices;
- providing scientific advice on medicines which may have the potential to treat, prevent or diagnose the diseases causing those crises;
- coordinating studies to monitor the effectiveness and safety of vaccines; and
- coordinating clinical trials.

The Commission announced that a proposal for a future Health Emergency Response Authority (HERA), supporting a better EU level response to cross-border health threats, would be presented by the end of 2021.

These legislative proposals are currently under discussion at the European Parliament and the Council.
BACKGROUND NOTE ON PAEDIATRIC AND RARE CANCERS

Though there are many different rare cancers, due to their rarity they share similar problems concerning diagnosis and treatment. On the patients’ side it leads to difficulties in accessing timely and accurate diagnosis, highly specialised care and adequate treatments; and on the side of the healthcare system, it manifests in poor research opportunities, difficulties in clinical trials and lack of therapies.

Paediatric cancers are all rare cancers and share the same challenges; but given their age-related, biological, clinical and organisational specificities, they need to be addressed distinctively.

With 5.1 million rare cancer patients in Europe, representing approximately 25% of all cancer cases, rare cancer is a major public health issue.

I. Overview on rare and paediatric cancers

In this note:

I. Overview on rare and paediatric cancers
II. Diagnostic and treatment challenges
III. European policy and legislation on rare and paediatric cancers
   III.1. Regulatory framework
   III.2. Research incentives
   III.3. RARECAREnet
   III.4. European Rare Cancer Agenda 2030
   III.5. European Reference Networks
   III.6. Europe’s Beating Cancer Plan initiatives on rare cancers
   III.7. Europe’s Beating Cancer Plan initiatives on paediatric cancers

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N. Couspel, R. Price: Strengthening Europe in the fight against cancer - study by the European Cancer Organisation, 2020
In EU legislation and regulatory decisions, rare diseases are considered as those affecting less than 5 in 10,000 people. The EU-funded Surveillance of Rare Cancers in Europe (RARECARE) project adopted a different approach, and proposed to define rare diseases based on incidence, i.e. on the basis of new cases each year\(^2\); according to this approach, rare cancers can be defined as those malignancies whose incidence is below 6 out of 100,000 people per year.

As mentioned above, rare cancer is a major public health concern with 5.1 million rare cancer patients in Europe, accounting for almost a quarter of all cancer cases. And though only 1% of all cancer cases fall into the "extremely rare" category (whose incidence is below 0.2 out of 100,000 people), they represent 61% of rare tumorous cancers. Haematological malignancies, female genital cancers and digestive cancers are the most frequent rare cancers, with more than 100,000 annual new cases each, and rare skin cancers represent only approx. 7,000 annual new cases. Estimated 5-year relative survival is significantly lower for rare cancers than for their common counterparts (48.5% and 63.4% respectively); and the overall relative survival for rare adult cancers has been improving to a lesser extent than that for common adult cancers. Moreover, the geographical divide is also significant, with lower survival values in Eastern European countries (falling all below 45%, down to less than 35% in Bulgaria) than in all others (all above 45%), especially in Northern and Central European countries (up to more than 55% in Iceland)\(^3\).

<table>
<thead>
<tr>
<th>Rare cancer families as presented by RARECARENet, based on robust data set collected from cancer registries</th>
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<tbody>
<tr>
<td>head and neck cancers</td>
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<tr>
<td>digestive cancers*</td>
</tr>
<tr>
<td>thoracic cancers*</td>
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<tr>
<td>female genital cancers*</td>
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<td>male genital and urogenital cancers*</td>
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<td>neuroendocrine tumours</td>
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Cancer remains the principal cause of death by disease in children beyond the age of one. Pursuant to the most recent estimates from the European Cancer Information System for EU-27, as cited by the Commission in the Europe’s Beating Cancer Plan, in 2020 over 15,500 children and adolescents were diagnosed with cancer, and more than 2,000 young patients died of cancer.

\(^2\) Prevalence: proportion of persons having a condition at or during a particular time period; incidence: proportion or rate of persons developing a condition during a particular time period.

With over 100 types of childhood cancer, each case is considered as a rare cancer. Though high dose ionising radiation and prior chemotherapy are accepted causes of paediatric cancers, apart from those, no further environmental risk factors have been identified for paediatric cancers. What concerns known risk factors, genetic predisposition account for approximately 10% of paediatric cancers. A Cancer Predisposition Syndrome (CPS) diagnosis is important, because it opens the door to prevention, surveillance, counselling and psychological support, and adapted therapy; though these are currently underdeveloped services in Europe.\(^{254}\)

Thanks to advancement in research, survival at five years is 80%; however, there has been very little advancement for some types of paediatric cancers. Based on survival and prognosis, paediatric cancers form three main groups:

- **paediatric cancers with good prognosis**, with a higher than 85% chance of survival after five years under current standard multidisciplinary treatments, using cytotoxic drugs in often an intensive mode: acute lymphoblastic leukaemia, lymphomas, retinoblastoma and renal tumours;

- **paediatric cancers with poor prognosis**, with 50% or less chance to reach the 5-year survival mark: acute myeloid leukaemia, several Central Nervous System tumours, neuroblastoma, bone and soft tissue sarcomas; and

- **the extremely rare tumours**, for which there is insufficient information on their real incidence and survival.

\(^{254}\) Cancer prevention: Modifiable risk factors - Workshop report
There are nearly half a million childhood cancer survivors in Europe, and the positive trend is that survival rates are expected to further increase in the future. By 2030, there will be an anticipated 750 000 paediatric cancer survivors in Europe. But the majority of survivors experience adverse long-term effects, and even beyond five years from diagnosis, disease-free survivors have higher mortality rates. Seventeen years after diagnosis, 27% of survivors report severe or life-threatening chronic condition related to prior therapy. Moreover, the geographical divide is present here as well, resulting in up to 20% of difference in children's survival rates among European countries.

The social consequences of childhood cancer and its effects later in life are long-lasting, and affect education, employment, work ability, and income. Though the majority of survivors of childhood cancer can return to their studies and enter employment (with the exception of brain tumour survivors, who are more often unemployed or economically inactive), access to insurance for loans and mortgages is difficult. In most countries, they face additional challenges as they have to disclose that they had a cancer diagnosis in the past, and they are denied insurance or have to pay a premium that is significantly higher than for a person with other chronic conditions.255

In the EU, as there is no uniformly applied specific criteria in the Mortgage Credit Directive concerning cancer survivorship, the practice of creditworthiness assessment is fragmented. Recognising the problem, France, Belgium, Luxembourg and the Netherlands have passed legislation about the right to be forgotten for cancer survivors. The provisions of the legislation in these Members States are very similar. They stipulate that the longest period for which medical information relating to cancer can be collected is ten years after the end of treatment if there is no relapse, and, for cancers occurring before the age of 18 (age of 21 in the Netherlands), five years after the end of treatment. A list of exceptions for cancers with an excellent prognosis complement the provisions, where a shorter timeline is applicable to exercise the right to be forgotten. The provisions are subject to regular review, in order to adjust them to scientific data and advancement in treatments.256

Another important topic for many young cancer survivors is fertility. The impact of cancer therapy on fertility is related to the age of the patient and to the duration, dose/intensity, and type of treatment. It does not only affect the crucial issue of being able to have a child and raise a family.

255 A.Dumas & others: The right to be forgotten: a change in access to insurance and loans after childhood cancer? Journal of Cancer Survivorship
https://link.springer.com/article/10.1007/s11764-017-0600-9

256 G. Scocca and F. Meunier: A right to be forgotten for cancer survivors: A legal development expected to reflect the medical progress in the fight against cancer. Journal of Cancer Policy.
but influences a broad range of matters from body image to sexuality, dating relationships, marriage patterns and sense of wellbeing.

Different methods to preserve fertility exist. In girls before puberty, ovarian tissue freezing, in vitro maturation, and surgical movement of ovaries outside the field of irradiation are still experimental. In pubescent and postpubescent girls and young women, oocyte-embryo freezing is an established option. In men, the options are sperm cryopreservation, gonadal transposition, and testicular tissue or spermatogonial cryopreservation and re-implantation. Despite these advancements, cancer patients in the EU are still not receiving appropriate counselling and do not have adequate access to fertility preservation solutions. Apart from the emotional burden, it is also a financial matter, namely to what extent health insurance covers the preservation of patient sperm and eggs, fertility treatment and psychological support.\textsuperscript{257,258}

II. Diagnostic and treatment challenges

**Diagnosis for rare and paediatric cancers can be delayed** due to (i) the presence of perhaps only negligible symptoms, (ii) the lack of associated risk factors, and (iii) the fact that patients developing rare cancers are not from the usual population groups considered as “at risk of cancer”. An additional difficulty with the accurate and timely diagnosis of paediatric cancers is that in early stages symptoms can be mistaken for symptoms of childhood diseases; by the time of diagnosis, 80% of paediatric cancers have already spread to other parts of the body, compared to about 20% of adult cancers.

After diagnosis, rare and paediatric cancer patients have the best chance if they receive treatment in **centres of expertise**. Well trained, specialised oncology workforce; multidisciplinary approach to care; adequate equipment and medicines; the possibility for the patients and their family or guardians to travel in order to receive treatment and receiving reimbursement are among the key conditions for the success of treatment.

The centres of expertise follow a multidisciplinary approach to care, in order to address the complex and diverse conditions. The Council, in its recommendation of 2009, encouraged Member States to identify or create such centres for rare diseases. In 2016 the European Parliament, in its resolution on Paediatric Medicines Regulation pointed out unmet paediatric medical needs, and called for appropriate incentives and funding in research and drug development and an overview of the regulatory framework. Ten years later the Parliament, in its resolution of 2019, underlined the importance of EU-wide cooperation to tackle rare and chronic diseases, including rare cancers; and encouraged the Commission to support the setting up of specialised centres for rare diseases in the EU, which should be fully integrated into the European Reference Networks. **Comprehensive training for rare cancer specialists and paediatric oncologists** is lacking in many Member States;
such those training programmes should be worked out and the qualifications should be recognised via mutual recognition schemes.

The availability of medicines and other treatments also poses a problem. The difficulty to organise clinical trials due to small patient populations, lack of available quality epidemiological and clinical data, shortages of dedicated public funding, and low attractiveness of private research and investment hinder the development of, and through that the access to, rare cancer medicines and other treatments.

III. European policy and legislation on rare and paediatric cancers

III.1. Regulatory framework

Satisfactory treatments for patients with rare diseases and for children were lacking for a long time, and given the small patient population, the pharmaceutical industry did not invest sufficiently into research and the development of these medicines. To bridge that gap, the EU put in place a regulatory framework to foster the development of medicines in the early 2000’s.

The Regulation on medicinal products for paediatric use (“Paediatric Regulation”, Regulation (EC) No 1901/2006) aims to ensure that paediatric medicines have been researched and tested specially for children in an ethical way, that they meet the needs of children and that they have age-appropriate doses and formulations. Pharmaceutical companies carry out studies on children to obtain evidence about the safety and efficacy of new medicines before requesting marketing authorisation. The EMA’s Paedriatric Committee assesses those studies and the data generated by them.

Orphan medicinal drugs are specifically designed to treat rare diseases. The Regulation on orphan medicinal products (“Orphan Regulation”, Regulation (EC) No 141/2000) lays down the centralised procedure for the designation of orphan drugs. The regulation foresees giving orphan designation for substances that could be used for treating, preventing or diagnosing a rare and serious condition. Orphan designation can help the medicine’s developer to advance the medicine to the stage where it can be authorised for being put on the market. Applications for orphan designation are examined by the EMA’s Committee for Orphan Medicinal Products (COMP), using the network of experts that the Committee has built up. Formal approval (marketing authorisation) is needed before a medicine can legally be marketed.

To date, the EU has authorised just a few orphan medicines and paediatric cancer drugs, as, owing to the low number of people who are affected by rare diseases, research in this field has been neglected.

In its 2016 resolution, the Parliament pointed out the shortcomings of the Paediatric Regulation. The resolution notes that, according to the current situation, pharmaceutical companies can ask to waive the obligation to investigate the potential benefit of a drug in children if the adult cancer for which the medicine was originally developed does not exist in children. However, what matters for cancer drugs is the mechanism of action rather than the specific cancer type targeted, and such medicines could still be used to treat other childhood cancer types. One of the key calls of the resolution was to
limit room for pharmaceutical companies to avoid the obligation to investigate and develop drugs for children, and the Parliament proposed to revise the regulation in this regard.

In 2020, the Commission published a comprehensive evaluation of the two regulations, looking into the period from the date of application until 2017. The two regulations were evaluated together, given that the majority of rare diseases may appear already in children and many children’s diseases are also rare.

- The evaluation concludes that both regulations promoted the development and availability of orphan drugs and paediatric medicines, owing to redirecting private and public investment through incentives, obligations and rewards. EU and national research programmes in the field of rare diseases complemented the regulatory framework. The number of medicines increased, became available faster and reached a higher number of patients in the Member States, and the number of clinical trials in children increased.
- The evaluation also shows, however, that the medicines developed thanks to the two regulations are not accessible by patients equally in all Member States. This is mainly due to factors outside the scope of the regulations, such as strategic launch decisions by pharmaceutical companies and national pricing policies and reimbursement systems.
- The evaluation points out that the two regulations have not succeeded to support adequately drug development in those areas where the need for medicines is greatest, as products tend to be developed in certain more profitable therapeutic areas for which the number of available treatments is increasing.
- The Paediatric Regulation obliges companies to test new medicines in children, but it has no dedicated instrument to direct development in areas relevant for children. The development of new medicines for children therefore remains mainly driven by adults’ needs. As a result, it does not necessarily address the greatest therapeutic needs of children such as treatments for children’s cancers and for newborns.
- The evaluation points out that while both regulations have increased costs for healthcare systems, thanks to the treatment with medicines for rare diseases, patients benefited from an improvement in their quality of life, and the benefits the legislation brought for children appear to outweigh the costs imposed on both industry and society.
- In conclusion, the Commission notes that any future solution to the and inefficiencies should strike a balance between the needs of fostering innovation and ensuring the availability of and access to medicines.

III.2. Research incentives

EU-supported work on innovative medicines started already under the Sixth Framework Programme for Research (FP6). The European Technology Platform on Innovative Medicines (INNOMED) brought together a range of stakeholders and was led by the pharmaceutical industry. IMI1, the Innovative Medicine Initiative was created as a joint undertaking, in the form of a public-private partnership, for the period of 2008-2013. Its overall goal was to significantly improve the efficiency and effectiveness of the drug development process with the long-term aim that the pharmaceutical sector produce more effective and safer innovative medicines. It had a budget of 2 bn EUR, of which 1 bn EUR came from the Seventh Framework Programme (FP7), and the rest as in-kind contributions from European Federation of Pharmaceutical Industries and Associations (EFPIA) and its member companies. Building on the successes of the IMI, IMI2 was set up for 2014 to 2020 as a joint undertaking, with the total budget of up to 3.276 bn EUR. Similarly to IMI, for IMI2 had half of the
budget from Horizon 2020, and the remaining half from EFPIA and its member companies. IMI2 carried out its research pursuant to the Strategic Research Agenda. They concentrated their efforts on delivering ‘the right prevention and treatment for the right patient at the right time’; cancer and rare diseases are amongst their focus areas.

Through the Seventh Framework Programme (FP7) and Horizon 2020, more than 200 research and innovation projects into rare diseases received over 1.4 bn EUR of EU financial support. Major lines of research in rare diseases include basic research to understand rare diseases; pre-clinical research to develop diagnostics and new therapies; proof-of-concept (pre-clinical and exploratory clinical validation studies of new therapies); clinical research (clinical trials and prospective cohort studies). In addition, several EU projects enabled the creation of infrastructures, in particular linking research and clinical data repositories, databases, biobanks, registries and other valuable resources in support of research into rare diseases.

Via the research programmes the EU have been facilitating the formation of multidisciplinary consortia with participants from universities, research organisations, healthcare providers, SMEs, industry and patient organisations.259

In the new programming period of 2021-2027, cancer research will be conducted under Horizon Europe’s Cancer Mission, with the budget of 2 bn EUR. The Mission Board of the Cancer Mission presented their report in September 2020, outlining ambitious research targets by 2030. Pursuant their agenda, research efforts in this decade should focus on, among others, increasing understanding the molecular processes at the cancer cell level and the interactions of the tumour and its host. It requires a new level of investment in innovative research, including high-potential/high-risk projects. The Mission Board proposes a Europe-wide platform, UNCAN.eu, making use of relevant research infrastructure and investing in the development of new models and technologies; UNCAN.eu has now been integrated into the Europe’s Beating Cancer Plan (EBCP). The Mission Board also proposed to focus efforts on cancers in children, adolescents and young adults. These recommendations have also been taken up in the EBCP.

III.3. RARECAREnet

The Information Network on Rare Cancers project (RARECAREnet, 2012-2016) was a Europe-wide epidemiological study. It producing updated data about rare cancers in the EU and studied the degree of centralisation of treatment of rare cancers.

III.4. EU Joint Action on Rare Cancers and the Rare Cancer Agenda 2030

259 Collaboration: A key to unlock the challenges of rare diseases research; European Commission, 20202
**EU Joint Action on Rare Cancers** (JARC) was a multi-stakeholders collaboration between 18 Member States and the European Commission, coordinated by the Fondazione IRCCS Istituto Nazionale dei Tumori of Milan. 34 partners involved in the JARC included ministries of health and representatives of national cancer control programmes, universities, public health institutions, population-based cancer registries, oncolgical institutes, patients associations (ECPC, EURORDIS, CCI-Europe) and other societies and organisations (including the Organisation of European Cancer Institutes, OECI and European Society for Paediatric Oncology, SIOPE). The JARC produced the **Rare Cancer Agenda 2030**, including ten key policy recommendations on rare cancers, which are to be implemented at national and EU level.

### Rare Cancer Agenda 2030: Ten Recommendations from the EU Joint Action on Rare Cancers

1. Rare cancers are the rare diseases of oncology, needing specific approaches by the cancer community and national health systems

2. Rare cancers should be monitored epidemiologically and clinically, properly valuing population-based cancer registry data and real-world clinical data, encouraging all efforts to make all available databases interoperable

3. Health systems should exploit networking around multidisciplinary centres of reference, to improve quality of care in rare cancers by rationalizing patient access to available best expertise and lowering/rationalizing health migration

4. Medical education should exploit and serve healthcare networking by proper integration of the university system and all educational players, being instrumental to dedicated career mechanisms and opportunities

5. Research should be fostered by networking and should take into account an expected higher degree of uncertainty exploiting clinically annotated biobanking, clinical registering, patient referral to ongoing clinical studies, as well as innovative methodologies for clinical research

6. Patient-physician shared clinical decision-making should be especially valued, being crucial to the appropriate approach to the high degree of uncertainty posed by rare cancers

7. Appropriate state-of-the-art instruments (*such as clinical practice guidelines*) should be developed in rare cancer, fit to serve clinical decision-making in conditions of uncertainty

8. Regulation on rare cancers should tolerate a higher degree of uncertainty, being disease-adapted and providing developers of innovation with certainty of rules across the EU

9. Policy strategies on rare cancers and sustainability of interventions should be based on networking, exploiting national cancer plans, listening to networks and disease-based communities, integrating the EU and the national levels, funding networking

10. Rare cancer patients should be engaged in all crucial areas, such as disease awareness and education, healthcare organization, state-of-the-art instruments, regulatory mechanisms, clinical and translational research

*Source: JARC*
III.5. European Reference Networks

The EU plays a central role in improving collaboration across countries in respect to rare and paediatric cancers. Launched in 2017 in connection to the EU’s Cross-Border Healthcare Directive (Directive 2011/24/EU), several European Reference Networks (ERNs) were constructed and have been operational since then. ERNs are virtual networks that bring together healthcare providers and centres of expertise, in particular in the area of complex and rare diseases and conditions that require highly specialised treatment and a concentration of knowledge and resource. These networks are based on voluntary participation by their members; to ensure excellence, the directive sets the criteria for healthcare providers to join the network.

ERNs are "peer-to-peer" networks, comprising centres of expertise endorsed by their national healthcare authorities, and European Patient Advocacy Groups established by EURORDIS - Rare Diseases Europe. ERNs on rare cancers liaise with national or regional "hub-and-spoke" networks, and link centres of expertise to more generalist centres taking charge in part or in whole the management of some rare cancer cases. Connecting expert clinicians via a secure web-based platform, ERNs enable patients to get access, without travelling, to multidisciplinary expert assessment and faster diagnosis and treatment.

In small countries, where no institution will see enough patients with certain rare cancers to meet the case volumes thresholds generally used to define highly specialised centres of expertise, ERNs identify “affiliated centres” which then will liaise with their “full members”. This way, rare cancer patients of small countries can also benefit from the specialised expertise of the network.

24 ERNs were launched in 2017, involving more than 900 highly specialised healthcare units from over 300 hospitals in 26 Member States. EURACAN: European Reference Networks on rare adult solid cancer; EuroBloodNet: European Reference Networks on Rare Haematological Diseases; ERN PaedCan: European Reference Networks on paediatric cancers; and ERN GENTURIS: European Reference Networks on genetic tumour risk syndromes are specifically devoted to rare cancers.

III.6. Europe’s Beating Cancer Plan initiatives on rare cancers

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260 See footnote 1
Published by the Commission on 3 February 2021, Europe’s Beating Cancer Plan (COM(2021)44) addresses rare cancers in its Flagship 5.

- The Cancer Mission Board of Horizon Europe and the EU Joint Action CanCon recommended the establishment of National Comprehensive Cancer Centres and their networking at EU level. Building on this recommendation, in Flagship 5 of the EBPC the Commission undertakes to establish by 2025 an EU Network that links recognised National Comprehensive Cancer Centres in every Member State.

This cross-border collaboration will improve patients’ mobility and patients’ access to high-quality diagnostics and care and the latest innovative treatments. It will be supported by a new “EU Cancer Treatment Capacity and Capability Mapping” project, helping to map and share the different capabilities and expertise available across the EU. With the target to ensure that 90% of eligible patients have access to such centres by 2030, this action aims at delivering higher-quality care and reducing inequalities across the EU.

The EU Network will be supported by the existing four rare-cancer focused ERNs and a group of newly-created ERNs. These new ERNs will look at specific, challenging cancer conditions, including metastatic diseases, co-morbidities in cancer care, complex cancers with poor prognosis, paediatric cancers and specific conditions related to genomics in cancer care, palliative care and survivorship.

- Building on experiences with repurposing of medicines to treat COVID-19, in 2021 the Commission will launch an EU platform to improve access to cancer medicines to support the repurposing of existing medicines. Using High-Performance Computing will allow to rapidly test existing molecules and new drug combinations. The work will start with cancers with poor prognosis and rare cancers.

**III.7. Europe’s Beating Cancer Plan initiatives on paediatric cancers**

A chapter is dedicated to paediatric cancers in the EBPC, underlying the political commitment of the EU, and highlighting the complexity of the issue.

- Flagship 10 of the EBPC is to launch, in 2021, the Helping Children with Cancer Initiative. Funded under the EU4Health programme, the initiative will use the new Network of Comprehensive Cancer Centres as infrastructure, and will complement the actions implemented by the new European Reference Networks, with the aim to ensure that children have access to rapid and optimal detection, diagnosis, treatment and care.

- A new EU Network of Youth Cancer Survivors will be set up in 2022 to (i) complement the actions under the “Helping Children with Cancer Initiative”, (ii) connect young cancer survivors, their families, and informal and formal carers, and (iii) contribute to strengthen long-term follow-up in cancer care plans at national and regional level.
A new **Cancer Survivor Smart-Card** will be introduced by 2023 to address the specific needs of childhood cancer survivors, such as long-term monitoring of outcomes and potential toxicity of treatments, tailor follow-up care, rehabilitation, psychological support, educational modules, connectivity with healthcare staff, and information about past clinical history.

A new section, dedicated to childhood cancers, will be introduced into the **European Cancer Information System** to facilitate monitoring and research.

**Horizon Europe Cancer Mission**, via the planned “**Childhood cancers and cancers in adolescents and young adults: cure more and cure better**” initiative would increase understanding of cancer initiation and progression, and provide evidence-based information to advance diagnostics, treatment and survivorship support.

On the regulatory side, the **review of the Regulation on orphan medicinal products (Regulation (EC) No 141/2000)** and the **Regulation on medicinal products for paediatric use (Regulation (EC) No 1901/2006)** have the objective of improving the conditions for studying and authorising new cancer medicines for use in children.
BACKGROUND NOTE ON SCREENING AND EARLY DIAGNOSIS OF CANCER

According to the estimates of the EU’s Joint Research Centre, in 2020 about 2.7 million people were expected to be diagnosed with cancer in the EU-27, and nearly 1.3 million to die from it\(^{261}\). As over 40% of cancer cases are preventable, primary prevention remains the most cost-effective intervention in cancer control. Detecting as early as possible those cancers which could not be prevented, and providing appropriate treatment, is crucial for increasing significantly the chances for successful treatment, improving considerably patient outcomes, reducing further cancer mortality, as well as reducing notably the cost and complexity of cancer treatment.

Thanks to population-based screening programmes, a large population, who are asymptomatic and seemingly healthy but in an age group when they are susceptible to certain cancers, can be examined and their doubtful or positive test results can be followed up. Similarly, early diagnosis of cancer in already symptomatic...

\(^{261}\)\(^{3}\) The estimates of cancer incidence and mortality are based on trends from previous years and do not reflect yet the effect of the COVID-19 pandemic on cancer burden.
patients at a stage when their cancer is not so advanced, can ensure the timely start of treatment before the cancer spreads and the patient’s condition worsen. E.g. the five-year survival rate for women diagnosed with cervical cancer at an advanced stage is 15%, compared to 93% if diagnosed when the cancer has not spread\footnote{American Society of Clinical Oncology: \url{https://ascopost.com/News/59711}}; 57% of people with lung cancer survive their disease for 5 years or more when diagnosed at stage I compared with only 3% of those diagnosed at stage IV\footnote{Office for National Statistics: Cancer survival in England: adults diagnosed 2013–2017 \url{https://www.thelancet.com/action/showPdf?pii=S1470-2045%2820%2930593-3}}.


**Screening** consists of a set of tests run across a targeted, seemingly healthy population group in order to identify those individuals who have cancer but their symptoms have not appeared yet, or who are unaware that their symptoms are cancer-related.


- **Suitable disease**: a cancer that is detectable at preclinical phase, for which early treatment is available, and which has a relative burden within the population.
- **Suitable screening test**: a valid testing method with high sensitivity (as few as possible with cancer get through undetected) and high specificity (as few as possible without cancer are subject to further diagnostic tests), which is accepted and of a reasonable cost.
- **Suitable screening programme**:
  - there is a clear definition of the target population;
  - the individuals to be screened are identifiable;
  - measures are available to ensure high coverage and attendance;
  - there are adequate field facilities for collecting the screening material and adequate laboratory facilities to examine it;
  - there is an organised quality control programme to assess the screening material and its interpretation;
  - adequate facilities exist for diagnosis and appropriate treatment of confirmed neoplastic lesions and for the follow-up of treated individuals;
  - there is a carefully designed referral system for management of any abnormality found; and
  - evaluation and monitoring of the total programme is organised.

**Weighing harms against benefits** is pivotal when deciding about carrying out screening programmes. Screening programmes should be undertaken only when their effectiveness have been demonstrated; when resources (personnel, equipment, etc.) are available to cover sufficiently the target group; when the health care system has facilities for confirming diagnoses and for treatment and follow-up; and when prevalence of the disease is high enough to justify the effort and costs of screening. Even with the best intention and proper implementation, screening programmes may cause harm: false positive results lead to additional testing, invasive diagnostic procedures and anxiety and psychological harm; false negative results come with false reassurance and defer diagnosis at a later
stage, once symptoms have appeared; and over diagnosis or over treatment of preclinical cancers, which could have not caused symptoms nor posed a serious health threat, involve unnecessary treatment.

**Early diagnosis programmes** include increasing awareness about the first signs of cancer among the general public, but also among doctors (in particular primary health care providers), nurses and other health care providers; and improving accessibility and affordability of diagnostic and treatment services, and improving referral from primary care providers to specialised doctors and centres. Early diagnosis aims at reducing the proportion of patients who are diagnosed at a late stage. It is particularly relevant in cases of cancers of the breast, cervix, mouth, larynx, colon and rectum, and skin.

II. **Cancer registries**

Cancer registries are **systems for data collection, storage, validation and analysis**, which allow for extracting and disseminating information on cancer incidence, mortality, survival, and prevalence rates, time trends, and projections in the populations covered. On a more advanced plan, cancer registries can give information on the stage at diagnosis, diagnostic and treatment delay, type of treatment, medical equipment use, and compliance with clinical care guidelines.

Cancer registries have a key role in:

- epidemiologic research, for monitoring the trends of cancer incidence, survival, and prevalence rates in geographical areas, social groups, or time periods;
- investigation of aetiological factors for cancer, by supporting the analysis of the impact of different social or environmental factors on cancer risk;
- public health policy measures:
  - planning of cancer control measures, helping to prioritise different actions according to the current and projected cancer burden;
  - assessment and monitoring of the effectiveness of cancer control measures such as primary prevention, screening programmes, treatment patterns, and health care quality;
  - assessment of the impact of differences in access to diagnosis and treatment between geographical areas or social groups, in order to create programmes for reducing health inequalities;
- clinical and translational cancer research.

The **completeness and validity of data, and data quality** is key for cancer registries assuming their roles. Data from screening programmes is one of the important inputs for cancer registries.

At international level, countries have been cooperating under the aegis of the **International Association of Cancer Registries**. At EU-level, it is the **European Network of Cancer Registries** (ENCR), operational since 1990, that promote collaboration between cancer registries, defines data collection standards, provides training for cancer registry personnel and regularly disseminates information on cancer incidence and mortality in Europe.

The ENCR aims at improving the quality, comparability and availability of cancer incidence data; creating a basis for monitoring cancer incidence and mortality in the EU; providing regular information on the burden of cancer in Europe; and promoting the use of cancer registries in cancer research.

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267 A-M Forsea: Cancer registries in Europe - going forward is the only option; eCancer, 2016
https://ecancer.org/en/journal/article/641-cancer-registries-in-europe-going-forward-is-the-only-option
control, health-care planning and research. Its full membership is open (upon the fulfilment of other, well-defined criteria) for population-based cancer registries, i.e. registries that collect data on all new cases of cancer occurring in a specified population in a defined geographical area. ENCR is affiliated to the International Association of Cancer Registries; it is supported by the Commission, and its secretariat is hosted at the Joint Research Centre.

III. Modern technologies: Artificial intelligence and big data in cancer screening and diagnosis

Artificial intelligence (AI) refers to systems with intelligent behaviour, which analyse their environment and take actions with some degree of autonomy in order to achieve specific goals. AI-based systems can be purely software-based and act in the virtual world, e.g. voice assistants, image analysis software, search engines, speech and face recognition systems; or can be embedded in hardware devices, as it is the case with advanced robots, autonomous cars or drones.

Machine learning refers to algorithms that autonomously improve their performance, without humans directly encoding their expertise. Usually, machine learning algorithms improve by training themselves on data. Deep learning is a sub-field of machine learning; it is concerned with algorithms called ‘artificial neural networks’ that are modelled on the structure and function of the brain. A deep learning algorithm is trained to classify objects by exposing it to a large number of labelled examples that are correctly categorised. Once trained, algorithms can correctly classify objects that they have never seen, in some cases with accuracies that exceed those of humans. Obviously, the development of AI requires massive datasets; the larger the amount of data is, the better even subtle relations in the data can be discovered.

There is increasing interest in the use of AI and machine- and deep learning in healthcare, for conducting complex calculation and assessing diagnostic images with minimal human intervention. In the field of oncology and cancer management, AI is used in screening and early detection, and in tailored or targeted therapy by obtaining genetic information of the patient and predictions of future outcomes.

In most oncology-related diagnosis, the applications of AI are crucial in radiology for various modalities such as X-rays, ultrasounds, computed tomography (CT/CAT), magnetic resonance imaging (MRI), positron-emission tomography (PET) and digital pathology. Differentiating between normal and abnormal medical images is a key aspect to accurate diagnosis. It is done by analysing images with highly specialised algorithms with increased speed and accuracy. The generated datasets include information about variants with classifications such as benign, likely benign, variant of unknown significance, likely pathogenic and pathogenic variants. Categorising all variants into classes and recognising its clinical significance is imperative. Additional to diagnosis, data obtained can be useful for cancer management.

AI brings a surge in big data and costs: big data management and interpretation is resource-intense, it requires large servers and skilled bio-informaticians; AI systems have specialised computational requirements for fast processing of data; and intended users need proper training before implementing

268 Z. Dlamini, F. Z. Francies, R. Hull, R. Marima: Artificial intelligence (AI) and big data in cancer and precision oncology; Computational and Structural Biotechnology Journal, 2020
269 European Parliament Research Service: How artificial intelligence works, 2019
AI-based systems for routine clinical practice. Using patient data for training AI and enabling machine learning, and the protection of patients’ safety and privacy remain crucial.

In 2018 the Commission set out the EU’s AI strategy (COM(2018)237) with the aim to place Europe ahead of technological developments and encourage the uptake of AI by the public and private sectors; prepare for socio-economic changes brought about by AI; and ensure an appropriate ethical and legal framework. Together with the strategy, the Commission also proposed a set of initiatives to grow the European data space, including a communication on enabling the digital transformation of health and care in the Digital Single Market, including sharing of genomic and other health data sets (COM(2018)233)271.

Europe’s Beating Cancer Plan (COM(2021)44)272 announced the launch of a new European Cancer Imaging Initiative, promoting new methods to improve the quality and speed of screening programmes using AI. The work of the Cancer Mission of the Horizon Europe research programme will also contribute to the initiative by developing novel approaches for screening and early detection.

IV. Population-based screening programmes in the EU - screening for specific cancers273,274

IV.1. Overview of the current European framework on cancer screening

Pursuant to the 2003 Council recommendation275, Member States should implement systematic population-based national or regional screening programmes to reduce the burden of common

275 Council Recommendation on cancer screening (2003/878/EC)
In 2020, cancers. Female breast, cervical and colorectal cancer, the three cancers in the scope of the recommendation, caused a collective burden of over 261 000 deaths in the EU-27 (estimates from the European Cancer Information System).

To achieve this, the following tests have been recommended:

- pap smear screening for cervical cancer precursors, starting not before the age of 20 and not later than the age of 30;
- mammography screening for breast cancer in women aged 50 to 69; and
- faecal occult blood screening for colorectal cancer in men and women aged 50 to 74.

The recommendation underlines the importance of quality assurance at all appropriate levels of screening programmes, on the basis of European evidence-based guidelines on best practice. For the appropriate organisation and monitoring of the screening programmes, Member States should ensure adequate human and financial resources.

Since the adoption of the Council recommendations, several initiatives have been developed (and kept updated) for the rolling out, management and monitoring of cancer screening programmes:

- **European guidelines for quality assurance in breast**, cervical and colorectal cancer screening, published by European Commission Directorate General for Health and Food Safety (DG SANTE). The guidelines aim at optimising all aspects of screening from information and invitation messages, to administration of tests and interpretation of results, and patient referral. The guidelines are kept updated based on new evidence and best practices, e.g. for breast cancer the preparatory work for the 5th edition has already started.

- **European Commission Initiatives on Breast Cancer** (ECIBC) is a multidisciplinary platform, bringing together health care professionals, researchers and patient advocates. The initiative aims at reviewing, developing and facilitating the implementation of European guidelines addressing the entire care pathway for these cancer types, including screening programmes.279

- **European Commission Initiative on Colorectal Cancer** (ECICC): The Joint Research Centre has launched the call for experts and patients to form a working group for the development of evidence-based guidelines and a quality assurance scheme for the new European Commission Initiative on Colorectal Cancer.280

- **Implementation reports** on the 2003 Council recommendation on cancer screening, prepared by the International Agency for Research on Cancer (IARC) for the European Commission. The first edition was published in 2007, the second one in 2017. The report keeps track of the progress with the implementation of recommended cancer screening programmes across the EU. It also assesses the performance of the programmes in terms of population coverage and

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276 European guidelines for quality assurance in breast cancer screening and diagnosis: 4th edition, supplements

277 European guidelines for quality assurance in cervical cancer screening: 2nd edition, supplements

278 European guidelines for quality assurance in colorectal cancer screening and diagnosis
https://op.europa.eu/en/publication-detail/-/publication/e1ef52d8-8786-4ac4-9f91-4da2261ee535/language-en/format-PDF/source-194464733


detection rates, and provides justification for further initiatives at the European and the national level in relation to cancer screening.\textsuperscript{281}

- **The European Code Against Cancer** and its recommendation on cancer screening encourages European citizens to take part in organised cancer screening programmes for breast, colorectal and cervical cancer.\textsuperscript{282}

**IV.2. State of play with the implementation and performance of recommended cancer screening programmes**

Member States have made substantial progress over the last years with the **implementation of cancer screening programmes**. As of 2016, when closing the 2nd implementation report,

- 25 Member States were planning, piloting or rolling out (ongoing or completed) population-based breast cancer screening programmes\textsuperscript{283} (compared to 18 Member States in 2007);
- 22 Member States were planning, piloting or rolling out (ongoing or completed) population-based cervical cancer screening programme (17 in 2007); gradual introduction of the HPV test as primary screening modality is offered in the context of organised screening in (some programmes or areas of) six Member States\textsuperscript{284}; and
- 20 Member States were planning, piloting or rolling out (ongoing or completed) population-based colorectal cancer screening programmes, and 3 non population-based programmes (12 in 2007)\textsuperscript{285}.

Despite the progress, considerable differences still exist across the EU, as it is also shown in footnotes 24-26; some programmes are still at a planning phase owing to recent legislation, at a pilot phase only in a limited geographical area, or having their rollout ongoing or complete.


\textsuperscript{282} European Code Against Cancer's 12th recommendation \url{https://cancer-code-europe.iarc.fr/index.php/en/}

\textsuperscript{283} All the EU Member States (and the UK), except Bulgaria, Greece and Slovakia had population-based screening programmes at the time of closing the 2nd implementation report. • Bulgaria, Greece and Slovakia had only non-population based screening programmes. • Bulgaria had implemented a pilot programme that was concluded in 2014. • Romania had only a small-scale pilot or demonstration project, so the majority of the potential target population was subject to non-population-based screening.

\textsuperscript{284} Germany adopted on 2013 the law to convert their current non-population-based screening programme into population-based screening programme; in 2016, the new programme was still in the planning phase. Slovakia initiated planning for population-based screening programme, but in 2016 only non-population-based service was available. • Non-population-based screening programmes were reported for Austria, Greece, Luxembourg and Spain. • Bulgaria completed a pilot in 2014, and no population-based programme was initiated. No programme was reported for Cyprus. • Ten Member States had their population-based cervical cancer screening programme still in the process of rolling out: Belgium, Croatia, Czechia, France, Hungary, Ireland, Italy, Lithuania, Portugal and Romania. • Denmark, Finland, Italy, Sweden, Romania and Portugal offers HPV tests as primary screening modality of cervical cancer.

\textsuperscript{285} Greece and Latvia only had non-population-based screening programmes. • Germany adopted law in 2013 to transform their current non-population-based screening programme into a population-based one. • No programme was initiated in Bulgaria, Romania and Slovakia. • In Austria, Sweden and Portugal the screening activity was not yet covering the entire country.
The 2nd implementation report evaluates the performance of the screening programmes based on their examination coverage rate. The examination coverage rate is the proportion of individuals from the recommended target population group who (i) in the framework of the screening program, received a personal invitation to screening within the scheduled screening interval (invitation coverage rate), and (ii) participated in the test within the scheduled screening interval (participation rate).

### Implementation of recommended breast, cervical and colorectal cancer screening programmes in EU Member States and the UK in 2016

<table>
<thead>
<tr>
<th>Population-based screening program</th>
<th>Breast cancer screening</th>
<th>Cervical cancer screening</th>
<th>Colorectal cancer screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rollout complete</td>
<td>21 (88%)</td>
<td>9 (28%)</td>
<td>9 (27%)</td>
</tr>
<tr>
<td>Rollout ongoing</td>
<td>3 (3%)</td>
<td>10 (27%)</td>
<td>8 (26%)</td>
</tr>
<tr>
<td>Piloting</td>
<td>1 (4%)</td>
<td>1 (&lt;1%)</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>Planning</td>
<td>0</td>
<td>2 (17%)</td>
<td>2 (18%)</td>
</tr>
<tr>
<td>Non-population-based screening program</td>
<td>3 (5%)</td>
<td>4 (25%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>No screening program</td>
<td>0</td>
<td>2 (2%)</td>
<td>3 (24%)</td>
</tr>
</tbody>
</table>

Source: Strengthening Europe in the fight against cancer - Going faster, further

Note: Numbers correspond to the number of EU Member States (and the UK) reporting their situation regarding the respective cancer screening program; percentages in brackets correspond to the proportion of EU populations targeted by the respective screening program living in the corresponding countries.

Average screening rates within recommended (or common) target populations for breast, cervical and colorectal cancer screening programmes in the EU. Data provided by Member States mostly concerning year 2013.

<table>
<thead>
<tr>
<th></th>
<th>Breast cancer screening</th>
<th>Cervical cancer screening</th>
<th>Colorectal cancer screening</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Invitation coverage rate</strong></td>
<td>78.9%</td>
<td>59.2%</td>
<td>32.6%</td>
</tr>
<tr>
<td><strong>Participation rate</strong></td>
<td>60.2%</td>
<td>50.7%</td>
<td>38.2%</td>
</tr>
<tr>
<td><strong>Acceptable standard for participation rate</strong></td>
<td>70%</td>
<td>70%</td>
<td>45%</td>
</tr>
<tr>
<td><strong>Desirable standard for participation rate</strong></td>
<td>75%</td>
<td>&gt;85%</td>
<td>65%</td>
</tr>
<tr>
<td><strong>Examination coverage rate</strong></td>
<td>49.2%</td>
<td>29.8%</td>
<td>14.0%</td>
</tr>
</tbody>
</table>

The WHO considers that for cancer screening programmes to be efficient, the examination coverage of the target population (by organised screening) should be over 70%286. This as efficiency threshold.

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286 WHO guide for effective programmes: Cancer control - Knowledge into action
was only achieved by five EU Member States and the UK in breast cancer screening, one in cervical cancer screening and by no EU Member State in colorectal cancer screening\. In addition, the IARC in the 2nd implementation report sets acceptable and desirable standards for participation rates, differentiated by cancer types, ranging between 45-70% and 65-85% respectively.

However, the coverage rates above do not take into account participation in opportunistic screening, when screening is not part of a nation-wide campaign but initiated by the patient or his/her healthcare provider. It leads to lower coverage and participation rates in organised screening programmes, while the actual screening rates in the target population is higher. It is especially true for cervical cancer screening, where opportunistic activity accounts for the majority of examinations in several Member States (up to more than 90%).

Another important consideration is that all screening rates differ considerably across the EU, but even within the territory of Member States across regions. The 2nd implementation report shows e.g. that in certain Member States examination coverage rates within their territory ranged between 17% and 84% for breast cancer screening, 4% and 71% for cervical cancer screening and 1% and 53% for colorectal cancer screening. These rates also demonstrate a low or very low coverage and participation of the target population in recommended cancer screening programmes in many European countries.

Organised cancer screening programmes also have to comply with a number of organisational requirements, including:

- an explicit screening policy, stipulated by law or an official notification, which defines the target population, screening tests and screening intervals;
- public funding of the screening programme, and provision of screening tests free of charge;
- well-defined plan for invitation to the eligible population, through letters or through primary healthcare providers;
- a management team responsible for programme implementation and quality assurance;
- existence of screening registries and linkage with cancer registries.

Data shows that the vast majority of Member States have publicly funded screening programmes, thus access to free screening and diagnostic tests is ensured. Almost all Member States with population-based screening programmes have teams responsible for implementation and quality assurance. The invitations to participate in the screening programmes are sent by specified organisations, by primary health care or by the general practitioners. A majority of Member States practice sending invitation letters with pre-fixed appointments or with faecal occult blood test kits for colorectal screening. However, many screening programmes still do not have screening registries linked to the cancer and cause-of death registries that is a necessary condition to identify the cancer occurrence and deaths in the targeted population.

**IV.3. Adaptation to scientific and technological developments, and possible broadening of the scope of screening to new cancer types**

**Scientific and technological developments** have advanced cancer screening since the entry into force of the 2003 Council recommendation. New screening tests are being progressively implemented

\[287\] Examination coverage reaching or over 70% for **breast cancer** screening: Denmark, Finland, Ireland, The Netherlands, Sweden and the UK. • Examination coverage reaching or over 70% for **cervical cancer** screening: Sweden
within screening programmes, such as full field digital mammography, digital breast tomoography or supplemental magnetic resonance imaging (MRI) in women with extremely dense breast tissue, for breast cancer screening; HPV test for cervical cancer screening; and faecal immunological test or endoscopy for colorectal screening. In addition to the implementation of new screening tests, cancer screening programmes may also benefit from scientific progress in the field of cancer risk prediction allowing for the development of risk-adapted screening.

For the **introduction of new screening programmes**, establishing effectiveness, benefit-harm ratios and cost-effectiveness through evidence is the first step. Upon supporting evidence, implementation research in each country is needed to assess the feasibility of fulfilling the national requirements in practice. Screening programmes need good governance, monitoring with standard key indicators throughout the screening chain and evaluation of outcome. Establishing sustainable models for funding is still in focus in many Member States. The wide variation in resources for health care between Member States should be taken into account when planning for Europe-wide recommendations and research strategies.

The **Europe’s Beating Cancer Plan** considers extending cancer screening programmes to additional cancers (prostate, lung or gastric cancers). The **European cancer community keeps discussing intensively the possibility of screening programmes for additional cancer types**. In particular, Prostate-Specific Antigen (PSA) test for prostate cancer screening, and low-dose computed tomography (CT) screening for lung cancer are being discussed. Other prospects for additional cancer screening tests include gastric cancer screening, through endoscopy/fluoroscopy, pepsinogen testing or *Helicobacter pylori* testing, and CA125-based ovarian cancer screening. The **EU co-funded Cancer Control Joint Action** (CanCon), which concluded its work in 2017, acknowledged the untapped potential for cancer prevention through extending population-based screening to new cancer sites, but was of the view that further evidence was needed and advocated for financing mechanisms for trials through pan-European cooperation. In particular, CanCon noted that some prostate cancer screening policies might be cost-effective but questions remain on the optimal benefit-harm balance; forthcoming results of European trials would inform policy-making on lung cancer screening in Europe; and new trials would be needed to be financed to investigate optimal strategies for gastric cancer screening.

V. **Europe’s Beating Cancer Plan**

Europe’s Beating Cancer Plan (**COM(2021)44**) thrives to make improvements in three key areas of early detection of cancer: access, quality and diagnostics.

- **Access**: The Commission plans to put forward a proposal by 2022, **updating the Council Recommendation** on cancer screening. In the context of the revision, the broadening of the scope of targeted cancer screening by including additional cancers (prostate, lung and gastric cancer) will be considered. Furthermore, in 2021-2022 the **European Cancer Information System will be upgraded**, and will start to routinely collect indicators to monitor and assess cancer screening programmes.

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290 ESR/ERS white paper on lung cancer screening; *European Respiratory Journal*, 2015 [https://erj.ersjournals.com/content/early/2015/04/29/09031936.00033015](https://erj.ersjournals.com/content/early/2015/04/29/09031936.00033015)
Quality: In addition to the ongoing Commission Initiative on Breast Cancer, the Knowledge Centre on Cancer will provide **new guidelines and quality assurance schemes** on cancer screening, diagnosis, treatment rehabilitation, follow-up and palliative care for colorectal and cervical cancer. These will include voluntary accreditation and certification programmes for cancer centres and screening programmes.

Diagnostics: As ‘Flagship 4’ of the EBCP, a **new EU-supported Cancer Screening Scheme** will be established, with the purpose to help Member States to offer breast, cervical and colorectal cancer screening to 90% of their eligible population by 2025. This will be accompanied by the **new European Cancer Imaging Initiative**, promoting new methods to improve the quality and speed of screening programmes using AI. The **Cancer Mission** of the Horizon Europe research programme will strengthen further the Cancer Screening Scheme, and will generate evidence on optimising existing population-based cancer screening programmes, develop novel approaches for screening and early detection, and provide options to extend screening to new cancers.

Funding: The **EU4Health programme** will provide funding for the new scheme, together with support from the **Technical Support Instrument**, and loans from the European Investment Bank. The **European Regional Development Fund** can also support investments in early detection.

BACKGROUND NOTE ON SHARED KNOWLEDGE IN CANCER CARE AND RESEARCH

Though public health is the competence of the Member States and EU actions are complementary to national policies, sharing knowledge and pooling expertise in the field of cancer treatment, research and training is the strength of the Union. Thanks to the cross-border healthcare directive, cancer patients can have access to treatment abroad, and via the European Reference Networks their doctor can refer complex cases for virtual consultation amongst specialists. The Europe-wide and international network of cancer registries, the eHealth platform and the electronic health records and the upcoming European Health Data Space are the contributions of the EU for making large amount of health data available for secondary use. Data will drive next-generation cancer research and treatment; technical and interoperability standards and clarity about the legal framework for the use of data will be key in this regard.

“Sharing is caring”, for the benefit of the cancer patients and for the advancement of treatment and care. This message clearly projects through Europe’s Beating Cancer Plan as well, which plans to step up cooperation and incentives in several areas.

In this note:
- The data driving cancer treatment, research and policy-making
- Cancer registries and networks
- Electronic health records
- eHealth systems and the European Health Data Space
- Data protection rules
- Sharing expertise and thriving for the highest standards
- European Reference Networks
- Partnerships and joint actions, Commission initiatives
- Knowledge Centre under the EBCP
- Keeping up with excellence: continuing training of oncology professionals
- Educating cancer patients and the general public, improving health literacy
I. The data driving cancer treatment, research and policy-making

I.1. Cancer registries and networks

Cancer registries are systems for data collection, storage, validation and analysis, which allow for extracting and disseminating information on cancer incidence, mortality, survival, and prevalence rates, time trends, and projections in the populations covered. On a more advanced plan, cancer registries can give information on the stage at diagnosis, diagnostic and treatment delay, type of treatment, medical equipment use, and compliance with clinical care guidelines.

Cancer registries have a key role in:
- epidemiologic research, for monitoring the trends of cancer incidence, survival, and prevalence rates in geographical areas, social groups, or time periods;
- investigation of aetiological factors for cancer, by supporting the analysis of the impact of different social or environmental factors on cancer risk;
- public health policy measures:
  - planning of cancer control measures, helping to prioritise different actions according to the current and projected cancer burden;
  - assessment and monitoring of the effectiveness of cancer control measures such as primary prevention, screening programmes, treatment patterns, and health care quality;
  - assessment of the impact of differences in access to diagnosis and treatment between geographical areas or social groups, in order to create programmes for reducing health inequalities; and
- clinical and translational cancer research.

The completeness and validity of data, and data quality is key for cancer registries for assuming their roles. Screening programmes are one of the important data sources for cancer registries, as it was highlighted during the previous BECA hearing in March 2021. As the roll-out and coverage of screening programmes differ substantially across the EU and even across the regions in some Member States, this affects the completeness of data included in cancer registries. Aiming for quality-controlled nation-wide screening programmes with sufficient coverage is crucial for cancer prevention, and it remains the primary purpose; and, as improved screening programmes provide more complete and better data, the data feed into the cancer registries also improves.

There are some 200 population-based cancer registries in Europe, including national, regional and local ones. At international level, countries have been cooperating under the aegis of the International Association of Cancer Registries (IARC). At EU-level, it is the European Network of Cancer Registries (ENCR), operational since 1990, that promotes collaboration between cancer registries, defines data collection standards, provides training for cancer registry personnel and regularly disseminates information on cancer incidence and mortality in Europe. ENCR is also

291 A-M Forsa: Cancer registries in Europe - going forward is the only option; eCancer, 2016
https://ecancer.org/en/journal/article/641-cancer-registries-in-europe-going-forward-is-the-only-option

292 JRC technical reports: The European Cancer Information System (ECIS) web application

293 BECA hearing of 18 March 2021: “Saving lives and improving patient outcomes: Why screening and early detection of cancer matter”

294 Summary of the BECA hearing of 18 March 2021 on “Saving lives and improving patient outcomes: Why screening and early detection of cancer matter”
affiliated to the International Association of Cancer Registries, and it currently comprises 178 individual registries across Europe (including non-EU countries).

The ENCR aims at improving the quality, comparability and availability of cancer incidence data; creating a basis for monitoring cancer incidence and mortality in the EU; providing regular information on the burden of cancer in Europe; and promoting the use of cancer registries in cancer control, health-care planning and research.

Its full membership is open (upon the fulfilment of other, well-defined criteria) for population-based cancer registries, i.e. registries that collect data on all new cases of cancer occurring in a specified population in a defined geographical area.

Fed by data from the cancer registries, as well as from UN, WHO and Eurostat sources, the European Cancer Information System (ECIS) provides the latest information on indicators related to the cancer burden across Europe. The web-based tool thus supports research and decision making in public health policy in the field of cancer and serves as a point of reference and information for European citizens. ECIS allows for monitoring cancer burden, its trends and future evolution (over time, and across Europe and its geographical regions); and assessing the magnitude of the cancer burden and its likely future evolution. It provides data to illustrate the effects of health policy interventions; establishes a reference base for cancer epidemiological research; and provides information for further research on possible underlying causes of cancer as well as best practices for prevention, treatment, and follow-up. Its web-based application for data visualisation was launched in 2018. The ECIS is managed by the European Commission's science and knowledge service, the Joint Research Centre (JRC), which supports EU policies with independent scientific evidence throughout the whole policy cycle.

Under Europe’s Beating Cancer Plan (COM(2021)4295), ECIS will be expanded to understand cancer more, and tackle it better. New indicators detailed also by cancer staging, a new section on childhood cancers, and more detailed data at sub-national level will facilitate linkages with environmental and socioeconomic data.

I.2. Electronic health records

Electronic health records (EHRs) are collections of longitudinal medical records or similar documentation of a patient, in digital form. In order to achieve secure, interoperable, cross-border exchange and access to electronic health data in the EU, Commission Recommendation (EU) 2019/243 sets out the framework for the development of a European EHR exchange format. In addition to the governing principles on access and exchange, the recommendation also includes common technical specifications.

Communication from the Commission: Europe’s Beating Cancer Plan
Electronic health records can improve healthcare and patient outcomes in a number of situations:

- **Cross-border healthcare:** There are over two million recorded instances a year where a citizen living in one Member State has sought healthcare in another. Secure access and sharing of health records across borders facilitate citizens’ life in cross-border situations; e.g., citizens having moved within the EU can have access to health records between the Member States in which they have been resident; and quality of care is improved when medical treatment is required while travelling in the EU, or as part of a cross-border agreement. The Recommendation also mentions the link, in the future, between EHRs and EU initiatives in the field of social security coordination.

- **Telemedicine:** A system that allows a citizen secure access to their own health data combined with digital solutions linked to health applications or wearable devices, also enable patients with chronic conditions such as cancer to monitor their own symptoms at home and share them quickly with their clinical teams. This not only reduces the number of visits to a health facility for monitoring, but also helps to detect early a need for a change in treatment, resulting in fewer hospitalisations due to complications.

- **Sharing clinical information between treating doctors:** Europe’s Beating Cancer Plan forecasts that electronic health records will become crucial tools in cancer prevention and care. They will ensure that oncologists, radiologists and surgeons can share clinical information efficiently with each other, enhancing the patients’ treatment and survival chances. EHRs can also give a clearer picture on the experiences and outcomes of oncology patients than clinical trials. Combining health records with other data sets (in compliance with data protection rules), such as genomics, can provide even better insights into the efficacy of treatments and their optimisation.

The Beating Cancer Plan underscores the importance of EHRs in the European Health Data Space (more on this in the next section), and commits the Commission to work with Member States on a common exchange format for EHRs taking into account data security, privacy and interoperability.

### I.3. eHealth systems and the European Health Data Space

The development and deployment of eHealth solutions in healthcare systems is a national competence, but the EU has been supporting Member States’ efforts through funding and collaboration platforms for almost a decade now. Certain areas like interoperability and quality standards are addressed at European level, through coordinated action and digital alignment.

Several structures provide a platform for collaboration and cooperation:

- Set up under Directive 2011/24/EU on cross-border healthcare, the [eHealth Network](https://ec.europa.eu/health/ehealth/cooperation_en) is a voluntary network connecting national authorities responsible for eHealth. The network helps shape policy on eHealth interoperability and standardisation, and can give direction to eHealth developments in Europe.
**eHAction**, the Joint Action supporting the eHealth Network, was launched in 2018 to support the eHealth Network with technical and scientific advice, facilitate cross-border healthcare and provide the necessary policy support to the eHealth Digital Service infrastructure (eHDSI). eHAction develops strategic recommendations and instruments to support the political discussions between the eHealth Network, Member States and the Commission on certain priority areas, which are based on the eHealth Network Multiannual Work Programme.

The roll-out of the eHealth Digital Services Infrastructure was supported by the Connecting Europe Facility (CEF) Programme.

The eHealth stakeholder group (eHSG) is composed of altogether 30 members, who are representatives of European umbrella organisations and associations, and organisations with a European outreach in the fields of research, industry, standardisation and associations representing users (patients, professionals, providers etcetera) active in the eHealth sector. It was established in 2012, and its mandate ends in 2022.

The Joint Action for the European Health Data Space, **TEHDAS** (Towards the European Health Data Space) was launched in February 2021, bringing together 25 European countries, including 21 Member States. It supports the Commission’s work on the European Health Data Space by bringing together relevant actors on the secondary use of patient data; collecting best practices across the EU on the secondary use of data; and developing ‘concepts’ and ‘options’ for efficient secondary use of health data on governance, data quality, infrastructure and the empowerment of citizens.

The 2018 Communication from the Commission on the digital transformation of health and care (COM(2018)233) gave a new impetus to the eHealth sector. It builds on the digitisation of the health and care sectors around three axes:

- **Secure data access and sharing**, via the establishment of the eHealth Digital Service Infrastructure, in which all Member States would participate by 2025. It allows the exchange of e-prescriptions and patient summaries between healthcare providers; the first cross-border exchanges started in 2019. Work is also underway to establish a European EHR exchange format that is accessible to all EU citizens.

- **Connecting and sharing health data for research, faster diagnosis and improved health.** Digitising health records and enabling their exchange for secondary use supports the creation of large health data structure. Combined with the use of new technologies, such as big data analytics and artificial intelligence, it supports the search for new scientific discoveries and improves prevention, diagnosis, treatments, drugs and medical devices. This is reflected in the TEHDAS Joint Action, mentioned above.

- **Strengthening citizens’ empowerment and individual care.** Digital services help citizens to be more in charge of their own health. By using those services, citizens can more easily follow prevention guidelines, find motivation to lead healthier lifestyles, manage chronic conditions and provide feedback to healthcare providers. The use of telehealth and eHealth also helps to ease the stress on the health care system, derived from the rise of chronic conditions and an ageing European population, and help with the transformation towards integrated and personalised care systems.

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297 Communication from the Commission on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (COM(2018)233)  
The creation of a European Data Space, including a common European Health Data Space (EHDS), is one of the priorities of the Von der Leyen-Commission. It will allow better exchange and access to different types of health data (EHRs, genomics data, data from patient registries etcetera), both for primary and secondary use. From the patients’ point of view, it will enable them to securely access and share their health data in an integrated format in the EHRs between healthcare providers and across borders in the EU; this way, health and care delivery happens along the entire patient pathway. For secondary data use, it will connect with the Knowledge Centre on Cancer that will be launched in 2021 as one of the Flagship initiatives of Europe’s Beating Cancer Plan, to ensure that learnings are shared efficiently.

The legislative proposal on the European Health Data Space is expected later in 2021 and will be built on three main pillars: (i) a strong system of data governance and rules for data exchange; (ii) data quality; and (iii) strong infrastructure and interoperability. The new Joint Action, TEHDAS, has already been set up, as mentioned above.

I.4. Data protection rules

As it is clear from the above, health data can be used for different purposes: the primary use of data is for direct patient care; and secondary data use consists of supporting the safe and efficient functioning of healthcare systems, and driving health research and innovation. Data protection rules play a key role in ensuring safe data flow.

The EU’s General Data Protection Regulation (Regulation (EU) 2016/679, GDPR), applicable since 2018, is part of the EU data protection reform package. The regulation modernises and unifies rules, allowing businesses to reduce red tape and to benefit from greater consumer trust, and citizens to better control their personal data. Its relevance for cancer research and cancer registries is that the regulation recognises the principle of one-time consent for retrospective research and biobanking, and the principle of no consent for population-based registries.

Article 7 of the GDPR regulates consent, and some key recitals elaborate on the secondary use of data. With regard to one-time consent for retrospective research and biobanking, Recital 33 of the GDPR acknowledges that it is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection, i.e. the subject of future research may be unknown at the time when a patient gives his/her consent on the use of clinical data for scientific purposes. The recital also explains that patients should be allowed to give their consent (withdrawable any time) to certain areas of scientific research, or certain areas of research or parts of research projects.

The new Clinical Trials Regulation (Regulation (EU) No 536/2014, CTR, not yet applicable) specifically acknowledges the notion of one-time consent with regard to clinical trials. CTR specifies that in order to collect data from clinical trials to be used for future scientific research, it is necessary that the trial subject gives consent (withdrawable any time) to the use of his/her data outside the trial protocol. In this case, the one-time consent is given to use data retrospectively beyond the end and scope of a clinical trial. CTR is very clear on that all this should comply with the framework of the GDPR.

Concerning epidemiological research, Recital 157 of the GDPR underlines that researchers can obtain new knowledge on widespread medical conditions such as cancer by coupling information

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298 P.G.Casali: Data protection and research in the European Union: a major step forward, with a step back; Annals of Oncology, 2020
https://www.annalsofoncology.org/article/S0923-7534(20)42964-3/fulltext
from registries. Provided that safeguards set by EU law or national law for the protection of privacy are complied with, registries should be allowed to process data even without patient consent.

A recent study, prepared for the Commission, has assessed Member States’ rules on health data in light of the GDPR. As the interpretation of the GDPR varies across Member States and national legislation linked to its implementation has created a fragmented approach, it has negatively affected cross-border cooperation for providing healthcare, healthcare system administration and research. During previous BECA hearings in November 2020 and February 2021, experts highlighted the unfortunate consequences of the GDPR on medical research, pointing to issues concerning comparability of the data needed for proper research. The GDPR left a margin of manoeuvre for Member States to further specify the application of the regulation in the area of health and Article 168 the Treaty on the Functioning of the European Union, therefore a fully harmonised approach to the rules on processing of data in the area of healthcare provision, administration or research across the EU has not been achieved. Furthermore, the interpretation of the law is complex for researchers at national level, and patients do not always find it easy to exercise the rights granted by the GDPR. The study has concluded that there is support for actions at EU level to promote health data access and sharing; such measures may include a combination of soft law, e.g. via a code of conduct, with other non-legislative and legislative actions. A code of conduct is considered desirable to explain concepts from the GDPR and to ensure a consistent approach to health data exchange at a more practical level, e.g. defining formats for data exchange.

299 J. Hansen, P. Wilson, E. Verhoeven, M. Kroneman, M. Kirwan, R. Verheij, E-B. van Veen: Assessment of the EU Member States’ rules on health data in the light of GDPR
300 BECA hearing of 12 November 2020: “Supporting research on cancer - New mission on cancer within Horizon Europe”
301 Summary of the BECA hearing on “Supporting research on cancer - New mission on cancer within Horizon Europe”
302 BECA hearing of 23 February 2021: “From lab to life: transforming childhood, adolescent and rare cancer care”
303 Summary of the BECA hearing on “From lab to life: transforming childhood, adolescent and rare cancer care”
II. Sharing expertise and thriving for the highest standards

II.1. European Reference Networks\textsuperscript{304}

The EU plays a central role in improving collaboration across countries in respect to cancer. Launched in 2017 in connection to the Cross-Border Healthcare Directive, several European Reference Networks (ERNs) were constructed and have been operational since then.

Four of these networks are specifically devoted to cancers:
- European Reference Networks on Rare Adult Solid Cancers (EURACAN)
- European Reference Network on Rare Haematological Diseases (EuroBloodNet)
- European Reference Network on Paediatric Cancers (ERN PaedCan)
- European Reference Network on Genetic Tumour Risk Syndromes (ERN GENTURIS)

To be recognised by the Commission, an ERN must fulfil the following requirements\textsuperscript{305}:
- have at least ten healthcare providers from at least eight different EU countries;
- each healthcare provider be endorsed by their respective EU country;
- all members of a network have common expertise in a specific field, treatments, diseases or health conditions;
- a proposal is submitted, once the Commission has launched the call for ERN;
- meet the criteria for networks and its members, as provided in the Commission delegated decision on ERNs (Commission Delegated Decision 2014/286/EU); and
- gain the approval for membership, which is granted by the Board of Member States based on the independent technical assessment of the proposal.

ERNs pool knowledge and resources via virtual networks of healthcare providers across Europe, to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment. The management of rare and complex cancers poses significant diagnostic challenges, sometimes with major consequences for patients’ quality of life and outcome. Inappropriate management of these patients may result in an increased risk of relapse, and risk of death. ERNs are opening new possibilities for improving cancer treatment and care by sharing clinical cases; rationalisation of patient referral; and improved rare cancer management in small countries.

In concrete terms, to review a patient’s diagnosis and treatment, ERN coordinators and other network leaders convene ‘virtual’ advisory boards of medical specialists across different disciplines, using a dedicated IT platform and telemedicine tools. Consultations are carried out through the Clinical Patient Management System (CPMS), which is a dedicated web-based clinical software application that allows healthcare providers to work together virtually to diagnose and treat patients. ERNs are not directly accessible to individual patients; it is their healthcare provider who refers the patient’s information to the competent ERN member, with the patient’s consent and in accordance with the rules of their national health system. Spreading information amongst oncology professionals and

\textsuperscript{304} https://ec.europa.eu/health/ern_en
\textsuperscript{305} https://ec.europa.eu/health/ern/implementation/faq_en
cancer patients about cross-border treatment options and the possibility for virtual consultation via the ERNs is key for exploiting the full potential of these networks for the benefit of the patients.

**ERNs collaborate beyond diagnosis and treatment.** They develop guidelines, provide training and foster knowledge exchange; facilitate large clinical studies to improve understanding of diseases; support the development of drugs and medical devices through gathering patient data; and contribute to the development of new care models, eHealth solutions and tools.

**Europe’s Beating Cancer Plan** has announced the establishment of an **EU Network** by 2025, linking recognised National Comprehensive Cancer Centres in every Member State. This cross-border collaboration will improve patients’ access to high-quality diagnostics and care and the latest innovative treatments, and help with patient mobility. The existing four rare-cancer focused ERNs and a **group of newly-created ERNs for specific, challenging cancer conditions** will support the Network. The new ERNs will deal with complex cancer cases such as metastatic diseases, comorbidities in cancer care, complex cancers with poor prognosis, paediatric cancers and specific conditions related to genomics in cancer care, palliative care and survivorship.

The Cancer Plan aims to ensure that 90% of eligible patients have access to Comprehensive Cancer Centres by 2030. The **EU Cancer Treatment Capacity and Capability Mapping** project will help to map and share the different capabilities and expertise available across the EU.

### II.2. Partnerships and joint actions, Commission initiatives

Through its Health Programme, the EU has been supporting partnerships in the field of cancer for more than a decade, with each project building on the results of the previous ones. The **European Partnership for Action against Cancer (EPAAC)** delivered documents on a broad range of topics, including the **European Guide for Quality National Cancer Control Programmes**.

The main deliverable of the **Joint Action on Comprehensive Cancer Control (CANCON)** was the **European Guide on Quality Improvement in Comprehensive Cancer Control** in 2017, the result of the work of hundreds of cancer experts, in 25 countries and 126 partner organisations. CANCON also published policy papers and briefs.

The **Innovative Partnership for Action against Cancer (iPAAC)**, the current Joint Action brings together 24 associated partners and 20 affiliated entities across Europe whose main objectives are to build upon deliverables of the CANCON Joint Action and to implement innovative approaches to cancer control. Its main product will be a Roadmap on Implementation and Sustainability of Cancer Control Actions; an impressive set of work package documents is already available.

The **European Commission Initiative on Breast Cancer (ECIBC)** is a multidisciplinary platform, bringing together healthcare professionals, researchers and patient advocates. The initiative aims at reviewing, developing and facilitating the implementation of European guidelines addressing the entire care pathway for breast cancer, including screening programmes.306

The Joint Research Centre has launched the call for experts and patients to form a working group for the development of evidence-based guidelines and a quality assurance scheme for the **new European Commission Initiative on Colorectal Cancer (ECICC)**.307

### II.3. Knowledge Centre

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Europe’s Beating Cancer Plan announced the launch of a new Knowledge Centre on Cancer within the Joint Research Centre in 2021, as one of the flagships of the Plan. It will diffuse best practice implementation, issue guidelines to feed the design and roll-out of new actions under the EBCP, and help coordinating scientific and technical cancer-related initiatives at EU level. E.g., it will contribute to the European Cancer Imaging Initiative, the European Health Data Space and research carried out under the Cancer Mission.

III. Keeping up with excellence: continuing training of oncology professionals

Given the rapid pace of advancement and innovation in oncology, continuing medical education (CME) and continuing professional development (CPD) of oncology professionals is crucial. Their commitment for life-long learning is for the benefit of the patients and the society at large; it is not only a professional requirement or a legal obligation in many Member States, but an ethical obligation as well which for many doctors is deeply rooted in their professional philosophy.

‘Training’ is to be understood broadly, as it includes meetings for the presentation of pioneering clinical data and the latest educational updates, multidisciplinary congresses or conferences, as well as e-learning. There is no centralised continuing training path for medical professions and for oncology professionals in particular. However, only the completion of accredited trainings/events earn CME/CPD credits and count into the learning history.

A comprehensive study, prepared for the Commission, evaluated the state of play of lifelong learning for medical professions in general. It concluded that for physicians, CPD was mandatory in the majority of Member States, with the trend of moving away from voluntary schemes. Most of the national regulatory bodies of health professions developed standards and guidelines on the use of CME/CPD, and set the minimum number of credits/hours doctors should gain/spend on CME/CPD on an annual basis in order to meet requirements. However, the consequences for non-compliance of mandatory CME/CPD vary and range in severity, and it is unclear as to whether more serious sanctions are enacted; where CME/CPD is mandatory, it is sometimes linked to financial and status benefits; and in a number of countries it is linked to revalidation, re-certification and registration. In a few countries, regulatory bodies determine the subject matters for CME/CPD or the type of CME/CPD that must be undertaken (e.g. formal programmes).

Accreditation of CME/CPD activities and providers is extensive and undertaken by a variety of actors, including regulatory bodies, medical chambers, medical associations, medical/professional societies, etc..

For high quality cancer care, the European Guide for Quality National Cancer Control Programmes (produced by the EPAAC Joint Action) requires several provisions to be in place to ensure that oncology professionals are well-prepared:
- licensing and certification systems;
- degree programmes for high-priority medical specialties, including one or more university or departmental chairs;

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308 Review and mapping of continuous professional development and lifelong learning for health professionals in the EU, 2013

- continuing education programmes related to oncological care, for both general and specialist physicians, nurses and medical support staff;
- inclusion of integrated care principles within medical curricula; and
- specific requirement for a module on patient communication for all staff working with cancer patients, in addition to clinical coursework.

In the field of oncology, professional medical societies, e.g. national/specialist colleges/cancer societies deliver CME/CPD schemes. At EU-level, cancer associations and organisations organise high-quality events, and so do the ERNs. On some occasions, they team up with universities and learning institutions. The Accreditation Council of Oncology in Europe (ACOE) runs accreditation to CME providers. By participation in accredited programmes, delegates earn CME credits in recognition of the high quality of the education received. In addition to CME/CPD accredited training, the European Institute of Innovation and Technology, the Marie Skłodowska-Curie Actions and the Erasmus+ programme offer training for oncology medical professionals.

Europe’s Beating Cancer Plan has announced the launch of an Inter-specialty cancer training programme in 2021. The programme builds on cross-border training and information-sharing in the fields of oncology, surgery and radiology; it will also focus on patients’ quality of life and well-being, including mental, psychosocial and nutritional support, along with patient empowerment. The training programme fits into the framework of the Pact for Skills large-scale partnership in the health sector, which was announced in the Skills Agenda for sustainable competitiveness, social fairness and resilience.310

IV. Educating cancer patients and the general public, improving health literacy

Education to the general public focuses mostly on prevention and early detection of cancer. Given that 40% of cancers are preventable, and that downstaging saves lives and considerably improves patient outcomes, the importance of health education cannot be underestimated. Spreading information by credible sources, in an accessible language, adapted to various ethnic, cultural and social backgrounds is key for success. Early education of schoolchildren with age-appropriate materials, reinforcing good lifestyle habits and preventing/combatting bad ones at an early age is paramount; it is an investment into a healthier new generation.

The different types of education programmes include increasing the public's awareness of cancer; changing specific risk behaviour; learning self-examination skills; and promoting early cancer detection.

Health education and health promotion campaigns should be part of the National Cancer Control Programmes (NCCPs), which should describe the use of those campaigns, health education in schools and other activities, which target different generations in society. International organisations’ initiatives such as the IARC’s European Code against Cancer311, and awareness raising campaigns by patient organisations contribute greatly to the education of the public.

Access to accurate information for cancer patients and their family is crucial throughout the whole cancer journey: at the time of receiving the cancer diagnosis, during treatment, and in remission and end-of-life care as well. Learning about the particular cancer, treatment options including treatment abroad, and possible outcomes enable patients to take informed decisions about their care. It is an integral part of patient empowerment and patient-centred cancer care.

**Europe’s Beating Cancer Plan** has introduced a series of initiatives to **improve health literacy** to be implemented in 2021-2015. It includes:

- promoting cooperation between health and social services and the community, involving social workers, teachers and nurses to educate the public on healthy behaviour, and patients on how to live well after cancer treatment;
- **updating the European Code against Cancer**, based on the latest scientific developments and completed by new evidence-based recommendations to improve health literacy, and ensuring that by 2025 at least 80% of the EU population will be aware of the Code;
- deploying an **EU Mobile App for Cancer Prevention**, to be funded under the EU4Health programme, that will reinforce the Code by offering individuals information on how to reduce their cancer risks and how to benefit from new developments in personalised cancer risk-assessment; and
- launching a new project on **Health Literacy for Cancer Prevention and Care** to develop and share best practice to strengthen health literacy in cancer prevention and care programmes, with a focus on disadvantaged groups.
Background note on the Financing of Europe’s Beating Cancer Plan

Europe’s Beating Cancer Plan will be financed using a whole range of Commission funding instruments with a total of €4 billion being earmarked for actions addressing cancer.

Additional support will be provided through programmes under shared management between Commission and Member States, in particular the Cohesion Policy Funds and the Next GenerationEU/Recovery and Resilience Facility. For these programmes, Member States and their national and regional authorities will be responsible for setting priorities on the basis of existing needs, and for carrying out these investments. To facilitate the use of EU funding instruments for cancer investment, the Commission will set up a knowledge sharing mechanism to inform Member States about the different EU funding mechanisms and how they can be utilised. Member States are strongly encouraged to make full use of all options to implement the measures included in the Europe’s Cancer Plan.

The table below illustrates the funding of the EBCP in more detail. Complexities such as the detailed composition of the overall funding for Horizon Europe or the MFF are not included for reasons of easier overview.
Breakdown of EBCP total funding
(source: EBCP (COM(2021) 44) - section 9. FUNDING)

<table>
<thead>
<tr>
<th>Programmes</th>
<th>Overall budget for 2021-2027 (in 2018 prices)</th>
<th>Share of Europe's Beating Cancer Plan</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU4Health</td>
<td>€ 5.1 billion</td>
<td>€ 1.25 billion</td>
<td>EU More, EU Neo, Helping, Better, Knowledge, EU Inter, (non-exhaustive list)</td>
</tr>
<tr>
<td>Horizon Europe (HE)</td>
<td>€ 95.5 billion (“Health” cluster within HE: € 8.2 billion)</td>
<td>€ 2 billion</td>
<td>Mission, Other research, (the amount of € 500 million is indicative; it reflects the budget of previous cancer-related projects in the period 2014-2020)</td>
</tr>
<tr>
<td>Erasmus+</td>
<td>€ 26 billion</td>
<td>€ 500 million (in total - from all three programmes)</td>
<td>Project in the field of the amount (not confirmed yet)</td>
</tr>
<tr>
<td>European Institute of Innovation and Technology</td>
<td>€ 3 billion</td>
<td></td>
<td></td>
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<tr>
<td>Marie Skłodowska-Curie actions</td>
<td>around 6.2 billion (not confirmed yet)</td>
<td></td>
<td></td>
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<tr>
<td>Digital Europe</td>
<td>€ 7.5 billion</td>
<td>€ 250 million</td>
<td>Cancer, Wider, cyber, health, infrastructure, equipment, digital transformation of healthcare, manufacturing capacity for medicines and medical devices, including for cancer care</td>
</tr>
<tr>
<td>TOTAL</td>
<td>€ 4 billion</td>
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</table>

Programmes under shared management

<table>
<thead>
<tr>
<th>Cohesion Policy Funds:</th>
<th></th>
<th></th>
<th>The EU funding includes the Interreg programmes for cross-border cooperation</th>
</tr>
</thead>
<tbody>
<tr>
<td>- European Regional Development Fund</td>
<td>€ 191 billion</td>
<td></td>
<td>MSs are prompted to identify investments that may include health infrastructure, equipment, digital transformation of healthcare, manufacturing capacity for medicines and medical devices, including for cancer care</td>
</tr>
<tr>
<td>- Cohesion Fund</td>
<td>€ 43 billion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- European Social Fund Plus</td>
<td>€ 87.9 billion</td>
<td></td>
<td></td>
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<tr>
<td>Next Generation EU/ Recovery and Resilience Facility</td>
<td>€ 672.5 billion</td>
<td></td>
<td>Complementary practical support to all MSs that express interest in</td>
</tr>
<tr>
<td>Technical Support Instrument</td>
<td>€ 864 million</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Programmes</td>
<td>Overall budget for 2021-2027 (in 2018 prices)</td>
<td>Share of Europe's Beating Cancer Plan</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>---------------------------------------------</td>
<td>---------------------------------------</td>
<td></td>
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<tr>
<td>InvestEU programme - and other EU budget guarantees</td>
<td></td>
<td>institutional, administrative and growth enhancing reforms</td>
<td></td>
</tr>
</tbody>
</table>

InvestEU is expected to mobilise around €372 billion of public and private investments with a budget guarantee of €26.1 billion put upfront by EU, to give an additional boost to investment, innovation and job creation over the period 2021-2027. It builds on the model of the Investment Plan for Europe (Juncker Plan), which mobilised more than €500 billion in the period 2015-2020.
BACKGROUND NOTE ON UNLOCKING THE POTENTIAL OF ARTIFICIAL INTELLIGENCE (AI) IN CANCER RESEARCH AND CARE

According to the 2018 European Commission’s definition, Artificial Intelligence (AI) refers to systems that display intelligent behaviour by analysing their environment and taking action - with some degree of autonomy - to achieve specific goals. AI includes a wide range of technologies and applications in non-medical (e.g. search engines) and medical (e.g. radiology) fields. Initially detailed in the 1950s, the use of AI has skyrocketed in the past decade. In medicine, more specifically in cancer, health ‘big data’ can be analysed with help of AI to accelerate the processing of these vast amounts of data and facilitate ‘precision medicine’. In other words, this could facilitate the development of more personalised and precise treatments based on an individuals’ genetic makeup. AI has the potential to revolutionise cancer care with the promise of a future optimised for the highest quality diagnosis and patient care.

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312 A definition of Artificial Intelligence: main capabilities and scientific disciplines | Shaping Europe’s digital future (europa.eu)

The recently published Artificial Intelligence Act proposal defines AI system as a “software that is developed with one or more of the techniques and approaches listed in (...) [the legislation] and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with”

313 ‘Big data’ refers to datasets that are so large and complex - including content from different sources, in different formats, and with different degrees of authenticity and accuracy - that they cannot be stored or processed in the same way as smaller datasets. ‘Precision medicine’ refers to the customisation of healthcare for a specific subgroup of patients.
Cancer care can benefit greatly from AI, however several potential barriers have been identified, when it comes to interoperability, legal and ethical standards, governance, cybersecurity, and technical requirements. Europe’s Beating Cancer Plan aims to stimulate and improve the use of new approaches to data analytics using AI. The possibilities and application of AI can play an important role in enhancing the quality of cancer detection, treatment and overall cancer care. This background note aims to demystify AI technology, to explain its applications in cancer care and research, and to present its opportunities, future perspectives and limitations with a view to the upcoming BECA Committee hearing. The hearing is organised in association with AIDA, and is complementary to the hearing held by the AIDA Committee about AI and health in December 2020.

I. Introduction to artificial intelligence (AI)

I.1. How AI works

AI-systems can be embedded either in hardware (e.g. advanced robots, drones) or in software (e.g. search engines, voice assistants, face recognition systems, image analysis). AI is an umbrella term for several different technologies and methodologies for approaching big data:

- **Symbolic AI (expert systems)**

Symbolic AI refers to the classical programming, embedding human knowledge and behaviour rules, represents the dominant paradigm of AI applications from its inception in the 1950s. This approach uses symbolic reasoning to represent and solve problems (i.e. using symbols for a particular solution, such as in a mathematical problem). Although symbolic AI is still used to date, it has its limitations: it requires human expertise to encode their knowledge in an understandable way and perform tasks, which can only be improved by direct human intervention. This means that symbolic AI is less effective for dynamic complex problems.

- **Machine learning (data-driven AI)**

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314 AIDA Working Paper on Artificial Intelligence and Health
315 N.Couspel and others, European Cancer Organisation: Strengthening Europe in the fight against cancer. Study for the ENVI Committee, by the Policy Department, 2020
316 AIDA hearing on AI and health; AIDA Working Paper on AI and health
317 Artificial intelligence: How does it work, why does it matter, and what can we do about it? Study by EPRS
318 Presentation Dr Mozzi Etemadi: How computers learn from humans; BECA hearing: “Why screening and early detection of cancer matter”
Machine learning (ML) is an automated learning process of algorithms that improve their performance without the interference of human encoding. In ML, the computer receives input data as well as answers expected from the data, and the ML agent needs to produce the rules. These rules can then be applied to new data to produce original answers. Therefore, in an ML system, the algorithm usually improves by training itself on large quantities of data (i.e. ‘data-driven’ AI).

- Artificial neural networks (ANNs): refer to computing systems that simulate the working of the brain, specifically in analysing and processing of information.
- Deep learning: is a subset of ML and refers to ANNs with more complexities, each containing many neurons, which may deliver more nuanced, and accurate responses. It has facilitated object recognition in images and video labelling *inter alia*.

**Reinforcement learning**

In reinforcement learning (RL), algorithms are used that focus on experience-driven sequential decision-making. This means that these algorithms lead to action to maximise some notion of cumulative reward. The combination of RL and ML is used in practical applications such as autonomous driving and stock markets.

![A schematic depiction of an AI-system](source:A definition of Artificial Intelligence: main capabilities and scientific disciplines | Shaping Europe’s digital future (europa.eu)

### I.2. AI in healthcare

Though data and analysis is not available on the specific angle of **uptake of AI in cancer**, the Joint Research Centre (JRC) monitors the **uptake of AI in health and healthcare in general**. Some of the conclusions from the JRC’s “AI watch 2020” appear to be particularly relevant:

- Within the global landscape, the EU is generally well-placed in the application of AI in the health and healthcare domains, somewhat behind China but at par with the USA.

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319 Joint Research Centre: **AI Watch - AI Uptake in Health and Healthcare**, 2020
The research dimension is particularly strong in the EU, with research institutions accounting for about two thirds of all EU players in this field, compared to one third of players in China, and a relatively small proportion in the US, where developments in this field are dominated by commercial companies.

- Though the level of interest and the number of pilot projects and experimentations are growing, the level of diffusion is still relatively low, most projects are just in initial stage to “test the water”, and investment in AI applications is still just a fragment of the overall expenditure of digital innovation in health.

- In the short term: AI development for operational applications and streamlining tasks and processes is at a mature stage and are already deployed in several industrial sectors.

- In the medium term: the priority is to increase access to health data and ensure its interoperability, which is crucial for enabling healthcare actors to develop and use AI technologies. Though the volume of data gathered by the Member States is impressive, common data spaces will be needed for exploiting the data.

- In the long term: upskilling of healthcare practitioners at all levels is the key for the uptake of AI applications, and data science should become part of their education and training.

### 1.3 EU policy and regulatory framework on AI and related initiatives

Launched in 2018, the EU’s Digital Transformation of Health and Care agenda\(^{320}\) gave a new impetus to the eHealth sector. A Joint Action, TEHDAS\(^ {321}\), is already in place, paving the way for the European Health Data Space. The creation of a European Data Space, including a common European Health Data Space (EHDS), is one of the priorities of the Von der Leyen-Commission. It will allow better exchange and access to different types of health data (EHRs, genomics data, data from patient registries etcetera), both for primary and secondary use. For secondary data use, it will connect with the Knowledge Centre on Cancer that will be launched in 2021 as one of the Flagship initiatives of Europe’s Beating Cancer Plan, to ensure that learnings are shared efficiently. The EHDS legislative proposal is expected later in 2021 and will be built on three main pillars: (i) a strong system of data governance and rules for data exchange; (ii) data quality; and (iii) strong infrastructure and interoperability.

In order to achieve secure, interoperable, cross-border exchange and access to electronic health data in the EU, Commission Recommendation (EU) 2019/243\(^ {322}\) sets out the framework for the

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\(^{321}\) Joint Action Towards the European Health Data Space, [TEHDAS](https://tehdas.eu/)

development of a European Electronic Health Record (EHR) exchange format. In addition to the governing principles on access and exchange, the recommendation also includes common technical specifications. Europe’s Beating Cancer Plan underscores the importance of EHRs in the European Health Data Space (more on this in the next section), and commits the Commission to work with Member States on a common exchange format for EHRs taking into account data security, privacy and interoperability.

The EU’s AI strategy, launched in 2018, aimed to encourage the uptake of AI by the public and private sectors; prepare for socio-economic changes brought about by AI; and ensure an appropriate ethical and legal framework. The High-Level Expert Group on Artificial Intelligence developed Guidelines for Trustworthy AI in 2019, and an Assessment List for Trustworthy AI in 2020 (more on these initiatives later, in point III.1). In parallel, the first coordinated plan on AI, published in 2018, represents a joint commitment with Member States for policy coordination on AI, and encourages Member States to develop national strategies. Bringing together the two streams, the Commission’s White Paper on AI was published in 2020, together with a report on the safety and liability aspects of AI, the Internet of Things and robotics.

In April 2021, the Commission presented a comprehensive policy and legislative framework on AI and a revised coordinated plan on AI. Since smooth access to data is pivotal for AI, the new AI framework is closely linked to the implementation of the European Data Strategy, including the recent proposal for a Data Governance Act. The AI regulatory framework will also work together with applicable product safety legislation and in particular the revision of the Machinery Directive, addressing the safety risks of new technologies, including the risks emerging from human-robot collaboration, cyber risks with safety implications, and autonomous machines.

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324 Coordinated Plan on Artificial Intelligence, COM (2018) 795
325 Report on the Safety and Liability Aspects of AI the Internet of Things and robotics, COM(2020)64
326 Proposal for a regulation laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act), COM(2021)206;
Communication from the Commission: Fostering a European approach to Artificial Intelligence, COM(2021)205
327 Proposal for a regulation on European data governance (Data Governance Act), COM (2020) 767
Funds for the promotion, development and deployment of AI

Thanks to the Digital Europe and Horizon Europe programmes, 1 billion EUR per year can be invested in AI; the Commission plans to mobilise additional investments from the private sector and the Member States to reach 20 billion EUR investment per year over the course of this decade.

The Recovery and Resilience Facility will enable Europe to raise its ambitions and become a first mover in adopting AI. The RRF makes 672.5 billion EUR in loans and grants available to support reforms and investments by Member States for the crucial first years of the recovery; at least 20% of the available funding, amounting to up to EUR 134 billion throughout the time span of the RRF will be allocated to measures fostering the digital transition. The RRF is expected to boost Member States’ investments in AI and support leading research, innovation and testing capacities, so that the accelerated development and use of AI can contribute to economic and social recovery and improve competitiveness in the longer term.

II. The application of AI in cancer research care

II.1. Computer-aided detection, diagnosis and decision support

At present, technology used for, for example, accurate lung cancer diagnosis (i.e. cancer type, stage of cancer and possible mutations) and treatment is through molecular biomarkers applied on biopsy material and/or blood testing. Although they are the gold standard, biopsies are specialised procedures, rather invasive, time-consuming, and can incur high costs. The use of new AI techniques, known as deep learning technology (DELT), can be used for the detection and classification of different tumours (e.g. lung cancer). DELT has increased rapidly during the last decade because of improved availability of ‘big data’,

Source: Singh et al.: Artificial Intelligence and precision medicine for oncology, ICICC 2020.
increasing computing power and advances in learning algorithms.\textsuperscript{331 332 333 334}

Whilst currently concentrated in the research domain, significant human and financial resources have been increasingly committed to the deployment of AI. The implementation of data-driven systems is believed to improve patient care by integrating them into clinical workflows. The clinical potential of AI lies in its ability to analyse large amounts of data to generate clinical decision support. In oncology, DELT can support expert clinicians in the qualitative interpretation of cancer imaging by, \textit{inter alia}, distinguishing different types of cancer from normal tissues, identifying stages of cancer, applying volumetric tumour delineation, and evaluating response to anti-cancer treatments.\textsuperscript{335}

In addition, DELT may lead to a more automated process of cancer image interpretation (e.g. in histopathology), and can assist pathologists in the detection of cancer subtypes or gene mutations, which can save time (i.e. accelerating access to appropriate therapies for patients) and costs. Furthermore, experts believe that digitalisation of the diagnostic process may lead to more equality in cancer care.

However, there are some limitations to the use of DELT in radiology (e.g. heterogeneity of datasets, lack of representative data \textit{inter alia}). Therefore, experts have underlined that deep learning applications for cancer imaging require further assessment and validation for reproducibility and generalizability in clinical practice.

Furthermore, AI brings a surge in big data and costs: big data management and interpretation is resource-intensive, it requires large servers and skilled bio-informaticians; AI systems have specialised computational requirements for fast processing of data; and intended users need proper training before implementing AI-based systems for routine clinical practice. Using patient data for training AI and enabling machine learning, and the protection of patients’ safety and privacy remain crucial.

\textsuperscript{331} Deep learning technology for improving cancer care in society: New directions in cancer imaging driven by artificial intelligence - ScienceDirect
\textsuperscript{332} Canadian Association of Radiologists White Paper on Artificial Intelligence in Radiology | Elsevier Enhanced Reader
\textsuperscript{333} Reviewing the relationship between machines and radiology; the application of artificial intelligence (nih.gov)
\textsuperscript{334} A comparison of deep learning performance against health-care professionals in detecting diseases from medical imaging: a systematic review and meta-analysis - PubMed (nih.gov)
\textsuperscript{335} Volumetric tumour delineation is the process in which the tumour is targeted as accurately as possible for radiation therapy applications.
Under Europe’s Beating Cancer Plan, the European Cancer Imaging Initiative will be set up in 2021 to develop an EU ‘atlas’ of cancer-related imaging, making anonymised images accessible to a wide range of stakeholders across the ecosystem of hospitals, researchers and innovators. It will provide a common EU data space, complemented by a new reference facility for Testing and Experimentation that will be launched to link the data to digital technologies such as High Performance Computing and AI. Supported by dedicated Digital Innovation Hubs, which will also provide assistance on regulatory aspects of AI, the Imaging Initiative will improve personalised medicine and innovative solutions by delivering greater accuracy and reliability in diagnostic imaging and follow-up of treatments.

**II.2. The AI revolution in cancer surgery and treatment**³³⁶, ³³⁷

Surgical decision-making is traditionally performed using hypothetical-deductive reasoning, individual judgement, and heuristics.³³⁸,³³⁹ These methods, however, are highly subject to variability (e.g. clinical knowledge of the surgeon and ability to interpret test results) and bias _inter alia_, and can introduce errors leading to preventable harm. The integration of AI techniques in surgical decision-making may address these impairments and will likely accelerate the capabilities of AI in augmenting surgical care. This will eventually improve patient care and overall quality of care.

Therefore, many experts believe that AI is able to transform cancer care (e.g. surgical care and personalised medicine) significantly. The theoretical potential of AI lies in the application in several aspects of cancer care and treatment, such as:

- computer-aided diagnosis;

³³⁶ _Translating cancer genomics into precision medicine with artificial intelligence: applications, challenges and future perspectives | SpringerLink_
³³⁷ _Artificial Intelligence in Surgery: Promises and Perils (nih.gov)_
³³⁸ _Artificial Intelligence and Surgical Decision-Making (nih.gov)_
³³⁹ Hypothetical-deductive reasoning refers to the diagnostic process in which patients are assessed to develop a list of possible diagnoses to consider; heuristics refers to any approach to problem solving, which is sufficient for a short-term goal, but possibly not optimal, or perfect (e.g. “trial and error”).
- cancer staging;
- clinical decision-making (e.g. treatment algorithms);
- informed consent process;
- treatment monitoring;
- surgery risk prediction;
- image-guided surgery;
- prediction of adverse events and postoperative complications;
- recovery monitoring and postoperative management;
- technical skills augmentation; and
- database management.

Although several studies have shown that clinician-machine interaction can augment human performance and clinical decision-making, there are limitations to be addressed.\(^{340} \) For example, AI cannot provide an automated clinical interpretation of its analyses nor can it determine causality in data necessary for clinical implementation. In addition, big data does not provide the appropriate clinical context with which to interpret the data.

### II.3. Personalised medicine: the right therapy for the right person at the right time

340 Deep Learning for Identifying Metastatic Breast Cancer (arxiv.org)
341 High-Risk Breast Lesions: A Machine Learning Model to Predict Pathologic Upgrade and Reduce Unnecessary Surgical Excision - PubMed (nih.gov)
342 Artificial intelligence performance in detecting tumor metastasis from medical radiology imaging: A systematic review and meta-analysis - PubMed (nih.gov)
Given the lack of a legal definition, **personalised medicine is best defined by the Horizon 2020 Advisory Group**: it is “a medical model using characterisation of individuals’ phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, (...) to determine the predisposition to disease and (...) to deliver timely and targeted prevention”.

The sequencing of the human genome and research developments in the genetic and molecular basis of diseases contributed to a **much better molecular understanding of diseases and of the impact of environmental factors**, down to the level of the individual. Tools developed for detection, diagnosis and treatment of diseases include ‘-omics’ technologies, such as genomics, glycomics, lipidomics, metabolomics, pharmacogenomics, epigenomics, proteomics, transcriptomics and metagenomics; and biomarkers and biobanking.

Research over the past decades proved that **there is heterogeneity not only between different tumour types and organs, but also within any tumour**: and that tumours on the same site, though deriving from the same organ, can differ in many aspects. Thanks to improvements in tumour biology, **cancers now can be classified based on critical molecular targets**; this enables creating targeted therapies, i.e. medicines that act specifically against molecular targets in cancer cells. With personalised cancer therapy, cancer patients receive the optimum treatment according to their personal medical history, their physiological status (including their genetics), and the molecular characteristics of their tumours. (For example, a subgroup of breast cancer patients is identified with HER2 gene amplification, which is the primary mechanism of HER2 over-expression in tumours. HER2 is a so-called oncogene, a gene that has the potential to cause cancer; amplification and over-expression of an oncogene can lead to uncontrolled cell growth, resulting in tumour growth. These patients can benefit from certain therapies that are effective specifically for their genetic profile.)

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343 The **Human Genome Project** was an international, collaborative research program whose goal was the complete mapping and understanding of all the genes (i.e. “genom”) of human beings. The project was completed in 2003. The **1+ Million Genomes** (1+MG) EU initiative is a cooperation mechanism, launched in 2018, involving by now 24 countries. Participating countries coordinate to link genomic databases, with the aim of having at least one million sequenced genomes accessible in the EU by 2022. Sharing more genomic data will improve understanding and prevention of disease, allowing for more personalised treatments and targeted drug prescription, in particular for rare diseases, cancer and brain related diseases.

344 **Personalised medicine** - Current status; **Briefing** for the ENVI Committee

345 **ESMO Patients Guide Series** - **Personalised medicines**
In oncology, AI platforms, ranging from machine learning to neural networks, can accelerate cancer drug discovery, harness biomarkers to accurately match patients to clinical trials, and personalise cancer therapy using only a patient’s own data:\(^{346}\):

- Testing all possible drug combinations at multiple doses for each drug is virtually impossible. However, AI can reduce the number of experiments needed to resolve drug and dose parameters, and thus optimise the development of combination therapy. AI can play a vital role in designing drug combinations without relying on predicted synergy between different drug targets and pathways. This could increase the pool of drugs considered for treatment, and identify unexpected combinations that outperform standards of care.

- Concerning clinical trials, including biomarkers in study recruitment has improved patient outcomes compared with traditional stratification information such as pathology or responses to prior treatments. Combining patient biomarker data and electronic health records for AI analysis may further affect trial outcomes. Although many types of data may be useful for stratification, AI would ultimately need both population-scale and individualised data to ensure that patients given therapies, including those designed by AI, have a high likelihood of responding.

- AI would also play a pivotal role in how cancer therapy is administered. Maximum tolerated dosing eliminates drug-sensitive tumour cells. However, drug-resistant cells can eventually cause treatment failure. Game theory is being explored to address this challenge, with dose-reduction algorithms competing against the tumour to prevent drug-resistant cells (which have high energy costs) from outnumbering drug-sensitive cells. This adaptive therapy may prolong treatment efficacy by maintaining threshold drug-sensitive cell populations in a tumour to combat drug-resistant cell proliferation.

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\(^{346}\) D. Ho: Artificial intelligence in cancer therapy - Artificial intelligence can optimize cancer drug discovery, development, and administration; Science, 2020
In the EU, several research initiatives support the development of personalised medicines:

- The **International Consortium for Personalised Medicine (ICPerMed)**\(^{347}\) was launched in 2016, bringing together over 30 European and international members representing research funders and policy-making organisations, and the Commission as observer. ICPerMed supports the personalised medicine science base via a common action plan with central research and research-supporting activities; and provides evidence to demonstrate the benefit of personalised medicine to citizens and healthcare systems.

- **ERA-LEARN**\(^{348}\) is a support platform for the research & innovation partnership community, funded as a support action by Horizon 2020, with a four-year lifespan (2018-2022). On behalf of the Commission, ERA-LEARN operates a unique database of partnership initiatives, their calls and funded projects and provides studies and analyses on thematic clustering, internationalisation, alignment, etc. **ERA-PerMed** serves as a funding vehicle of topics identified in the *Strategic Research and Innovation Agenda in Personalised Medicine* and the Action Plan of ICPerMed. ERA PerMed coordinates research & innovation efforts of the participating partners.

- The **Innovative Medicines Initiative Joint Undertaking (IMI2)**\(^{349}\) is a public-private partnership between the EU and the European Federation of Pharmaceutical Industries and Associations, EFPIA. It focuses on the needs of patients and society, and on delivering tools and resources to speed up the development of urgently-needed treatments. Its strategic research agenda includes, among others, research into personalised medicines.

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347 International Consortium for Personalised Medicine, [ICPerMed](https://www.icpermed.eu/)
348 [ERA-LEARN](https://erasus Leonardo/learn)
349 Innovative Medicines Initiative, [IMI2](https://www.imi.europa.eu/)

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### Improving multiple aspects of cancer therapy

Cancer therapy involves different stages, including drug discovery, development, and administration. Artificial intelligence (AI) is poised to benefit each stage but is also confronted by challenges that, when overcome, may lead to practice-changing cancer treatment.

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- As confirmed by Commissioner Gabriel in March 2021\textsuperscript{350}, personalised medicine will be of great importance in projects funded under Horizon Europe\textsuperscript{351} in the Health Cluster and for relevant projects funded in the European Research Council\textsuperscript{352}, the Marie Skłodowska-Curie actions\textsuperscript{353} and the European Innovation Council\textsuperscript{354}. Many fields will be open for proposals, without specifying the diseases to be addressed. In addition, the Commission is working on setting up a European Partnership for Personalised Medicine (EP PerMed) in collaboration with the Member States and regions, scheduled to start in the second half of 2023. It will address priorities for research and innovation in personalised medicine and its implementation in the healthcare sector, and co-fund projects between the Member States and the Commission.

III. AI legal and ethical challenges

The rise of new technologies brought on new ethical challenges, in the health sector and in general, that must be identified and mitigated.\textsuperscript{355,356} These issues relate to the whole lifecycle of AI, from creating algorithms (data collection, data entry and cleaning) to the application of AI and the dissemination of the results:

- the trustworthiness of AI systems;
- the opacity of algorithms or “black box issue” where no logical explanation can be provided of how the algorithm arrived at its given output;
- the algorithmic bias whereby the algorithm replicates existing inequities in socioeconomic status, race, ethnic background, religion, gender, disability, or sexual orientation, and amplifies inequities in health systems; poor training and design of AI systems potentially resulting in significant errors that may undermine privacy and non-discrimination;
- the secondary use of health data and the related issue of consent and the patient’s autonomy over his data,

are all valid concerns.

In health care, questions also arise about the cooperative or competitive relationship between AI and medical staff (in other words, whether there is a real risk that AI might not complement but replace the work of doctors, nurses and other healthcare staff in the future, raising questions about the nature of the future patient-doctor relationship); and the use of artificially intelligent, virtual patients in medical education.

Two challenges are described in more details below, the trustworthiness of AI systems and ethical standards, and the secondary use of health data in the light of the GDPR.

III.1 Trustworthiness of AI systems, ethical standards

\textsuperscript{350} Answer given by Commissioner Gabriel to a question to the Commission, E-000307/2021
\textsuperscript{351} Horizon Europe
\textsuperscript{352} European Research Council
\textsuperscript{353} Marie Skłodowska-Curie Actions
\textsuperscript{354} European Innovation Council
\textsuperscript{355} Ethical Dimensions of Using Artificial Intelligence in Health Care; Journal of Ethics, American Medical Association, 2019
\textsuperscript{356} K. J. Igoe: Algorithmic Bias in Health Care Exacerbates Social Inequities — How to Prevent It; Harvard School of Public Health
AI is trustworthy when three criteria are respected throughout the system's entire life cycle, i.e. during the development, deployment and use of AI systems: (i) AI has to be lawful, i.e. in compliance with all applicable laws and regulations; (ii) it has to be ethical, ensuring adherence to ethical principles and values; and (iii) it has to be robust, both from a technical and social perspective since, even with good intentions, AI systems can cause unintentional harm.

The independent High-Level Expert Group on AI\(^{357}\), set up by the Commission, adopted ethics guidelines for trustworthy AI\(^{358}\). In those guidelines, they identify the ethical principles and values that must be respected throughout the system's entire life cycle:

- Develop, deploy and use AI systems in a way that adheres to the ethical principles of: respect for human autonomy, prevention of harm, fairness and explicability. Acknowledge and address the potential tensions between these principles.
- Pay particular attention to situations involving more vulnerable groups such as children, persons with disabilities and others that have historically been disadvantaged or are at risk of exclusion, and to situations which are characterised by asymmetries of power or information, such as between employers and workers, or between businesses and consumers.
- Acknowledge that, while bringing substantial benefits to individuals and society, AI systems also pose certain risks and may have a negative impact, including impacts which may be difficult to anticipate, identify or measure (e.g. on democracy, the rule of law and distributive justice, or on the human mind itself.) Adopt adequate measures to mitigate these risks when appropriate, and proportionately to the magnitude of the risk.

The ethics guidelines also list the key requirements of trustworthy AI: (i) human agency and oversight, (ii) technical robustness and safety, (iii) privacy and data governance transparency, (iv) diversity, (v) non-discrimination and fairness, (vi) environmental and societal well-being, and (vii) accountability. The Assessment List for Trustworthy AI\(^{359}\) that the High-Level Group adopted a year later, translates AI principles into a checklist, and guides developers and deployers of AI in implementing those principles in practice.

In 2020 the European Parliament, in a legislative initiative report\(^{360}\), called for the establishment of a robust legal framework on AI, integrating a strong ethical approach into the legislation. In particular, the EP emphasised that future legislation should include into its scope AI, robotics and related technologies, including software, algorithms and data used or produced by such technologies; and legislation should cover the whole lifecycle of the system, from development to deployment and use. The Parliament also emphasised the importance to adhere to the Charter of Fundamental Rights; considered that the precautionary principle should be at the heart of any regulatory framework for AI; and called for a clear and coherent governance model. The EP cautioned about the asymmetry between those who employ AI technologies and those who interact and are subject to them, and

\(^{357}\) The High-Level Expert Group on Artificial Intelligence is group of experts, appointed by the Commission to provide advice on the EU’s AI Strategy. Members include representatives from academia, civil society and industry

\(^{358}\) High-Level Expert Group on Artificial Intelligence: Ethics Guidelines for Trustworthy Artificial Intelligence, 2019

\(^{359}\) High-Level Group on AI: Assessment List for Trustworthy AI (ALTAI), 2020

\(^{360}\) Framework of ethical aspects of artificial intelligence, robotics and related technologies, P9_TA(2020)0275
stressed that citizens’ trust in AI can only be built on an ethics-by-default and ethics-by-design regulatory framework. The resolution includes further specific provisions about risk assessment, safety features, transparency and accountability, non-bias and non-discrimination, etc. The resolution, in line with Rule 47 of Parliament’s Rules of Procedure \footnote{European Parliament’s Rules of Procedure, Rule 47}, includes the text of the proposed draft legislation.

In April 2021 the Commission presented a \textbf{proposal for an Artificial Intelligence Act} \footnote{Proposal for a regulation laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act), COM(2021)206}, which is a major step towards trustworthiness, while fostering the uptake of AI and boosting the EU’s competitiveness via a risk-based approach:

- The legislation sets a \textbf{technology-neutral definition of AI systems}. The definition is meant to be future-proof, to the extent that it can cover techniques and approaches which are not yet known or developed.

- To avoid over-regulation, the legislation focuses on the \textbf{use of AI in those cases where the risks that the AI systems pose are particularly high}. The risk classification of an AI system depends on its intended purpose, the severity of the possible harm and the probability of its occurrence. High-risk AI systems need to respect a set of specifically designed requirements, which include the use of high-quality datasets, the establishment of appropriate documentation to enhance traceability, the sharing of adequate information with the user, the design and implementation of appropriate human oversight measures, and the achievement of the highest standards in terms of robustness, safety, cybersecurity and accuracy. High-risk AI systems must be assessed for conformity with these requirements before being placed on the market or put into service.

- Finally, the legislation \textbf{bans a limited set of uses of AI that contravene EU values or violate fundamental rights}, such as AI systems that distort a person’s behaviour through subliminal techniques or by exploiting specific vulnerabilities in ways that cause or are likely to cause physical or psychological harm. It also covers general purpose social scoring of AI systems by public authorities. The legislation includes specific provisions for remote biometric identification systems (e.g. facial recognition tools to check passers-by in public spaces).

- \textbf{Other uses of AI systems would be only subject to minimal transparency requirements}, for example in the case of chatbots, emotion recognition systems or deep fakes. Finally, the legislation encourages the use of \textbf{regulatory sandboxes}, i.e. a controlled environment to test innovative technologies for a limited time, access to Digital Innovation Hubs and access to testing and experimentation facilities.

\textbf{III.2 Big data and data protection rules} \footnote{P.G.Casali: Data protection and research in the European Union: a major step forward, with a step back; Annals of Oncology, 2020}
Health data can be used for different purposes: the primary use of data is for direct patient care; and secondary data use consists of supporting the safe and efficient functioning of healthcare systems, and driving health research and innovation such as feeding AI. Data protection rules play a key role in ensuring safe data flow.

The EU’s General Data Protection Regulation (Regulation (EU) 2016/679, GDPR), applicable since 2018, is part of the EU data protection reform package. The regulation modernises and unifies rules, allowing businesses to reduce red tape and to benefit from greater consumer trust, and citizens to better control their personal data. Its relevance for cancer research and cancer registries is that the regulation recognises the principle of one-time consent for retrospective research and biobanking, and the principle of no consent for population-based registries.

Article 7 of the GDPR regulates consent, and some key recitals elaborate on the secondary use of data. With regard to one-time consent for retrospective research and biobanking, Recital 33 of the GDPR acknowledges that it is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection, i.e. the subject of future research may be unknown at the time when a patient gives his/her consent on the use of clinical data for scientific purposes. The recital also explains that patients should be allowed to give their consent (withdrawal any time) to certain areas of scientific research, or certain areas of research or parts of research projects.

The new Clinical Trials Regulation (Regulation (EU) No 536/2014, CTR, not yet applicable) specifically acknowledges the notion of one-time consent with regard to clinical trials. CTR specifies that in order to collect data from clinical trials to be used for future scientific research, it is necessary that the trial subject gives consent (withdrawable any time) to the use of his/her data outside the trial protocol. In this case, the one-time consent is given to use data retrospectively beyond the end and scope of a clinical trial. CTR is very clear on that all this should comply with the framework of the GDPR.

Concerning epidemiological research, Recital 157 of the GDPR underlines that researchers can obtain new knowledge on widespread medical conditions such as cancer by coupling information from registries. Provided that safeguards set by EU law or national law for the protection of privacy are complied with, registries should be allowed to process data even without patient consent.

A recent study, prepared for the Commission, has assessed Member States’ rules on health data in light of the GDPR. As the interpretation of the GDPR varies across Member States and national legislation linked to its implementation has created a fragmented approach, it has negatively affected cross-border cooperation for providing healthcare, healthcare system administration and research. During previous BECA hearings in November 2020365,366 and February 2021,367,368 experts

364 J. Hansen, P. Wilson, E. Verhoeven, M. Kroneman, M. Kirwan, R. Verheij, E-B. van Veen: Assessment of the EU Member States’ rules on health data in the light of GDPR
365 BECA hearing of 12 November 2020: “Supporting research on cancer - New mission on cancer within Horizon Europe”
366 Summary of the BECA hearing on “Supporting research on cancer - New mission on cancer within Horizon Europe”
367 BECA hearing of 23 February 2021: “From lab to life: transforming childhood, adolescent and rare cancer care”
368 Summary of the BECA hearing on “From lab to life: transforming childhood, adolescent and rare cancer care”
highlighted the unfortunate consequences of the GDPR on medical research, pointing to issues concerning comparability of the data needed for proper research. The GDPR left a margin of manoeuvre for Member States to further specify the application of the regulation in the area of health and Article 168 the Treaty on the Functioning of the European Union, therefore a fully harmonised approach to the rules on processing of data in the area of healthcare provision, administration or research across the EU has not been achieved. Furthermore, the interpretation of the law is complex for researchers at national level, and patients do not always find it easy to exercise the rights granted by the GDPR. The study has concluded that there is support for actions at EU level to promote health data access and sharing; such measures may include a combination of soft law, e.g. via a code of conduct, with other non-legislative and legislative actions. A code of conduct is considered desirable to explain concepts from the GDPR and to ensure a consistent approach to health data exchange at a more practical level, e.g. defining formats for data exchange. These aspects were detailed further during the BECA hearing of April 2021.369,370

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369 BECA hearing of 15 April 2021: “Cooperation is strength: sharing knowledge and data, improving cross-border care to beat cancer”
370 Summary of the BECA hearing on “Cooperation is strength: sharing knowledge and data, improving cross-border care to beat cancer”
XIII. Notice to Members
“The Union’s legislative competences in policies for fighting cancer”
NOTICE TO MEMBERS

Subject: The Union’s legislative competences in policies for fighting cancer

Parliament’s resolution establishing the BECA Committee calls on the committee to evaluate the possibilities where, in accordance with the TFEU, the EU can take concrete steps to fight cancer and where only recommendations to the Member States and exchange of best practices are possible and focus on the concrete actions.

Further to the decision of the Coordinators, the BECA Committee secretariat, in cooperation with the Policy Department on Economic, Scientific and Quality of Life Policies and the Legal Service, presents this note outlining the Union’s competence to act in matters related to the fight against cancer. It looks into the Treaty legal bases as well as secondary legislation in force or in preparation.

(a) **Analysis of the Treaty legal base, shared and supporting competences**

The direct competences conferred upon the Union in the field of public health are twofold. In some specific aspects, the Treaty on the Functioning of the European Union (TFEU) foresees a shared competence (within the meaning of Art. 2(2) TFEU) while, on other aspects, the Union has a more general supporting competence (within the meaning of Art. 2(5) TFEU).

In essence, “shared” competence means that both the Union and the Member States are entitled to legislate and adopt legally binding acts in the corresponding policy area. However, the Member States may exercise their competence only as far as the Union has not intervened. As far as public health is concerned, shared competence between the Union and the Member States applies in the area of “common safety concerns in public health matters, for the aspects defined in the [TFEU]” (Art. 4(2)(k) TFEU).

In contrast, “supporting” competence means that the Union is entitled carry out actions to support, coordinate or supplement at European level the actions of the Member States in the relevant policy area. It should be reminded that, according to Art. 2(5) TFEU, legally binding acts of the Union adopted in an area of supporting competence may not entail harmonisation of Member States' laws or regulations. Pursuant to Art. 6(a) TFEU, the Union has a supporting competence in the areas of “protection and improvement of human health”.

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The exact scope and content of those direct competences are materialised in Art. 168 TFEU. However, the Union competences in other policy areas, such as e.g. social security or the internal market, may also be used for actions having an impact on public health issues, and in particular as regards the fight against cancer, as is clear from the list of legal acts provided in this note (see below). In this regard, it may be recalled e.g. that, pursuant to Art. 114(3) TFEU, the Union institutions have to take a high level of health protection as a basis when legislating in the field of internal market.

Art. 168(1) TFEU states that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. In doing so, Article 168(1) sets out a general clause, similar to those of Art. 11 TFEU in the field of environment or Art. 10 TFEU in the field of social policy. Such clauses provide guidance for rule-making in all policy areas, but are not themselves legal bases for adopting Union legal acts.

Supporting competences of the Union in the field of public health are dealt with in the second subparagraph of Art. 168(1), in Art. 168(2) and in Art. 168(5). The second subparagraph of Art. 168(1) provides that the Union is to complement national policies in preventing illness and diseases, and obviating sources of danger to health. Such action may cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health. Reducing drugs-related health damage is also specifically mentioned.

Likewise, according to Art. 168(2), the Union is to encourage cooperation between the Member States in the areas referred to in that Article, in particular to improve the complementarity of their health services in cross-border areas. If necessary, the Union may lend support to Member States’ action to that effect. In this regard, Art. 168(2) provides that the Member States are to coordinate their policies and programmes, in liaison with the Commission. The latter may take “any useful initiative” to promote such coordination, inter alia establishing guidelines and indicators, organising exchange of best practice, and preparing the necessary elements for periodic monitoring and evaluation. Parliament must be “fully informed” of any such initiative.

Article 168(5) provides a legal basis for incentive measures designed to protect and improve human health, in particular “[measures] to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol”. As such measures are to be adopted through the ordinary legislative procedure, Parliament enjoys full legislative powers in that regard. However, it should be noted that the incentive measures referred to in Article 168(5) may not amount to any form of harmonisation of national laws and regulations.

By contrast, Art. 168(4) singles out the specific aspects of public health policy where the Union enjoys shared competence. With regard to those aspects, the Union’s intervention is therefore not limited to supporting, coordinating or supplementing the actions of the Member States. Within this framework, Article 168(4) provides a legal basis for adopting the following measures “in order to meet common safety concerns”:

(a) measures setting high standards of quality and safety of organs and substances of human origin (without affecting national provisions on the donation or medical use of organs and blood, which remain within the competence of the Member States);

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;
(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

The above measures are to be adopted through the ordinary legislative procedure, and hence Parliament enjoys full legislative powers in that regard.

Furthermore, Article 168(6) enables the Council to issue recommendations (i.e. non-binding legal acts) in all the fields of Union competence referred to in that Article.

Finally, Article 168(7) makes it clear that any Union intervention in the field of public health must respect the Member States responsibilities in the definition of their health policy and for the organisation and delivery of health services and medical care, including the management of health services and medical care and the allocation of the resources assigned to them.

It is against this background that one should look at the list of legislative acts with an impact on public health, and on the fight against cancer in particular. As is apparent from the list, only a limited number of those acts are adopted under a Union direct competence in the field of public health, i.e. under one of the legal bases contained in Article 168 TFEU. In fact, the majority of the relevant Union legislation, is adopted in other fields of competence, like social security and internal market, but indirectly (albeit not less importantly) achieves public health objectives. This is possible thanks, in particular, to the general clause in art. 168(1) TFEU, which as explained above requires a high level of human health protection to be taken into account in all Union policies, or the more specific clause in Article 114(3) TFEU, whereby a high level of health protection must be taken as a basis when legislating in the field of internal market.

(b) Relevant Treaty articles and secondary legislation

### I. Possible Treaty legal bases for law- and policy-making in the field of cancer

#### I.1 Public health

**I.1.1 Article 168, paragraph 1 of TFEU: Ensuring a high level of human health protection:**

- When defining and implementing EU policies and activities, a high level of human health protection to be ensured.
- EU action complements national policies. The purpose of EU action is to improve public health, prevent physical and mental illness and diseases, and obviate sources of danger to physical and mental health. Actions cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

**I.1.2 Article 168, paragraph 2: Cooperation between Member States**

- EU encourages and supports the cooperation of Member States, in particular to improve the complementarity of their health services in cross-border areas.
- Commission’s initiatives to encourage cooperation include the establishment of guidelines

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371 With the entry into force of the Lisbon Treaty, the Treaty articles were moved and renumbered. Several pieces of legislation, adopted in the pre-Lisbon time, are still applicable, and have their legal base indicated according to the old Treaty numbering. A table of equivalence was drawn up to show the correlation between the old and new numbering. [https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:326:0363:0390:EN:PDF](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:326:0363:0390:EN:PDF)
and indicators, the organisation of exchange of best practices, and the preparation of periodic monitoring and evaluation. This is done in close cooperation with the Member States, and the Parliament is fully informed.

I.1.3 Article 168, paragraphs 4-5: List of public health issues falling under the OLP

- measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;
- measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;
- measures setting high standards of quality and safety for medicinal products and devices for medical use;
- incentive measures to protect and improve human health, and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

I.1.4 Article 168, paragraph 6 of TFEU: Scope of Council recommendations

The Council, based on the Commission’s proposal, may adopt recommendations for the purposes of Article 168.

I.1.5 Article 168, paragraph 7: Respect for the responsibilities of Member States

Member States are responsible for the definition of their health policy and for the organisation and delivery of health services and medical care, including the management of health services and medical care and the allocation of the resources assigned to them. EU action must respect these responsibilities.

I.2 Environment

Article 191, paragraph 1 of TFEU: Environmental policy as contributor to the protection of human health. The contribution to the pursuit of the protection of human health is included into the objectives of EU environmental policy.

I.3 Social policy

Article 153, paragraph 1, point (a) of TFEU: EU to support and complement the action of Member States to improve the working environment to protect workers’ health and safety. OLP applies.

I.4 Internal market

Article 114 of TFEU, paragraphs 1 & 3: OLP applies for the adoption of laws concerning the establishment and functioning of the internal market. If those proposals concern health matters, a high level of protection will be taken as a base.

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372 OLP, the ordinary legislative procedure, set out in Article 294 of TFEU: https://www.europarl.europa.eu/olp/en/ordinary-legislative-procedure/overview
I.5 Overarching principles

- Article 5 of TEU\textsuperscript{373}: conferral of powers to the EU, and the principles of subsidiarity and proportionality;
- Article 4, paragraph 2, point (k) of TFEU\textsuperscript{374}: common safety concerns in health matters are shared competence between the EU and the Member States;
- Article 6, point (a) of TFEU: EU to support, coordinate or supplement the action of Members States at European level in the area of the protection and improvement of human health;
- Article 9 of TFEU: the promotion of a high level of protection of human health is to be taken account when defining and implementing EU policies and activities.

II. Legislation in force and upcoming legislation, concerning or affecting the fight against cancer

II.1 Modifiable risk factors and prevention

II.1.1 Tobacco


  Key points of the legislation are health warnings on the packaging, a ban on flavours and slim packaging, mandatory health warnings on e-cigarette packs, and detailed reports by the manufacturers on the ingredients and advance notification on any new items. Ensuring that tobacco products look and taste like tobacco would help to reduce the number of new smokers, especially amongst the young population; therefore several provisions aim at making tobacco products less appealing and less attractive.

- **Tobacco advertising:** Directive 2003/33/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products\textsuperscript{376} - legal base: Articles 53(2), 62 and 114 TFEU

  Advertising rules cover (i) press and printed publications: advertising shall be limited to publications intended exclusively for professionals in the tobacco trade and to publications which are printed and published in third countries; as well as (ii) radio: all forms of advertising are banned, and programmes may not be sponsored by companies whose main activity is the manufacture and sale of tobacco. Sponsorship is banned for all events and activities involving or taking place in more than one EU country; the ban extends to the free distribution of tobacco products.

  The **Audiovisual Media Services Directive (AMSD)\textsuperscript{377}** complements the directive by banning advertising and product placement of tobacco products on television and through on-

\textsuperscript{373} TEU, Treaty on the European Union: 

\textsuperscript{374} TFEU, Treaty on the Functioning of the European Union: 
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT

\textsuperscript{375} https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02014L0040-20150106

\textsuperscript{376} https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003L0033-20030620

\textsuperscript{377} https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010L0013
demand services. The Tobacco Directive (above) extended the rules on tobacco advertising and promotion to electronic cigarettes.


Increasing taxes on tobacco is one of the most effective ways to reduce tobacco use and to encourage users to quit smoking. The Council Directive requires Member States to levy excise duty on tobacco, and sets the harmonised minimum rates and the structure of the excise duty.


The WHO Framework Convention on Tobacco Control (WHO FCTC) to which the EU and all Member States are parties calls for adopting measures which provides for protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places and, as appropriate, other public places. The Council Recommendation elaborates further on this provision, calling on the Member States to adopt and implement laws to fully protect their citizens from exposure to second-hand smoke, enhance smoke-free laws with supporting measures, and strengthen cooperation at EU level by setting up a network of national focal points for tobacco control.

### II.1.2 Alcohol


Alcohol taxation is the main tool, used by all Member States, to influence alcohol prices to moderate and prevent consumption. Council Directive 92/83/EEC sets out the structures of excise duties on alcohol and alcoholic beverages; the categories of alcohol and alcoholic beverages subject to excise duty; and the basis on which the excise duty is calculated. In 2020 the Council amended its directive by a series of new rules (Council Directive (EU) 2020/1151[^382]), which will be applicable from 1 January 2022. Council Directive 92/84/EEC sets out minimum rates that must applied to each category of alcoholic beverage, and as well as reduced rates for certain Greek, Italian and Portuguese regions. As the legislation only sets harmonised minimum rates, Member States are free to apply excise duty rates above these minima, according to their own national needs.

- **Audiovisual Media Services Directive (AMSD)**: Directive 2010/13/EU on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services[^383]

In the international scene, the WHO Global Alcohol Strategy recommends to regulate the

[^379]: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009H1205%2801%29
[^380]: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A3A32009H1205%2801%29
[^382]: https://eur-lex.europa.eu/eli/dir/2020/1151/oj
content and the volume of alcohol marketing, while its European Action Plan proposes a total ban on alcohol advertising for Europe. At EU-level, the AMSD regulates alcohol advertising on television, and it imposes restrictions for the protection of minors and for promoting moderate, responsible consumption of alcohol.

- **Alcohol labelling**: Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC)\(^{384}\) - legal base: Article 114 TFEU

According to the FIC Regulation, the alcoholic strength by volume is a mandatory element of the label for alcoholic beverages with more than 1.2% alcohol content. However, these alcoholic beverages are exempted from indicating the list of ingredients and the nutrition declaration on the label. The regulation tasked the Commission with monitoring the situation and presenting a report whether these labelling requirements should apply to alcoholic beverages as well.

**II.1.3 Nutrition, diet**


The General Food Law Regulation is the foundation of food and feed law, laying down the general principles governing food and feed in general, and food and feed safety in particular, at EU and national level. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety. It lays down procedures for matters with a direct or indirect impact on food and feed safety; it establishes EFSA, and creates the main procedures and tools for the management of emergencies and crises as well as the Rapid Alert System for Food and Feed (RASFF). The regulation applies to all stages of production, processing and distribution of food and feed.


Particularly relevant from cancer point of view are nitrites (E 249–250) which are needed as a preservative in meat products to control the possible growth of harmful bacteria, in particular Clostridium botulinum, but the use of nitrites in meat may lead to formation of nitrosamines which are carcinogenic substances.

- **Food information to consumers (FIC)**: Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers\(^{387}\) - legal base: Article 114 TFEU


The regulation applies to businesses at all stages of the food chain, and to all foods intended for final consumption. It is the manufacturer marketing the food under his name who is responsible for providing the necessary information, and ensuring its accuracy; if the food manufacturer is based outside the EU, these obligations fall on the importer.

Information such as the food’s name, list of ingredients, net quantity, use by date, instructions for use if necessary, operator's name and address and a nutrition declaration are mandatory. In addition, the actual alcoholic strength must be given for any drinks with more than 1.2% by volume of alcohol; and further information is made mandatory for certain types of food, such as those containing sweeteners, ammonium salt or with a high caffeine count. Certain foods are exempt from the mandatory nutrition declaration (herbs and spices, flavourings and herbal teas); others do not need to provide a list of ingredients (notably fresh fruit and vegetables, carbonated water, vinegars, and dairy items like cheese, butter, cream and fermented milk). Food information has to be accurate, clear and easy for the consumer to understand, and it should not mislead the public by suggesting it possesses special characteristics or effects it does not have.


  The regulation ensures that claims on food such as “low sugar”, “high fibre”, “essential for healthy growth of the children”, etc. are scientifically sound and not misleading. A [publicly accessible register](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1924-20141213) holds all permitted claims and their condition for use.

### II.1.4 Radiation


  The Euratom Community drew up a set of basic safety standards to protect workers, members of the public, and patients against the dangers from ionising radiation. These standards also include emergency procedures, which were further strengthened after the Fukushima nuclear accident. The directive guarantees a uniform threshold level of protection; it applies to any planned, existing, accidental or emergency exposure which might arise. It provides for the publication of maximum radiation doses so that the public can check whether they have received, from various sources, more than the legal limit.


  The directive sets parametric values and frequencies and methods for monitoring radioactive substances.

shipments of radioactive waste and spent fuel

All Member States produce radioactive waste, originated from either facilities like nuclear power plants and research reactors, or though activities like radioisotope applications in medicine, industry, agriculture, research and education. The shipment of radioactive waste and spent fuel, through import, export and transit are common practices in the EU that occur regularly. establishes a system of prior authorisation for such shipments in Europe.


Health and safety hazards stemming from the use of sunbeds, including exposure to UV radiation, are determined by the safety of the sunbed and by the way the consumer (mis)uses the product. The directive covers all risks related to the safety of the sunbeds, it is not limited to electrical safety. The harmonised standard EN 60335-2-27:2013 sets out requirements for the safety of sunbeds, including limits for ultraviolet radiation emission. It is a voluntary standard but when a sunbed complies with the standard, it gives reassurance that it is also conform with the directive.

**II.1.5 Air quality**


*Directive 2008/50/EC* sets objectives for fine particulate matter (PM2.5). Arsenic, cadmium, nickel and some polycyclic aromatic hydrocarbons are human genotoxic carcinogens and that there is no identifiable threshold below which these substances do not pose a risk to human health. In order to minimise harmful effects on human health, the fourth so-called daughter directive, *Directive 2004/107/EC sets the* target values. In addition to the limits set by the EU directives, the WHO Air Quality Guidelines also set recommended limit values.


The directive transposes the 2020 reduction commitments to which the EU and the Member States agreed under the under the UN Convention on Long-range Transboundary Air Pollution (LRTAP Convention) and its *Gothenburg Protocol*; sets national emission reduction commitments for each Member State for the period of 2020-2029; and sets more ambitious targets from 2030 onwards. The pollutants responsible for serious health and environmental damages targeted by the directive are nitrogen oxides (NOx), non-methane volatile organic

393 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008L0050-20150918
compounds (NMVOCs), sulphur dioxide (SO2), ammonia (NH3) and fine particulate matter (PM$_{2.5}$). The directive also requires Member States to draw up National Air Pollution Control Programmes that should contribute to the successful implementation of air quality plans established under the Air Quality Directive.


  IED, Directive 2010/75/EU lays down rules on integrated prevention and control of pollution arising from industrial activities. It also sets rules to prevent/reduce emissions into air, water and land, and to prevent the generation of waste. Substances or mixtures which, because of their content of volatile organic compounds classified as carcinogens, mutagens, or toxic to reproduction, must be replaced, as far as possible by less harmful substances or mixtures within the shortest possible time. MCPD, Directive (EU) 2015/2193 lays down rules to control air emissions of sulphur dioxide (SO2), nitrogen oxides (NOx) and dust (particles) from medium combustion plants, as well as rules to monitor carbon monoxide (CO) emissions from these plants.

**II.1.6 Drinking water**


  The directive lays down the essential quality standards at EU level. The WHO guidelines for drinking water, and the opinion of the Commission's Scientific Advisory Committee are used as the scientific basis for setting the quality standards. The directive requires the regular testing and monitoring of 48 microbiological, chemical and indicator parameters; it establishes a minimum harmonised level of human health protection, allowing Member States to set higher standards or include additional requirements (e.g. regulate additional substances that are relevant within their territory). The recently adopted Directive (EU) 2020/2184 introduces new rules to improve the quality of tap water by tightening the maximum limits for certain pollutants such as lead and harmful bacteria.

- **Nitrate**: Council Directive 91/676/EEC on the protection of waters against pollution caused by nitrates from agricultural sources$^{400}$

  The directive requires Member States to monitor the quality of the waters, and to identify areas that are polluted or at risk of pollution i.e. waters that due to agricultural activities are eutrophic or contain or that could contain a concentration of more than 50 mg/l of nitrates. Member States action programmes under the Nitrates Directive are accessible in the NAPINFO database; implementation is monitored by the Commission.

**II.1.7 Chemicals**

$^{399}$ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020L2184
$^{400}$ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01991L0676-20081211

REACH sets up a comprehensive legal framework for chemicals manufacture and use in Europe. It applies to all chemical substances, i.e. manufactured, imported, sold, used on their own, in mixtures or in products; but radioactive substances, substances under customs supervision, and waste, are not in the scope of REACH as these are regulated extensively under other legislation.

The regulation sets up a central database, where companies register all chemicals which they manufacture or import in quantities of one tonne or more per year. The European Chemicals Agency manages the databases, co-ordinates the in-depth evaluation of suspicious chemicals and builds up a public database in which consumers and professionals can find hazard information.

The responsibility for ensuring that chemicals produced, imported, sold and used in the EU are safe is placed on the industry; companies must identify and manage any risks linked to the substances they manufacture and market in the EU.

The regulation lists the substances whose use could represent a hazard, and therefore placing them on the market require authorisation (Annex XIV). The list includes, among others, carcinogens.


The regulation harmonises the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures; it establishes a list of substances with their harmonised classifications and labelling elements at EU level, including carcinogens.


Biocidal products are used for pest control (except on plants and crops, for which a separate piece of legislation applies) or to protect materials. As their properties can pose risks to humans, animals and the environment, they are regulated thoroughly. First, the active substance used in the product is evaluated at EU-level; if it is found carcinogenic, mutagenic or toxic to reproduction, endocrine disruptors, persistent, bioaccumulative or toxic, it is not approved (unless it is demonstrated that the risk is negligible). Once the active substance is approved, the product itself needs authorisation. The authorisation can be done at EU-level by ECHA, or at national level; in this latter case the product can be marketed in other Member States under mutual recognition.


  The regulation applies to pesticides used for protecting or preserving plants, influencing their growth, and destroying and stunting undesired plants. The **active substance** must not have any harmful effects on human health, or any unacceptable effect on the environment. The **final product** must be effective, have no immediate or delayed harmful effect on human health, no unacceptable effects on plants or the environment and not cause unnecessary suffering or pain to vertebrates.

  The approval of an active substance is done at EU-level, while the authorisation of the final product is at national level. A product authorised in one Member State can be marketed in another one under the mutual recognition procedure.


  The regulation makes cosmetics products sold in the EU safer, by tightening safety requirements. The manufacturers are required to compile a safety report; products can be marketed only when a ‘responsible person’ for the given product is designated, who must ensure the product meets all the relevant safety requirements under the legislation; and serious undesirable effects must be reported. The products are registered only once, with the EU’s Cosmetic Products Notification Portal. Packaging must contain a range of information, including the name and the address of the responsible person, the content, precautions for use and the list of ingredients. The regulation also includes lists of substances which are prohibited or restricted for use in cosmetics, including carcinogens.


  The directive sets out the safety requirements for toys (for use in play by children under 14) that are made available in the EU, and identifies the particular responsibilities of different operators in the supply chain from manufacturer to importer/retailer/distributor.

  It is the responsibility of the manufacturers, given their detailed knowledge of their own product, to ensure that their toys meet all the applicable safety requirements. Importers can place on the market only those toys from outside the EU, which are complying with all the applicable safety requirements. Distributors and retailers must also act with due care, and national authorities perform market surveillance. Furthermore, for toys to be sold in the EU, they must be accompanied by the EC’ declaration of conformity, and bear the CE.

  The directive is updated periodically, generally to set safe limits for chemicals used in toys in particular with regard to children aged under 3 and in toys intended to be placed in the mouth\(^ {407}\).

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of carcinogens)


This Directive sets the framework for the basic health and safety measures in work context, and is the foundation of further, specific legislation. It applies to all sectors of public and private activity, and establishes the general duty of employers to ensure the health and safety of their workforce. Risk assessment and risk management, having an overall safety policy in place, providing appropriate training to staff, appointing someone responsible for the prevention of risks at work are amongst the key provisions.

- **Artificial optical radiation**: Directive 2006/25/EC on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents - artificial optical radiation (19th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)\(^{409}\)

The directive refers to the risk to the health and safety of workers, arising or likely to arise, due to adverse effects caused by exposure to artificial optical radiation to the eyes and to the skin. The directive sets out the exposure value limits. The employer shall assess the levels of exposure to optical radiation to which workers are likely to be exposed; the employer shall then devise and implement an action plan based on technical and/or organisational measures for preventing the exposure exceeding the limit values.

- **Chemical agents**: Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (14th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)\(^{410}\)

This directive applies where hazardous chemical agents are present or may be present at the workplace. It is without prejudice to the provisions for chemical agents to which measures for radiation protection apply pursuant to directives adopted under the Euratom Treaty. For carcinogens at work, the provisions of this directive apply without prejudice to more stringent and/or specific provisions contained in the CMD Directive.

- **Carcinogens and mutagens (CMD)**: Directive 2004/37/EC of the European Parliament and of the Council on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth Individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC - codified version)\(^{411}\) - legal base: point (b) of Article 153(2), in conjunction with point (a) of Article 153(1) TFEU

The directive applies to chemical agents that may cause cancer or are suspected of causing cancer, according to the CLP Regulation; and to the substances, mixtures and processes referred to the annex of the CMD. It sets minimum requirements to eliminate or reduce exposure to carcinogens and mutagens, and establishes occupational exposure limit values. Identifying and assessing exposure-associated risks for workers, and preventing exposure, are the responsibility of the employer. Where technically possible, the process or chemical agent must be substituted with safer alternative; where substitution is not possible, chemical...
carcinogens/mutagens must be used in a closed system, or worker exposure must be reduced, while respecting the occupational exposure values.

The Commission has presented its proposal for the fourth update of the directive (‘CMD4’) (COM(2020)571; 2020/0261(COD)).


  Even though it has not yet been possible to identify the exposure threshold below which asbestos does not involve a cancer risk, occupational exposure of workers to asbestos should be reduced to a minimum. The directive applies to activities in which workers are, or may be, exposed during their work to dust arising from asbestos or materials containing asbestos.


- **Physical agents**: Directive 2013/35/EU of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th Individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) - legal basis Article 153(2) TFEU

  It is a repeal and replacement of Directive 2004/40/EC. That Directive did not address the long-term effects, including the possible carcinogenic effects, of exposure to time-varying electric, magnetic and electromagnetic fields, for which there is currently no conclusive scientific evidence establishing a causal relationship. This present directive addresses all known direct biophysical effects and indirect effects caused by electromagnetic fields, not only to ensure the health and safety of each worker on an individual basis, but also to create a minimum basis of protection for all workers in the Union.


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II.2 Early detection of cancer

- **Cancer screening**: Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC)\(^{420}\)

The recommendation urges the Member States to implement cancer screening programmes for cervical, female breast and colorectal cancer. It deals with registering and managing screening data, monitoring the process and training of personnel. The Commission reports on the implementation of these programmes, encourages cooperation on research and best practice, and helps develop guidelines on cancer screening.

European guidelines have been established on breast (2013), cervical (2007, updated in 2014) and colorectal (2010) cancer\(^{421}\); the Commission published its second implementation report\(^{422}\); and the WHO-IARC published the fourth version of the European Code Against Cancer\(^{423}\).

II.3 Cancer treatment and therapies

II.3.1 Medicines and medical devices


These legal acts lay down the requirements and procedures for marketing authorisation, and the rules for monitoring authorised products; they also include harmonised provisions for the manufacture, wholesale or advertising of medicinal products for human use.

Medicines benefitting from the Union authorisation procedure include those that contain a new active substance indicated for the treatment of, among other diseases, cancer; as well as medicines that are designated as orphan medicinal products.


Several conditions need to be met for a medicine to be designated as an orphan medicinal product:

- (a) the medicine is intended for the diagnosis, prevention or treatment of a life-


threatening or chronically debilitating condition which affects not more than five in
10 thousand persons in the EU, or
(b) intended for the diagnosis, prevention or treatment of a life-threatening, seriously
debilitating or serious and chronic condition and without incentives it is unlikely that
the marketing of the medicinal product in the EU would generate sufficient return to
justify the necessary investment;
   o and (2) there exists no authorised satisfactory method of diagnosis, prevention or
treatment of the condition in question or, if such method exists, the medicinal product
will be of significant benefit to those affected by that condition.

- **Paediatric regulation**: Regulation (EC) No 1901/2006 of the European Parliament and of the
Council on medicinal products for paediatric use\(^{427}\), which lays down rules concerning the
development of medicines to meet the specific therapeutic needs of the paediatric population
(i.e. children from birth until the age of 18), without subjecting them to unnecessary clinical
or other trials.

The regulation established an EU inventory of the therapeutic needs of children to focus the
research, development and authorisation of medicines; an EU network of investigators and
trial centres to carry out research; a system of free scientific advice for the industry; a public
database of paediatric studies; and EU funding to promote research into off-patent medicines
for children. An independent paediatric committee at EMA was also set up.

- **Advanced therapy medicinal products (ATMP regulation)**: Regulation (EC) No
products\(^{428}\) covers the authorisation, supervision and monitoring of new medicines that are
based on gene or somatic-cell therapy and tissue engineering. The legislation protects patients
from scientifically unsound treatments and ensures that ATMPs can be available throughout
the EU.

A Committee for Advanced Therapies (CAT) was created at EMA to give scientific *opinions*
on the quality, safety and efficacy of ATMPs; *authorisation* to market the medicine is given
by the Committee for Medicinal Products for Human Use. Once authorisation is granted, the
item is considered safe for human use throughout Europe.

Traceability of the products and raw materials is key throughout the manufacturing,
distribution and the use of the products. For additional safety, where there is particular cause
for concern, the Commission may request the manufacturer concerned to establish a risk
management system.

on clinical trials on medicinal products for human use\(^{429}\), which provides for common rules
for the conduct of clinical trials, to test the safety and efficacy of medicines under controlled
conditions, in the EU. - legal base: Articles 114 and 168(4)(c) TFEU

The regulation establishes less bureaucratic procedures, as sponsors of clinical trials only need
to submit a single application for approval, and low-risk clinical trials benefit from even less
red tape. The procedure becomes shorter in comparison to the current one, as the timeline to
authorise clinical trials is set at 60 days. The regulation mandates the use of specific expertise


to assess clinical trials involving vulnerable participants (such as those in emergency situations, minors, incapacitated, pregnant and breast-feeding women, older people or those suffering from rare and extremely rare diseases). All trials are subject to scientific and ethical review; and before the trial, participants must give their informed consent. For the sake of transparency, EMA to set up a database containing information on all clinical trials held in the EU, whether successful or not.

The regulation has not become applicable yet, as the EU portal and the EU database, indispensable for the functioning of the regulation, have not been fully functioning and audited yet. Until then, Directive 2001/20/EC remains in force.

- **EDCTP2**: Decision No 556/2014/EU of the European Parliament and of the Council on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme jointly undertaken by several Member States[^430] - legal base: Article 185, and the second paragraph of Article 188 TFEU


HTA reviews the medical, economic, organisational, social and ethical issues related to the use of a new health technology (medicinal products, medical equipment, diagnostic and treatment methods, rehabilitation, and prevention methods), and measures its added value compared to existing ones. EU-level cooperation on HTA already exists via the HTA Network and the EUnetHTA Joint Action. The proposal would bring it to a new level by establishing a support framework and procedures for cooperation, and common rules for the clinical assessment of health technologies.

Parliament in its first reading position emphasised that the HTA Regulation would not affect the pricing and reimbursement of medicines, as it would continue to fall within the exclusive national competence of the Member States. It also underlined that HTA should be used to promote innovations that produce the best results for patients and society in general.


Medical devices are instruments, apparatuses, appliances, software, implants, reagents, materials or other articles intended to be used for specific medical purposes. Such purposes include the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of diseases, and the investigation, replacement or modification of the anatomy or of a physiological or pathological process or state.

The regulation concerns the placing on the market, making available on the market or putting into service of medical devices and accessories for such devices in the Union. It also applies to clinical investigations concerning such medical devices and accessories conducted in the Union.


The regulation concerns the placing on the market, making available on the market or putting into service of *in vitro* diagnostic medical devices and accessories for such devices in the Union. It also applies to performance studies concerning such *in vitro* diagnostic medical devices and accessories conducted in the Union.

Annex VIII on the classification rules classifies devices as “class C” if they are intended to be used in screening, diagnosis, or staging of cancer.

**II.3.2 Free movement of health workers**


Health professions, more precisely nurses, midwives, doctors (basic medical training, general practitioners and specialists), dental practitioners and pharmacists benefit from automatic recognition of professional qualification, on the basis of harmonised minimum training requirements. The system enables cross-border move of health workers.

During the first wave of the coronavirus pandemic in spring 2020, which put national health care systems under enormous pressure, the Commission issued guidance to help the Member States to speed up the recognition of health workers’ professional qualifications, and clarify the rules to allow doctors and nurses in training to practise their profession. The guidance sets out how EU countries can speed up procedures to facilitate the mutual recognition of qualifications in line with the flexibilities provided by the directive.

**II.3.3 Cross-border access to healthcare**


The directive sets out the conditions how a patient of a Member State may travel to another Member State for receiving safe and high-quality medical care, and have the cost reimbursed by his own health insurance scheme. In particular, according to Article 8, treatments under the scope of this directive include those which require the use of highly specialised and cost-intensive medical infrastructure or medical equipment; rare diseases; healthcare that cannot be provided in the Member State of the patient within a time limit which is medically justifiable. These are highlighted examples of treatment that can be relevant for patients in a cross-border context.

**II.4 Overarching aspects**

**II.4.1 EU health programme**

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- **EU4Health**: Regulation (EU) 2021/522 of the European Parliament and of the Council establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027[^38] - legal base: Article 168(5) TFEU

One of the specific objectives of the programme, as stipulated in Article 4, point (a) is “supporting actions for the improvement of the surveillance, diagnosis and treatment of communicable and non-communicable diseases, in particular cancer and paediatric cancer”. Annex I, paragraph 1 gives details about the eligible actions related to cancer. It includes:
- promotion and implementation of the European Code against Cancer, and the revision of the current edition;
- implementation of cancer registries in all Member States;
- cooperation among Member States in support of the creation of a virtual European network of excellence; that will strengthen research on all types of cancer, and advance the collection and exchange of clinical data and the translation of research findings into everyday cancer care and treatment;
- improving the quality of cancer care, including prevention, screening, early diagnosis, monitoring and treatment, supportive and palliative care, in an integrative and patient-centred approach;
- establishment of quality assurance schemes for cancer centres or other centres treating cancer patients;
- establishment of quality assurance schemes for cancer centres and centres treating cancer patients;
- supporting mechanisms for cross-specialty capacity building and continuous education, in particular in the area of cancer care; and
- supporting the quality of life of cancer survivors and caregivers, including provision of psychological support, pain management and health-related aspects of professional reintegration.

### II.4.2 Research programme

- **Horizon Europe**: Regulation of the European Parliament and of the Council establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination; the final text of the regulation will be published after signature by the EP President and the Council Presidency on 28 April 2021.[^39]

The regulation sets out the provisions on research missions. Missions operate as a portfolio of actions to achieve a measurable goal that could not be achieved through individual actions; those include research projects, policy measures or even legislative initiatives. Cancer mission is one the missions.

### II.4.3 E-health and data protection


[^38]: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0522&qid=1618231187236
‘eHealth Network’ is a voluntary network connecting national authorities responsible for eHealth in the context of the Directive on patients’ rights in cross-border healthcare.

- **GDPR:** Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)\(^{441}\) - legal base: Article 16 TFEU

The GDPR strengthens existing rights, provides for new rights and gives citizens more control over their personal data. These include easier access by citizens to their data; a new right to data portability; the ‘right to be forgotten’; and the right to know when their personal data has been hacked. It is a single set of EU-wide rules, streamlining the legislative framework. EU rules apply for non-EU companies when offering services or goods, or monitoring behaviour of individuals within the EU.

The regulation, in its recitals, recognises the necessity and peculiarities of data collection and data processing for scientific research, specifically mentioning cancer registries. On the basis of registries, research results can be enhanced, as they draw on a larger population. Research results obtained through registries provide solid, high-quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy. In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law.

- In Europe’s Beating Cancer Plan the Commission announced that it would submit the legislative proposal on the European Health Data Space to the co-legislators later in 2021. The proposal will be built on three main pillars: (i) a strong system of data governance and rules for data exchange; (ii) data quality; and (iii) strong infrastructure and interoperability.

XIV. Mission Briefing
European Parliament’s Special Committee on Beating Cancer (BECA)

MISSION TO GENEVA AND LYON
2-4 NOVEMBER 2021

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Scene setter

The current 9th legislative period has seen Public Health policy increasingly gaining in prominence on the European Political Agenda.

From the very beginnings in 2019, Members of the European Parliament have demanded that beating cancer should be a priority of the next Commission. In response, President Von der Leyen has instructed Commissioner Kyriakides in her mission letter 442 to put forward an ambitious Europe’s Beating Cancer Plan, which should propose actions to strengthen the EU’s approach at every key stage of the disease: prevention, diagnosis, treatment, life as a cancer survivor and palliative care.

In addition, in early 2020, another urgent Public Health issue started to dominate the European political agenda: the emerging Covid-19 pandemic.

In June 2020, the European Parliament re-emphasised its commitment to addressing cancer by setting up the Beating Cancer (BECA) Committee, which started its work in September 2020 443. Soon afterwards, in October 2020, BECA put forward some initial ideas 444 of what the Beating Cancer plan should encompass.

In her September 2020 State of the Union Address 445, President Von der Leyen announced the political goal of building a genuine European Health Union 446, in which all EU countries prepare and respond together to health crises, medical supplies are available, affordable and innovative, and countries work together to improve prevention, treatment and aftercare for diseases such as cancer.

In February 2021, on the eve of World Cancer Day, the Commission presented its long-awaited Beating Cancer Plan 447. The Plan is structured around four key areas: prevention, early detection, diagnosis and treatment, and improving quality of life. It includes multiple supporting actions, along ten flagship initiatives. In the EU budget €4 billion have been earmarked to address cancer, including from the EU Health programme, Horizon Europe and the Digital Europe programme.

BECA has in the meantime carried out its ambitious programme of hearings and debates. BECA rapporteur Véronique TRILLET-LENOIR presented her draft report 448 in June 2021. BECA is currently debating the over 1500 amendments that have been submitted, and plans to vote on the report on 6 December 2021, with the plenary expected to vote on it in early 2022.

Mission to Geneva and Lyon

While BECA has conducted its meetings and hearings mostly virtually, the present mission is a unique chance to get first-hand information and engage in direct and frank exchange of ideas with key stakeholders at the international level as well as practitioners on the frontline of the fight against cancer, including how Covid-19 has affected the conditions for cancer prevention and care.

The visit to World Health Organisation (WHO) will allow to discuss how the EU's fight against cancer and more broadly, its renewed ambition in the area of Public Health, can best be interlinked with

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the wider international efforts. It will provide an opportunity to discuss longer-term synergies with the WHO’s work, exploring options to ensure that cancer remains high on the political agenda in the long term, and how the European Parliament will best continue to be instrumental in promoting health of European citizen even after the formal conclusion of the work of the BECA committee.

The visit to IARC will help gain insight into the important role of the research community in fighting cancer at all different levels, from the molecular level to the societal level. It will be an opportunity to reinforce the exchange of ideas between the research community and policy makers in the longer term.

The visit to Lyon-area hospitals and cancer institutes will help get a better understanding for the views and concerns of health care professionals active on the ground in the fight against cancer, and researchers, including their efforts to help patients benefit as quickly as possible from advances in medical research.

**European Union and WHO**

Cooperation between the European Commission and WHO goes back to 1972 and is currently based on an exchange of letters from 2001, which sets out general principles, objectives and procedures, including regular Senior Official Meetings.

In 2020, the Commission and the WHO Regional Office for Europe renewed their commitment to working together, in line with the Sustainable Development Goals (SDG), in particular Sustainable Development Goal 3 on health and well-being. This includes cooperation on health security, health systems, non-communicable diseases with a focus on cancer, sustainable food systems and health, health cooperation with non-EU countries.

Cooperation takes place at 3 geographic levels, with the WHO Headquarters in Geneva on issues of global concern, with the WHO Regional Office for Europe (in Copenhagen) and with the WHO Representation Office to the European Union (in Brussels) on European issues, and in countries around the world (country-level cooperation).

The European Centre for Disease Prevention and Control (ECDC) also directly works together with WHO on the political, senior management and technical level on a range of issues, in particular communicable diseases.

The Commission participates as an observer in annual meetings of the WHO Executive Board and the World Health Assembly in Geneva, as well as in the annual meetings of the WHO Regional Committee for Europe. In collaboration with the European External Action Service (EEAS), it works with EU countries to prepare joint statements, and to negotiate texts with other countries. In addition, it participates in the regular consultations that WHO organises, working to ensure consistency between the policies and action of both parties.

Since 2005, the Commission has also supported WHO through project funding provided by the EU public health programme (currently EU4Health 2021-2027).

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449 https://ec.europa.eu/health/international_cooperation/international_organisations_en
452 https://ec.europa.eu/health/funding/eu4health_en
The European Union is currently the third-largest contributor[^53] to WHO, contributing 7.2% to its 2020-21 budget, behind Germany (13.8%) and the Bill and Melinda Gates Foundation (10.5%), and just ahead of the US (7.1%).

In 2003, WHO presented the Framework Convention on Tobacco Control (FCTC)[^44], the first treaty negotiated under the auspices of the World Health Organization, and to which the EU is a signatory.

In 2005, the European Commission was closely involved in negotiations on the International Health Regulations (IHR)[^45] developed under the auspices of the WHO, which define countries’ rights and obligations in handling public health events and emergencies that have the potential to cross borders.

In May 2021, the European Union expressed its support to the WHO process for establishment of a Pandemic Treaty[^46].

The EU and the WHO also work together in the framework of the Global Health Security Initiative (GHSI)[^47], an informal, international partnership among like-minded countries and organizations to strengthen public health preparedness and response globally to threats of chemical, biological, and radiological/nuclear terrorism (CBRN), as well as pandemic influenza.

**NCCPs**

The World Health Organization (WHO) defines a National Cancer Control Programme (NCCP) as “a public health programme designed to reduce cancer incidence and mortality and improve quality of life of cancer patients, through the systematic and equitable implementation of evidence-based strategies for prevention, early detection, diagnosis, treatment and palliation, making the best use of available resources”. The WHO identifies NCCPs as the most appropriate mechanism for exploiting existing knowledge with the potential to save millions of lives.

National Cancer Control Programmes are key elements in cancer control, and their role in national cancer policies of European countries has grown significantly. In 2009 the European Commission called upon all Member States to adopt national cancer plans/strategies by 2013. Based on this recommendation, many countries have decided to take steps and begun to develop their national/ regional cancer documents.

At Member State-level, National Cancer Control Programmes (NCCP) play a key role in the implementation of initiatives to improve cancer patients’ rights. The NCCPs are integrated plans, bringing together all efforts for cancer prevention and care at national level. With sufficient resources, and being conform to European guidelines and good international practices, NCCPs ensure the quality of care. NCCPs should develop patient-centred cancer services, taking into consideration the views and needs of patients and their families. Through access to information about the disease and its treatment and the available cancer care services, good communication with healthcare professionals and shared decision-making, patients are empowered to seek the best available and suitable care. Furthermore, NCCPs should develop a model based on cancer centres, cancer networks or multidisciplinary teams, addressing the entire cancer care continuum through a comprehensive and holistic approach. Sharing of best practices across European cancer healthcare systems, promoting research and innovation and its translation to maximise its impact to improve outcomes, and improving access to new and established cancer care are also key in delivering on patient’s rights.

[^43]: https://open.who.int/2020-21/contributors/contributor
[^44]: https://www.who.int/fctc/text_download/en
[^45]: http://www.who.int/ihr/en/
[^47]: http://ghsi.ca/
Visit of the EU Delegation in Geneva

Programme

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<td>Welcome and setting the scene</td>
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<tr>
<td><strong>08.30 – 08.45</strong></td>
<td><em>Lotte KNUDSEN, Head of the Delegation of the European Union to the United Nations and other international organisations in Geneva</em></td>
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<td></td>
<td><strong>Opening remarks</strong></td>
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<td></td>
<td><em>Bartosz ARŁUKOWICZ, BECA Committee Chair</em></td>
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<tr>
<td><strong>08.45 – 09.25</strong></td>
<td>Exchange of views/open discussion between BECA Members and the Delegation’s health experts:</td>
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<tr>
<td></td>
<td><em>Dr Canice Nolan, Minister Counselor responsible for health and food safety</em></td>
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<td></td>
<td><em>Mr Jérôme Cassiers, First Counselor</em></td>
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<td><em>Ms Corinna Hulnhagen, First Secretary</em></td>
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<td>Refreshments will be offered by the EU Delegation.</td>
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<tr>
<td><strong>09.25 - 09.30</strong></td>
<td>Conclusions and closing</td>
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<td></td>
<td><em>Bartosz ARŁUKOWICZ, BECA Committee Chair</em></td>
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Specific Issues

The EU and WHO can look back at several decades of cooperation relating to a wide range of health policies. Cancer has always been a major focus area of the work of the WHO, and the EU can find in the WHO a valuable partner in its fight against cancer. The Covid19 pandemics has not only propelled global health cooperation to the top of the political agenda, it has also highlighted the strategic partnership between the EU and the WHO during the temporary withdrawal of the US under the Trump presidency. The EU delegation will be able to offer its view on:

- The EU-WHO cooperation in the management of the COVID-19 pandemic, including on aspects such as the impact of the pandemic on non-communicable diseases like cancer
- How the strategic partnership between the EU and WHO could evolve in the future, what role it could play in strengthening the EU’s role as key actor in international cooperation and in attaining the Sustainable Development Goals.
- The role of EU-WHO cooperation in promoting better health worldwide, and the benefits the EU can reap on the international stage from taking leadership here.
- The current efforts of the WHO towards a Pandemics treaty that should serve as a legal framework for a coherent and coordinated response to future epidemics and pandemics, taking into account the continuity of cancer care delivery during health emergencies.
- The delegation will also be able to offer its views on how the issue of fighting cancer can be re-confirmed as key issue on the WHO agenda, and the structures through which the EU and WHO can coordinate their efforts.
# Visit of WHO Headquarters

## Programme

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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td><strong>Wednesday</strong>&lt;br&gt;3rd November&lt;br&gt;10.15 – 10.45</td>
<td>Welcome and setting the scene</td>
<td>Opening remarks (5 min)&lt;br&gt;- Dr Tedros Adhanom GHEBREYESUS, WHO Director-General&lt;br&gt;- Dr Bartosz ARLUKOWICZ, BECA Committee Chair&lt;br&gt;- Supporting remarks (10 min) Hans KLUGE – WHO Regional Director (virtual)&lt;br&gt;- Zsuzsanna JAKAB – WHO Deputy Director-General&lt;br&gt;- Oxana DOMENITI – WHO Representative to the European Union&lt;br&gt;- Strategic discussion&lt;br&gt;- Delegation photograph (5 min)</td>
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<tr>
<td>10.45 – 11.15</td>
<td><strong>Healthier lives</strong> tobacco, alcohol, environmental determinants</td>
<td>Chair: Dr Naoko YAMATO, WHO Assistant Director-General, Universal Health Care / Healthier Populations&lt;br&gt;- WHO strategic initiatives and activities in cancer prevention (5min)&lt;br&gt;- BECA delegation response on EU priorities (5min)&lt;br&gt;- Thematic discussion in directed topics (20min)</td>
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<td>11.15 – 11.25</td>
<td>Coffee break</td>
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<tr>
<td>11.25 – 12.55</td>
<td><strong>Cancer as part of Universal Health Coverage: screening, treatment (including anti-microbial resistance), access to medicines and WHO joint procurement mechanism</strong></td>
<td>Chair: Dr Ren Minghui, WHO Assistant Director-General, Universal Health Coverage / Communicable and Noncommunicable Diseases&lt;br&gt;- Thematic area 1: National cancer control programmes including rare cancers/childhood cancer, service models, digital health/health literacy (40min)&lt;br&gt;- WHO strategic initiatives and activities in cancer control (10min)&lt;br&gt;- BECA delegation response on EU priorities (5min)&lt;br&gt;- Thematic discussion in directed topics (25min)&lt;br&gt;- Thematic area 2: Increasing access to cancer medicines (20min)&lt;br&gt;- WHO strategic initiatives and activities in access to cancer medicines (5min)&lt;br&gt;- BECA delegation response on EU priorities (5min)&lt;br&gt;- Thematic discussion in directed topics (10min)</td>
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<tr>
<td>12.55 - 13.00</td>
<td>Closing remarks</td>
<td>- Dr Bartosz ARLUKOWICZ, BECA Committee Chair&lt;br&gt;- Zsuzsanna JAKAB – WHO Deputy Director-General</td>
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<tr>
<td>13.00 – 13.30</td>
<td><strong>Light lunch offered by WHO</strong> (outside meeting room)</td>
<td><em><strong>No interpretation will be provided during lunch</strong></em></td>
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*Full list of WHO participants:*

**WHO Headquarters**
- Dr Tedros Adhanom GHEBREYESUS – WHO Director-General
- Dr Zsuzsanna JAKAB – WHO Deputy Director-General
- Dr Samira ASMA – WHO Assistant Director-General, Data, Analytics and Delivery
- Prof. Hanan BALKHY – WHO Assistant Director-General, Antimicrobial resistance (to be confirmed)
<table>
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<tr>
<th>WHO Regional Office</th>
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<tr>
<td>Dr Hans KLUGE – WHO Regional Director (virtual)</td>
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<tr>
<td>Dr Carina FERREIRA-BORGES – WHO Acting Director, Division of NCDs (virtual)</td>
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<tr>
<td>Dr Marilyn CORBEX – WHO Senior technical officer, Department of Noncommunicable Disease</td>
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<th>WHO Office at the European Union</th>
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<tbody>
<tr>
<td>Dr Oxana DOMENTI – WHO Representative to the European Union</td>
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<tr>
<td>Patricia Lamas SANCHEZ – WHO External Relations Officer</td>
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<th>International Agency for Research on Cancer (IARC)</th>
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<tr>
<td>Dr Elisabete Weiderpass – Director (virtual)</td>
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**Specific issues**

The introductory session of the meeting with WHO officials will focus on presenting the overall work of WHO on cancer and provide an opportunity to discuss more in general possible synergies between WHO’s work and Europe’s Beating Cancer Plan, and the Member States National Cancer Control Plans (NCCP)[458], as well as the impact of the COVID-19-pandemic on cancer care[459] which has led to a growing cancer backlog[460]. WHO could be asked to explain to what extent it monitors the effects of the COVID-19 pandemic on cancer, and the activities it puts in place to support States in resorbing the cancer backlog. WHO could also provide information about how the creation of a Pandemic Treaty[461] could help ensure the continuity of cancer care delivery during future health emergencies. Further background information about WHO Cancer Programme and the NCCPs can be found in the annex.

The first thematic session will be dedicated to prevention:

- Lifestyle risk factors for cancer (Tobacco, alcohol and nutrition), vaccination and risks of UV exposure;
- Environmental risk factors for cancer, radiation and occupational exposure to carcinogens; Exposure to air pollution, chemicals and pesticides;

It will be chaired by Dr Naoko YAMAMOTO, who leads the WHO efforts in the areas of Universal Health Coverage and Healthier Populations, part of the WHO’s triple billion targets[462]. This is part of WHO’s core mission to promote health, alongside keeping the world safe and serving the vulnerable. Going beyond fighting disease – the aim is to ensure healthy lives and promote well-being for all at all ages. Since early 2021, she is also chair of the United Nations’ new coordination entity, UN Nutrition[463]. In this vein, she has...

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[460] https://www.europeancancer.org/2-standard/143-covid-urgently-address-cancer-backlog
[462] https://portal.who.int/triplebillions/
repeatedly warned that obese people are at a higher risk of cancer such as breast, ovarian, prostate, liver, gallbladder, lung and colon cancers.\(^{464}\)

To ensure a healthy lifestyle, WHO recommends eating lots of fruits and vegetables, reducing fat, sugar and salt intake and exercising\(^{465}\). These recommendations are echoed in the Commission’s Beating Cancer Plan under point 3.4. “Improving health promotion through access to healthy diets and physical activity”\(^{466}\), which addresses a broad range of aspects including combatting childhood obesity, reducing advertising for unhealthy food products, mapping fiscal measures and pricing policies for sweet or alcoholic drinks, a dedicated ‘HealthyLifestyle4All’ campaign promoting sport, physical activity and healthy diets, and initiatives linking sustainable urban mobility and health.

The second thematic session focusing on “Cancer as part of Universal health Care: screening, treatment, access to medicines, anti-microbial resistance” will be chaired by Dr Ren MINGHUI, Assistant Director-General, Universal Health Coverage / Communicable and Non-communicable Diseases. The WHO definition of Universal health Coverage is that “all people have access to the health services they need, when and where they need them, without financial hardship. It includes the full range of essential health services, from health promotion to prevention, treatment, rehabilitation, and palliative care.”\(^{467}\)

This session will explore WHO activities and synergies with Europe’s Beating Cancer Plan on, among others:

- Al in cancer research, cancer care and personalised cancer medicine: more in-depth discussions will also take place at IARC, in the afternoon;
- WHO support and activities in cancer screening;
- Childhood, adolescent and rare cancers research and care:

Equal access to cancer medicines and care: increasing access to cancer medicines is part of the activities of WHO, including several initiatives on joint procurement in this respect; WHO also supports efforts to strengthen health workforce by organizing policy dialogue using WHO cancer workforce optimization tool and to support workforce training;

Under point 10 of its Beating Cancer Plan\(^{468}\), the Commission underlined its “longstanding collaboration with international organisations such as WHO and OECD on health issues including on cancer. This cooperation will continue to be pursued for instance with WHO within the recently agreed framework of collaboration on non-Communicable diseases, which has a key focus on cancer. In addition, the Commission will re-inforce its work with specialised agencies and actors such as WHO’s International Agency for Research on Cancer, or the European Network of Cancer Registries to facilitate collaboration to take action against cancer also beyond the borders of the EU. Furthermore, continued EU support to strengthening health systems in partner countries and advancing universal health coverage including primary health care, directly contributes to improving prevention, detection, treatment and care of cancer.”

\(^{464}\) https://www.globalhealthnow.org/2019-09/lifesaving-power-nutrition
\(^{465}\) https://www.euro.who.int/en/health-topics/disease-prevention/nutrition/a-healthy-lifestyle
\(^{466}\) https://ec.europa.eu/health/sites/default/files/non_communicable_diseases/docs/eu_cancer-plan_en.pdf
\(^{467}\) https://www.who.int/health-topics/universal-health-coverage
The role of IARC in the world-wide fight against cancer

Article 168 TFEU empowers the EU to support, coordinate or supplement the actions of the Member States for the protection and improvement of human health. EU action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning and combating of serious cross-border threats to health. Research and innovation on cancer is a high priority for the EU; however, disparities exist within and between the Member States, which leads to inequalities in outcomes, cancer research and control. Designating cancer as one of the mission areas of Horizon Europe, the next research and innovation funding programme, and putting cancer research high on the agenda of the upcoming Europe’s Beating Cancer Plan will help to address the disparities across the EU.

To accomplish its task, the EU has been and will continue, working in close cooperation with the Member States, the World Health Organisation, the Joint Research Centre and the International Agency for Research on Cancer.

The International Agency for Research on Cancer (IARC)\textsuperscript{469}, established in 1965, is the specialized cancer agency of the World Health Organization. IARC is first and foremost a research organization, providing new knowledge to reduce the global burden of cancer. In addition, it promotes international collaboration in cancer research and provides leadership among the international cancer community. The independence of IARC enables it to provide reliable and authoritative assessments of many facets of cancer information valued by scientists, governments, nongovernmental organizations and the public the world over. About 320 people from some 50 countries are working for IARC at its Lyon headquarters. However, the number of people working with IARC worldwide stretches into the thousands through its wide network of collaborations and partnerships. IARC emphasises support to low and middle income countries where cancer remains an often neglected disease.

IARC coordinates international studies on the causes of human cancer, the mechanisms of carcinogenesis and strategies for cancer prevention.

IARC’s implementation research aims to support national cancer programmes by providing an evidence-based assessment of the factors that influence the successful integration of specific interventions into health-care services and an evaluation of their effectiveness at the population level. IARC has been an active participant in many projects funded under FP7 and Horizon 2020, and its director, Elisabete Weiderpass, is currently involved as member of the cancer mission board of Horizon Europe in defining the strategic priorities of this mission\textsuperscript{470}.

\textsuperscript{469} \url{https://www.iarc.who.int/}
\textsuperscript{470} \url{https://www.iarc.who.int/news-events/iarc-director-dr-elisabete-weiderpass-selected-as-member-of-mission-board-for-cancer/}
Visit of IARC

Programme

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<td>• Dr Elisabete WEIDERPASS, IARC Director</td>
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<td>• Véronique TRILLET-LENOIR, Rapporteur BECA report</td>
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<td>Delegation photograph</td>
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<td>16.40 - 17.00</td>
<td>Presentation about IARC, including the Nouveau Centre project</td>
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<td>• Mr Clement CHAUVET, Strategic Engagement and Resource Mobilization Specialist</td>
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<td>17.00 - 18.45</td>
<td>Short presentations followed by open discussions on:</td>
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<td>Cancer Surveillance and latest data</td>
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<td>• Dr Freddie BAY, Section Head of the Cancer Surveillance Section</td>
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<td>Environmental risk factors</td>
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<td>• Dr Joachim SCHÜZ, Section Head of Environment and Radiation and Acting Head of the Section of Early Detection and Prevention</td>
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<td>Childhood cancers</td>
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<td>• Dr STELIAROVA-FOUCHER, Scientist in the Section of Cancer Information</td>
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<td>• Dr Caroline ESPINA, Scientist in the Section of Environment and Lifestyle Epidemiology</td>
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<td>Screening in Europe</td>
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<td>• Dr A. CARVALHO, Scientist in the section of Early Detection Prevention and Infections</td>
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<td>Social inequalities in Europe</td>
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<td>• Dr S. VACCARELLA, Scientist in the Section of Cancer Surveillance</td>
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<td>Cervical Cancer control modelling in Europe and beyond</td>
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<td>• Dr Iacopo BAUSSANO, Scientist in the Section of Early Detection Prevention and Infections</td>
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<tr>
<td>18.45 - 19.00</td>
<td>Conclusions and closing</td>
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<tr>
<td></td>
<td>• Dr Elisabete WEIDERPASS, IARC Director</td>
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<td></td>
<td>• Véronique TRILLET-LENOIR, Rapporteur BECA report</td>
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<td>• Bartosz ARŁUKOWICZ, BECA Committee Chair</td>
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Specific issues

This meeting will be an opportunity to further deepen the exchange of ideas with four leading IARC experts who already gave presentations to BECA over the last couple of months, and meet additional experts on key topics. IARC, the International Agency on Cancer Research plays a leading role in coordinating the international collaboration in cancer research. The meeting will be an opportunity to discuss synergies between the IARC’s work, Europe’s Beating Cancer Plan, the BECA draft report and the amendments.

471 https://www.iarc.who.int/about-iarc-mission/
Following up from the more than 10 hearings we conducted and the resulting recommendations and observations, we would in particular like to exchange with you on:

- Cancer prevention: Lifestyle risk factors for cancer, particular Tobacco, alcohol and nutrition, including the Nutri-score, vaccination and risks of UV exposure;
- Environmental risk factors for cancer, radiation and occupational exposure to carcinogens; Exposure to air pollution, chemicals and pesticides;
- AI in cancer research, cancer care and personalised cancer medicine;
- Childhood, adolescent and rare cancers research and care;
- Impact of the Covid-19-pandemic on the continuity of cancer care delivery
- Further strengthening dialogue and cooperation between IARC and Parliament on thematic areas, with a view to providing (technical) expertise

IARC director, Dr Elisabete Weiderpass, not only oversees the wide range of collaborative research that IARC engages in, she is also one of the experts on the European Commission’s Mission Board for Cancer, as part of Horizon Europe, the 2021-27 research and innovation Framework Programme of the European Union. In this function, she will provide expert advice on several areas of cancer research, such as early detection and prevention. As such, she will remain a key source of expertise for European Policy makers as the beating Cancer plans rolls out, ensuring that European funds will support cancer research in an optimal way, and at the same time she could play a crucial role in facilitating that insights from cancer research in areas like early detection and prevention will inform the policy making processes in the most efficient way.

In her office, Clement Chauvet, Strategic Engagement and Resource Mobilization Officer, is in charge of mobilisation of donor support for future projects, including the crowdfunding campaign to support the construction of the new IARC headquarter building known as ‘Nouveau Centre’ due to be completed in 2022 in the heart of the Biodistrict in Lyon.

In his presentation to BECA in November 2020, Dr Freddie Bray, leader of the Global Initiative for Cancer Registry Development, discussed the global creation of indicators and databases to improve cancer surveillance, and highlighted the impact of COVID on cancer care. He will be able to provide an update on Cancer Surveillance and how Covid has further exacerbated the problem of the cancer backlog in the last 12 months.

In his presentation to BECA in December 2020, Dr Joachim Schüz, Head Environment and Radiation Section of IARC, explained how environmental and lifestyle factors such as tobacco, obesity, diet, alcohol, infections, radiation, occupation and environment contribute to the cancer risk. He stressed that environmental causes of cancer are particularly challenging to fight because of the delay in environmental changes leading to health changes, the cancer situation today representing chemical exposures from a few decades ago. Together with his coworker Dr Carolina Espina, he will be able to comment on how the European Code Against Cancer can help reduce the cancer risk.

In her February 2021 presentation, Dr Eva Stelianova-Foucher, who leads the childhood cancer team at IARC, had stressed the crucial role of monitoring rare cancers epidemiologically and clinically through population-based cancer registry data and real-world clinical data, and making all available databases interoperable. She pointed out that current GDPR rules sometimes provide barriers to data sharing across...
European states especially for childhood and rare cancers where there are few cases and data sharing would be particularly beneficial for research.

In addition to the experts who were already invited to present at a past BECA meetings, the meeting will be joined by additional experts: **Dr Andre CARVALHO**, Early Detection Prevention and Infections Section, will speak about “Screening in Europe”. **Dr Salvatore VACCARELLA**, Cancer Surveillance Section, will speak about “Social inequalities in Europe”. **Dr Iacopo BAUSSANO**, Early Detection Prevention and Infections Sections, will speak about “Cervical Cancer control modelling in Europe and beyond”

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**Cancer care facilities in the Lyon area**

**Hospices Civils de Lyon (HCL)**[^474] is an organisation that encompasses a total of 14 hospitals mostly in the Lyon area. This includes three predominantly general facilities providing emergency, medical and surgical services in a wide range of disciplines, seven specialist facilities and four geriatric facilities. It has a staff of about 24,000 full-time employees, including 5,000 medical doctors. It is France’s second biggest university hospital (after Paris-based Pitié-Salpêtrière), and is training more than 1,600 medical students per year.

HCL with its 200-year long tradition is at the heart of the healthcare ecosystem of Greater Lyon, one of the major biotechnology and healthcare markets in Europe. As a university hospital centre, research is a key area at HCL. It conducts numerous clinical trials, giving many patients an opportunity to benefit from innovative treatment not yet commercially available.

HCL is particularly active at cutting edge in the following fields:

- Ageing, frailty, neurodegenerative diseases
- Infectious diseases
- Cancer
- Nutrition
- Paediatrics
- Heart, lungs, metabolic disorders
- Transplantation

**HCL’s Cancer Institute** (Institut de cancérologie)[^475] brings together the wide range of cancer-related activities that HCL undertakes at its various sites, including dedicated cancer units as well as units specialised in the treatment of specific organs. This allows it to offer patients a comprehensive offer for all types of cancers and interventions, including rare and complex cancers, with a special attention given to cancers affecting children or the elderly.

**The Centre Leon Berard (CLB)**[^476] is a Lyon-based hospital that is dedicated 100% to cancer care and research. Together with HCL, it operates the **Cancer Research Center of Lyon (CRCL)**[^477]. One of the main goals of the CRCL is to support the development of strong translational research to enable patients to rapidly benefit from breakthroughs in basic research. This bridge from “bench to bedside”, involving clinicians and pathologists of the CLB and HCL and scientific teams of the CRCL, aims to create a continuity between basic research and clinical applications.

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[^474]: https://www.chu-lyon.fr/about-us
[^475]: https://www.chu-lyon.fr/cancer
The **Pediatric Hematology and Oncology Institute (Institut d’Hématologie et d’Oncologie Pédiatrique de Lyon – IHOPE)**\(^{478}\) is a specialized centre managed jointly by the HCL and CLB. It provides care for children and adolescents with cancers (solid tumours and hemopathies) and benign hematology, and serves as a reference centre for pediatric cancers.

The **Cancéropôle Lyon-Auvergne-Rhône-Alpes (CLARA)**\(^{479}\) encourages and supports cancer research in the Auvergne-Rhône-Alpes region, bringing together academic researchers, clinicians and entrepreneurs. In the context of the French National Cancer Plans\(^{480}\) since 2003, CLARA contributes to the regional, national and international effort against cancer. Its objective is the rapid transfer of scientific discoveries to clinical patient care as well as the economic valuation of research. Its activities include research in human and social sciences and public health, placing the patient at the heart of research. Its mission includes:

- strengthening the mobilization of research teams in the fight against social inequalities,
- boosting clinical research,
- promoting innovative projects,
- facilitating cooperation at European level,
- helping make France an international benchmark in cancer research.

It aims to generate synergies between biomedical innovations, technological innovations as well as social innovations in the area of prevention.

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**Visit of Hospices Civils de Lyon (HCL)**

**Programme**

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<td>- Patrick DENIEL, Secretary General Hospices Civils de Lyon</td>
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<td>- Bartosz ARŁUKOWICZ, BECA Committee Chair</td>
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<td></td>
<td>- Véronique TRILLET-LENOIR, Rapporteur BECA report</td>
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<tr>
<td>09.15 - 09.40</td>
<td>Strategic proposals for the HCL Institute of Cancerology, impact of the Covid-19 pandemic on cancer care</td>
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<td>- Prof. Gilles FREYER, Medical Director of the Cancerology Institute in HCL</td>
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<td>09.40 - 10.35</td>
<td>Care and research pathways: innovative coordination mechanisms</td>
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<td>Short presentations followed by an open discussion on:</td>
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<td>4. IMMUCARE, management of complications of immunotherapy</td>
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<td>- Prof. Stéphane DALLE</td>
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<td>5. ONCORAL, national experiment ONCOLINK, ambulatory follow-up of patients undergoing oral chemotherapy</td>
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<td>- Prof. Catherine RIUFOL</td>
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<td>6. JUMP and PULSIO, graduated organisation of treatment after-effects and accessibility to support care</td>
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<td>- Prof. Cyrrille CONFAVREUX/Prof. Sophie JACQUIN-COURTOIS / Prof. Elise PERCEAU</td>
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<td>10.35 - 11.15</td>
<td>Vulnerable populations. Short presentations followed by an open discussion on:</td>
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<td>1. Structuring care and research pathways in geriatric oncology</td>
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</tbody>
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\(^{479}\) [https://www.canceropole-clara.com/](https://www.canceropole-clara.com/)

### Specific issues

Patient empowerment is a strong objective of the EBCP, and is further strengthened by the rapporteur in the draft report, as well as in a number of amendments, to emphasise this aspect, throughout the whole cancer treatment pathway, and even after.

This meeting be a chance for the delegation to get a first-hand impression of the conditions under which the daily battle against cancer takes place in one of leading hospitals in France, with a focus on the patients themselves. It will also be a chance to better understand the impact of actions at EU level on the daily work in the field of cancer treatment, and what expectations such practitioners would have for future EU actions.

The meeting will touch in particular upon:

- The structure and organization of care for cancer patients,
- Coordination of the patient’s journey, including follow-up,
- Cancers of vulnerable people: paediatric cancers, cancers of the elderly,
- Applied research,
- Impact of COVID-19 on cancer care.

**Mr Patrick Déniel,** Secretary General of HCL, the second-highest representative of HCL will be able to welcome the delegation and give a brief overview over the mission of HCL, one of the leading hospitals in France in with a staff of 24.000 (including 5000 medical doctors) and an annual turnover of 1.7 b€. While HCL is one of the main cancer treatment centers in the Auvergne-Rhône-Alpes region, the greatest challenge over the last year was undoubtedly adapting to the new situation created by the Covid-19 pandemic. He will be joined by three of the key staff members of HCL in the field of cancer research and treatment:

**Professor Charles Dumontet** is deputy director of the **Cancer Research Center of Lyon (CRCL)**[^1], a unit operated jointly by HCL and the Centre Leon Berard (CLB)[^2]; a Lyon-based hospital that is dedicated 100% to cancer care and research. One of the main goals of the CRCL is to support the development of strong translational research to enable patients to rapidly benefit from breakthroughs in basic research.


<table>
<thead>
<tr>
<th>11.15 - 12.15</th>
<th>Lyon synergies in the field of research. Short presentations followed by an open discussion on:</th>
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| 11.15 - 12.15 | 3. **The Lyon Cancer Research Centre (CRCL)**
|               | - **Prof. Charles DUMONTET**, Deputy Director of the CRCL                                    |
| 12.15 - 12.30 | 4. **How can a large university hospital organise itself to develop multidisciplinary collaborative clinical research projects in oncology?**
|               | - **Prof. Benoit YOU**                                                                         |

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<th>12.15 - 12.30</th>
<th>Conclusions and closing</th>
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<td>12.15 - 12.30</td>
<td>- <strong>Patrick DÉNIEL</strong>, Secretary General Hospices Civils de Lyon</td>
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<td>- Bartosz ARŁUKOWICZ, BECA Committee Chair</td>
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Visits of Centres and Institutions

1. Presentation of Cancerople CLARA
   - Network
   - Missions
   - Structure
   - Key actions and success stories
   - International outreach
2. CLARA strategic vision 2023-2027
   - 5 strategic research areas
   - Integration within health/cancer plans at territorial level
   - Relevance to national and European strategies
3. The canceropole model: contribution to Europe’s cancer plan

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483 https://www.chu-lyon.fr/institut-de-cancerologie
484 https://www.centreleonberard.fr/en/our-institution/our-organization
485 https://www.ihope.fr/who-we-are/our-institute/?lang=en
**Specific issues**

This meeting will be a chance to learn more about the work of **CLARA** and the role it plays bringing together academic researchers, clinicians and entrepreneurs in the Auvergne-Rhône-Alpes region. It is one of seven “canceropoles” in France, set up in the context of France’s National Cancers Plans since 2003. Its objective is the rapid transfer of scientific discoveries to clinical patient care as well as the economic valuation of research. Its activities include research in human and social sciences and public health, placing the patient at the heart of research. Its mission includes:

- strengthening the mobilization of research teams in the fight against social inequalities,
- boosting clinical research,
- promoting innovative projects,
- facilitating cooperation at European level,
- helping make France an international benchmark in cancer research.

Since early 2020 CLARA is being led by its director **Pierre Hainaut** who succeeded Veronique Trillet-Lenoir elected to the European Parliament in 2019. Before joining CLARA, Pierre Hainaut worked at IARC as well as the University of Grenoble. His scientific work focusses on the mutagenic effects of tobacco and the cancer gene TP53.

The visit will include three presentations:

- Presentation of Canceropôle CLARA: its Network, Missions, Structure, Key actions and success stories, and international outreach
- CLARA’s strategic vision 2023-2027: its 5 strategic research areas, integration within health/cancer plans at territorial level, and relevance to national and European strategies
- The canceropole model, and their contribution to Europe’s cancer plan

This exchange of views could focus on:

- mapping of cancer needs and the role of cancer registries in the context of the National Cancer Control Programmes
- collaboration between cancer institutes and cancer excellence centres, within and between Member States
- better integration of territorial entities in the implementation of Europe’s Beating Cancer Plan, namely via NCCPs

In this context, the BECA draft report welcomes the Commission’s announcement in its Beating Cancer Plan to establish a “Cancer Inequalities Register” in 2021, which should make it possible to identify disparities in screening, treatment and survival rates between and within the 27 member states.

The BECA draft report also proposes the establishment of a “virtual European Cancer Institute”, a body that would bring together representatives of national cancer programmes, patients’ and carers’

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487 [https://www.canceropole-clara.com/](https://www.canceropole-clara.com/)
associations, and which would be tasked with coordinating national programmes, launching prevention campaigns and exchanging data and best practices.
WHO Cancer Programme
October 2021

Under the Department of Noncommunicable Diseases (NCDs) and Division of Universal Health Coverage (CD/NCD), WHO cancer programme works toward improve cancer control globally in line with its mandate from World Health Assembly resolutions 70.12 (2017) and as part of the WHO Global Action Plan for the Prevention and Control of NCDs (2013).

Objective: to improve access to quality cancer care as part of universal health coverage (UHC). Pertaining to increased access to cancer care and as measured by effective coverage, the objective is to ensure at least 100 million additional people have increased access (as measured by total populations living in countries where cancer services are being scaled-up) or at least 600,000 cancer patients by 2025.

Outcome 1. To improve access to quality essential health services through WHO NCD signature solutions in cancer, by implementing signature solutions in 70 countries by 2024 and by facilitating implementation networks. To date, WHO cancer programme has implemented its integrated cancer signature solutions in >50 countries.

Outcome 2. To increase the number of governments including cancer in their UHC/national benefit package schemes and supporting new policies and/or legislation in four countries. In 2021, five additional countries have adapted their UHC packages to include cancer and/or to introduce new legislation related to cancer care including survivorship care.

Outcome 3. To improve access to essential medicines, diagnostics and devices with a focus on childhood cancer medicines and radiotherapy products. WHO is planning to launch the Global Platform for childhood cancer medicines with St Jude Children’s Research Hospital in 2022 to provide free medicines to children with cancer in low- and middle-income countries with already $50 million committed to finance.

Technical support and country impact

- **imPACT Review**, coordinated by WHO, IAEA and IARC planned in at least six countries in 2022;
- Scale-up **WHO Global Initiative for Childhood Cancer** (GICC) that is being implemented in 40 countries including through GICC regional networks (as developed in three WHO Regions);
- **Women’s cancers**: Strengthen support for cervical cancer as part of WHO Global strategy to accelerate the elimination of cervical cancer; increase breast cancer technical support as part of WHO Global Breast Cancer Initiative in five countries;
- Utilize **WHO tools** to support countries in cancer control planning and costing including generation of investment cases including support for COVID-19 response and policy-dialogue;
- Strengthen health workforce by organizing policy dialogue using **WHO cancer workforce optimization tool** and to support workforce training;

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490 WHO Signature Solutions in NCDs (https://www.who.int/docs/default-source/ncds/ncd-department/ncds-2020-strategic-planner.pdf?sfvrsn=d1456c59_4) are flagship programmes of WHO Department of NCDs that have or are developing technical packages and implementations activities with crosscutting value in strengthening health systems for NCDs and other programmes (e.g., cancer prevention, child health, women’s cancers).

491 Implementation networks: WHO cancer team has developed implementation networks of more than 200 global non-state actors and has facilitated a dialogue through WHO Knowledge Action Portal (community of practice)
• Support dissemination of WHO global goods in cancer including publications on standards of cancer care, cancer centres, survivorship care, research and innovation in line with WHO 2020 Report on Cancer.

Leadership and partnership

WHO has an established network of more than 200 implementing partners, oriented around its three initiatives. In 2022, a Global Partner Forum in Cancer to convene key partners and stakeholders around a global and regional agenda in cancer control. Regional networks of cancer centres are being developed to support implementation of cancer programmes and to facilitate knowledge exchange between countries with similar health systems and capacity.

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XV. Topical Digests
1. Topical Digest September 2020

Parliament’s research capacities within the Directorates-General for Parliamentary Research Services (EPRS), Internal Policies (IPOL) and External Policies (EXPO) supported the work of the Special Committee on Beating Cancer (BECA) and its Members. This selection of publications and online resources had been prepared for BECA’s constituent meeting on 30 September 2020.
September 2020

Parliament’s research capacities within the Directorates-General for Parliamentary Research Services (EPRS), Internal Policies (IPOL) and External Policies (EXPO) stand ready to support the work of the new Special Committee on Beating Cancer (BECA) and its Members. This selection of publications and online resources has been prepared for BECA’s constituent meeting.

Strengthening Europe in the fight against cancer
Study coordinated by Zsuzsanna Laky and Christian Kurrer, June 2020
This study provides an overview of the current state-of-play in Europe in respect of the fight against cancer. It focuses in particular on four main areas: causation of cancer; cancer screening and early diagnosis; access to cancer treatment, care and research; and rare and childhood cancers. It provides key findings and recommendations in each of these areas.

Europe’s Beating Cancer plan: Launch of an EU-wide debate - EN - DE - FR - PL
‘At a glance’ note by Nicole Scholz, February 2020
This note provides initial elements of the Commission’s Europe’s Beating Cancer plan and summarises how Parliament has supported cancer-related policies in previous parliamentary terms.

A pharmaceutical strategy for Europe: First steps
‘At a glance’ note by Nicole Scholz, June 2020
On 1 June 2020, the European Commission published a roadmap for a pharmaceutical strategy for Europe. The strategy will have the overall goal of ensuring Europe’s supply of safe and affordable medicines and supporting the European pharmaceutical industry’s innovation efforts. Two consultations (on the roadmap and the strategy, respectively), are currently under way. Adoption of the strategy is envisaged in the fourth quarter of 2020.

Cancer prevention: Modifiable risk factors
Briefing by Zsuzsanna Laky, April 2020
This briefing summarises the presentations that were delivered by experts who participated in the workshop on cancer prevention, focussing on modifiable risk factors, in February 2020. The presentations included an overview of current knowledge and main challenges and dealt with prevention in practice (focusing on digestive cancers), eliminating HPV-caused cancers as a public health problem, and understanding modifiable risk factors in paediatric oncology.

Treatment optimisation in drug development
Study coordinated by Gianluca Quaglio, March 2020
In this qualitative research study, semi-structured interviews were performed with 26 experts across five stakeholder groups and 10 different EU Member States. The results offer an overview of the concept of treatment optimisation, including in relation to anti-cancer medicines.

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Supporting Analyses for Committees europarl.europa.eu/supporting-analyses
Limits on exposure to carcinogens and mutagens at work
Limits on exposure to carcinogens and mutagens at work: Second proposal
Limits on exposure to carcinogens and mutagens at work: Third proposal

*EU Legislation in progress briefings by Nicole Scholz, 2018 and 2019*

The European Commission proposed to amend Directive 2004/37/EC in three steps, expanding its scope by including and/or revising occupational exposure limit values for a number of cancer- or mutation-causing substances. The first proposal covered 13 priority chemical agents, and the corresponding Directive (EU) 2017/2398 had to be transposed into national law by 17 January 2020. The second proposal covered a further seven chemical agents, and corresponding Directive (EU) 2019/130 entered into force on 20 February 2019 and is to be transposed into national law by 20 February 2021 at the latest. The third proposal addressed an additional five substances. The corresponding Directive (EU) 2019/983 entered into force on 10 July 2019 and is to be transposed into national law within two years, by 11 July 2021.

Mobile phones and health: Where do we stand? - EN - FR
*Briefing by Nicole Scholz, March 2019*

There is a vast body of research on the possibility of a link between mobile phone radiation and health problems, including on the potential risk of cancer. This Briefing provides an overview of the research landscape, major studies on the health effects of mobile phones and conclusions of international and European expert bodies.

**What if manmade biological organisms could help treat cancer?**
*‘At a glance’ note by Mihalis Kritikos, September 2017*

Synthetic biology is expected to begin to design, construct and develop artificial (i.e. manmade) biological systems that mimic or even go beyond naturally occurring biological systems. Applications of synthetic biology in the healthcare domain hold great promise, but also raise a number of questions. What are the benefits and challenges of this emerging field? What ethical and social issues arise from this engineering approach to biology?

Further reading
*Chernobyl 30 years on: Environmental and health effects*, Briefing by Didier Bourguignon and Nicole Scholz, April 2016
*Can processed and red meat cause cancer? The World Health Organization’s classification raises concerns*, 'At a glance’ note by Nicole Scholz, October 2015

Further online resources
What Europe does for me: [Cancer patients, Protecting workers from cancer-causing chemicals, Protecting workers from carcinogenic chemicals](#)

European Science-Media Hub (ESMH): [Misinformation in science: how false medical news on social media mis-educates our society, EU project: CLARIFY, EU project: MAMMO1](#)

Upcoming publications

**What if human cells could be regenerated to renew our bodies?**
*‘At a glance’ note by Gianluca Quaglio, September/October 2020*

**Health impact of 5G**
Study coordinated by Gianluca Quaglio, October/November 2020

Or by scanning the QR code
2. Topical Digest September 2021

A selection of publications and online resources prepared by Parliament’s research capacities within the Directorates-General for Parliamentary Research Services (EPRS), Internal Policies (IPOL) and External Policies (EXPO) for the Interparliamentary Committee Meeting 'Turning the Tide on Cancer' on 27 September 2021.
Parliament’s research capacities within the Directorates-General for Parliamentary Research Services (EPRS), Internal Policies (IPOL) and External Policies (EXPO) stand ready to support the work of the Special Committee on Beating Cancer (BECA) and its Members. This selection of publications and online resources has been prepared for the Interparliamentary Committee Meeting ‘Turning the Tide on Cancer’.

**Europe’s Beating Cancer plan: Quick overview and initial reactions**
*Briefing by Nicole Scholz, March 2021*
On 3 February 2021, the European Commission presented Europe's Beating Cancer plan, slightly delayed on account of the pandemic. The plan is a key EU public health initiative and a cornerstone of the European health union process launched in November 2020. Responsibility for health lies primarily with the governments of the individual EU Member States. Europe's Beating Cancer plan sets out actions to support, coordinate or supplement Member States’ efforts at every stage of the disease: from prevention, early detection, diagnosis and treatment, to an improved quality of life for cancer patients and survivors. Cross-cutting themes include research and innovation, digital and personalised medicine, and action to reduce cancer inequalities across the EU. A particular focus will be on childhood cancers. The plan consists of 10 flagship initiatives and 32 supporting actions, to be rolled out over the coming years. Implementation will be monitored by means of a roadmap and progress indicators, and the Commission will establish an EU cancer plan implementation group. With a €4 billion budget, the plan will make use of all available funding instruments, including the new EU4Health programme, Horizon Europe, and the Digital Europe programme.

**Limits on exposure to carcinogens and mutagens at work: Fourth proposal**
*Briefing by Nicole Scholz, March 2021*
The European Commission has proposed to amend Directive 2004/37/EC, by expanding its scope and by including and/or revising occupational exposure limit values for a number of cancer- or mutation-causing chemical agents. The initiative is proceeding in steps and has now become a continuous process. Following on from three previous legislative amendments, which covered a total of 26 priority chemical agents, the present (fourth) proposal addresses an additional three. The proposal was announced as one of the first measures of the Commission's commitment to fight cancer under Europe's Beating Cancer Plan. Broad discussions with scientists and social partners fed into all four proposals. The Commission’s feedback period on the proposal ran until November 2020. While broadly welcoming the proposal, professional organisations, trade unions and patient groups would like carcinogenic and mutagenic hazardous medicines as well as substances toxic to reproduction to be brought within the scope of the current proposal. Parliament’s Committee on Employment and Social Affairs (EMPL) is in charge of the file. The rapporteur’s draft report was considered in the EMPL meeting on 27 January 2021 and adopted on 25 March 2021. The Council agreed its position on 25 November 2020. Second edition. The ‘EU Legislation in Progress’ briefings are updated at key stages throughout the legislative procedure.

**Protecting workers from asbestos**
*In-depth analysis by Klaus Müller, March 2021*
Asbestos is responsible for more than half of the deaths from occupational cancer in the world. Since 2005 asbestos is banned in Europe. The risks remain, because of the maintenance or demolition work on older buildings and their renovation (increasing energy efficiency) result in substantial exposure to asbestos and many people still work and live in asbestos contaminated buildings.
Europe's Beating Cancer plan - Pre-legislative synthesis of national, regional and local positions on the European Commission proposal

Briefing by Nicole Scholz and Klemen Zumer, November 2020

This briefing forms part of an EPRS series offering syntheses of the pre-legislative state of play and consultation on key European Commission priorities during the current five-year term. It summarises the state of affairs in the relevant policy field, examines how the existing policy is working on the ground, and, where possible, identifies best practice and ideas for the future on the part of governmental organisations at all levels of European system of multilevel governance. EPRS analysis of the positions of partner organisations at European, national, regional and local levels suggests that they would like the following main considerations to be reflected in discussion of the forthcoming Europe's Beating Cancer plan: * Submissions from all four levels of governance highlight the EU's key role in prevention, including as regards cancer-causing environmental factors and tobacco consumption. Input obtained refers to the active role Europe's local and regional actors can play in putting prevention into practice. * European and national levels point to predictive diagnostic tools and novel approaches in cancer medicine. Regional actors advocate for closer cooperation between primary care and hospital care in early diagnosis. Both the regional and local levels would like the EU to help improve screening. * Equitable access to cancer care is featured across all levels. National input raises the issue of availability and affordability of medicines. The local level underscores the merits of ambulatory care, and sees a role for the EU in the creation of local coordination platforms for doctors and patients. * The European level addresses cancer after-care in the local community and cancer survivorship and rehabilitation. Both the regional and local levels recommend fostering personalised care and follow-up for cancer patients. * European and national input stresses the importance of EU-wide cancer research cooperation, information sharing and better deployment of (big) data. Attention is drawn to improving information, communication, education and awareness-raising for both the wider public and healthcare professionals, with regional input encouraging the development of new technologies to ease doctor-patient communication. * All levels would like Europe's Beating Cancer plan to address health inequalities in cancer. EU-level action is considered key to help reduce socioeconomic and geographical disparities, and tackle differences in cancer prevalence and survival rates. A 'health in all policies' approach is supported.

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Cancer prevention: Modifiable risk factors

Briefing by Zsuzsanna Laky, April 2020

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Supporting Analyses for Committees  europarl.europa.eu/supporting-analyses
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In this qualitative research study, semi-structured interviews were performed with 26 experts across five stakeholder groups and 10 different EU Member States. The results offer an overview of the concept of treatment optimisation, including in relation to anti-cancer medicines.

**Effects of 5G wireless communication on human health**
*Briefing by Miroslava Karaboytcheva, February 2020*

The fifth generation of telecommunications technologies, 5G, is fundamental to achieving a European gigabit society by 2025. The aim to cover all urban areas, railways and major roads with uninterrupted fifth generation wireless communication can only be achieved by creating a very dense network of antennas and transmitters. In other words, the number of higher frequency base stations and other devices will increase significantly. This raises the question as to whether there is a negative impact on human health and environment from higher frequencies and billions of additional connections, which, according to research, will mean constant exposure for the whole population, including children. Whereas researchers generally consider such radio waves not to constitute a threat to the population, research to date has not addressed the constant exposure that 5G would introduce. Accordingly, a section of the scientific community considers that more research on the potential negative biological effects of electromagnetic fields (EMF) and 5G is needed, notably on the incidence of some serious human diseases. A further consideration is the need to bring together researchers from different disciplines, in particular medicine and physics or engineering, to conduct further research into the effects of 5G. The EU’s current provisions on exposure to wireless signals, the Council Recommendation on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz), is now 20 years old, and thus does not take the specific technical characteristics of 5G into account.

**Endocrine disruptors: An overview of latest developments at European level in the context of plant protection products**
*Study by Alina Dinu, April 2019*

Endocrine disruptors (EDs) are chemical substances present in many products of daily life, which interact with the hormonal system and can disrupt its proper functioning. There is a growing interest in understanding EDs and progress has been made on both the scientific and regulatory side, but the topic remains of high concern at decision-making and societal levels because of the challenges it still poses. This paper provides a desk-research based overview of the key moments of the (scientific and regulatory) debate on EDs, with a focus on the latest developments at European level, namely Commission Regulation (EU) 2018/605 and the 2018 Commission communication ‘Towards a comprehensive European Union framework on endocrine disruptors’, in the particular context of plant protection products (PPPs).

**The benefit of EU action in health policy: The record to date**
*Study by Niombo Lomba, March 2019*

European health policy measures taken to date are highly beneficial to and relevant for European citizens, economies and the Member States. The EU does acquit its responsibility and utilises its capacity to act on behalf of EU citizens in this policy area. The study concludes that EU health policy clearly achieves added value.

**Mobile phones and health: Where do we stand? - EN - FR**
There is a vast body of research on the possibility of a link between mobile phone radiation and health problems, including on the potential risk of cancer. This Briefing provides an overview of the research landscape, major studies on the health effects of mobile phones and conclusions of international and European expert bodies.

**Limits on exposure to carcinogens and mutagens at work**

**Limits on exposure to carcinogens and mutagens at work: Second proposal**

**EU Legislation in progress briefings by Nicole Scholz, 2018 and 2019**

The European Commission proposed to amend Directive 2004/37/EC in three steps, expanding its scope by including and/or revising occupational exposure limit values for a number of cancer - or mutation-causing substances. The first proposal covered 13 priority chemical agents, and the corresponding Directive (EU) 2017/2398 had to be transposed into national law by 17 January 2020. The second proposal covered a further seven chemical agents, and corresponding Directive (EU) 2019/130 entered into force on 20 February 2019 and is to be transposed into national law by 20 February 2021 at the latest. The third proposal addressed an additional five substances. The corresponding Directive (EU) 2019/983 entered into force on 10 July 2019 and is to be transposed into national law within two years, by 11 July 2021.

**What if manmade biological organisms could help treat cancer?**

‘At a glance’ note by Mihalis Kritikos, September 2017

Synthetic biology is expected to begin to design, construct and develop artificial (i.e. manmade) biological systems that mimic or even go beyond naturally occurring biological systems. Applications of synthetic biology in the healthcare domain hold great promise, but also raise a number of questions. What are the benefits and challenges of this emerging field? What ethical and social issues arise from this engineering approach to biology?

**Further reading**

**Chernobyl 30 years on: Environmental and health effects,**

Briefing by Didier Bourguignon and Nicole Scholz, April 2016

**Can processed and red meat cause cancer? The World Health Organization’s classification raises concerns,**

‘At a glance’ note by Nicole Scholz, October 2015

**Multimedia products**

**Tailoring medicine to patient needs**

EPRS in-focus video, July 2021

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Further online resources
What Europe does for me: Cancer patients, Protecting workers from cancer-causing chemicals, Protecting workers from carcinogenic chemicals

European Science-Media Hub (ESMH): Misinformation in science: how false medical news on social media mis-educates our society, EU project: CLARIFY, EU project: MAMMO1

You can access this Topical Digest at http://www.europarl.europa.eu/EPRS/TD_BECA_2021_final.pdf Or by scanning the QR code
PART 4
PRESS AND COMMUNICATION
XVI. Newsletters
NEWSLETTER: July 2021

Dear [Name],

We hope this message finds you well and continuing to engage in behavioral change to reduce your risk of cancer. In this issue of BECA News, we will be discussing the findings of the European Commission’s report on theır impact on cancer prevention and control. The report highlights the importance of integrating behavioral change into cancer prevention programs and outlines specific strategies to promote healthy lifestyles and reduce the risk of cancer.

The report also emphasizes the need for continued investment in research and development of new cancer prevention and control strategies. It calls for a multilevel approach, including individual-level interventions, community-level initiatives, and policy-level actions, to address the complex etiology of cancer.

We encourage you to read the full report and share it with your colleagues and stakeholders to raise awareness about the importance of behavioral change in cancer prevention.

Thank you for your continued support in promoting healthy lifestyles and reducing the burden of cancer. We look forward to hearing your feedback and suggestions for future issues.

Sincerely,
[Your Name]
XVII. Press releases
MEPs call for stronger EU action against cancer
09-12-2021
Parliament’s Special Committee on Beating Cancer adopted its final proposals on how to strengthen the EU’s role in the fight against cancer.

EP calls for action: strengthening Europe in the fight against cancer
09-12-2021
On 9 December 2021, Parliament’s Special Committee on Beating Cancer adopted its final proposals on how to strengthen the EU’s role in the fight against cancer.

Beating Cancer MEPs build strong international partnerships to deliver on EU Cancer Plan
05-11-2021
During a two-day mission to WHO, IARC and other cancer excellence centres, a delegation of the Special Committee on Beating Cancer called for coordinated efforts in the fight against cancer.

COVID-19 lessons learned: impact of the pandemic on cancer care
10-05-2021
The findings and recommendations of the BECA survey reveal important lessons on how to make EU health systems more resilient in order to ensure continuity of cancer care at all times.

Beating cancer: MEPs react to the EU Plan for joint action
04-02-2021
On the eve of World Cancer Day, Parliament’s Special Committee on Beating Cancer (BECA) backs EU wide effort to beat cancer.

Parliament’s contribution to Europe’s Beating Cancer Plan: a holistic approach
27-10-2020
In an exchange of views with health Commissioner Stella Kyriakides, MEPs presented their input and priorities for Europe’s future Beating Cancer Plan.
XVIII. Parlamentarium
Parlamentarium visitors can become acquainted with the activities of the Special Committee on Beating Cancer (BECA) as they reach the Topics media station, a recent addition to the permanent exhibition featuring Parliament’s policy priorities. These include a section devoted to health, where all details related to the work of BECA are provided, i.e. background information or key facts, a video statement by the Rapporteur and a list of the measures included in the Special Committee's final report. This information is provided in all EU official languages, including subtitles for the video statement.

The Parlamentarium team has curated this content hand in hand with the BECA secretariat, whose members have provided valuable input for all content updates.

**Text displayed in the Parlamentarium exhibition**

**Key facts**
Cancer, a term covering over 200 diseases, affects everyone regardless of age, gender or social status. In 2020, an estimated 2.7 million people in the EU were diagnosed with the disease, and another 1.3 million people lost their lives to it. Female breast cancer is the most commonly diagnosed cancer type in the EU.

If current trends continue, cancer could become the leading cause of death in the Union.

Yet, over 40% of cancer cases are preventable. Although it is caused by a combination of multiple factors including genetic predisposition and environmental influences, avoiding known risks and adopting a healthy lifestyle can greatly lower people’s risk of getting cancer.

The overall economic impact of cancer in Europe is estimated to exceed €100 billion each year.

**EP action**
The EU has been working to tackle cancer for decades and its actions, for example on tobacco control, protection from hazardous substances, rules for clinical trials for medicinal products and the promotion of cancer screening, have saved and prolonged lives.

In June 2020, the European Parliament set up a Special Committee on Beating Cancer, whose mandate ended in December 2021. The Special Committee examined how to realize the ambitions of Europe's Beating Cancer Plan, which sets out a new EU approach to cancer prevention, treatment and care. The cancer plan tackles the entire disease pathway, from prevention to quality of life of cancer patients and survivors, focusing on actions where the EU can add the most value.

In December 2021, the Special Committee voted in favour of a series of proposals. Among these, putting the patient first and fighting inequalities in cancer prevention and treatment, putting forward European prevention and management plans to address shortages of medicines, devices, products and staff in times of health crises and using Europe's Beating Cancer Plan as a blueprint for tackling other non-communicable diseases. The full Parliament is set to adopt these recommendations in early 2022.

The EU, with Parliament as a key player, will invest a total of €4 billion in actions addressing cancer until 2027, with a special focus on prevention, new technologies, research and innovation.
XIX. BECA Social Media
BECA Social Media

- EP [Multi Media Center](#)
- BECA committee website.
- Twitter [@EP_BeatCancer](#)