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”.

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 |
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| **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. |

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1 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)
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 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

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2 OLP, the ordinary legislative procedure, set out in Article 294 of TFEU: https://www.europarl.europa.eu/olp/en/ordinary-legislative-procedure/overview
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.

I.5 Overarching principles

- Article 5 of TEU3: conferral of powers to the EU, and the principles of subsidiarity and proportionality;
- Article 4, paragraph 2, point (k) of TFEU4: 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

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3 TEU, Treaty on the European Union:  

4 TFEU, Treaty on the Functioning of the European Union:  
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT

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 products⁶ -
  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)**⁷ complements the directive by
banning advertising and product placement of tobacco products on television and
through on-demand services. The Tobacco Directive (above) extended the rules on
tobacco advertising and promotion to electronic cigarettes.

- **Excise duty on manufactured tobacco**: Council Directive 2011/64/EU on the structure
  and rates of excise duty applied to manufactured tobacco ⁸ - legal base: Article 113
  TFEU

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.

- **Smoke-free environments**: Council Recommendation of 30 November 2009 on
  smoke-free environments (2009/C 296/02)⁹ - legal base: Article 168 TFEU

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.

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⁹ https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009H1205%2801%29
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), which will be applicable from 1 January 2022. Council Directive 92/84/EEC sets out minimum rates that must be 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

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 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) - 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

- **General Food Law Regulation**: Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of

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food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety\textsuperscript{15} - legal base: Articles 43, 114, 207 and Article 168(4)(b) TFEU

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\textsuperscript{17} - 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

\textsuperscript{15} https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1602178004741&uri=CELEX:02002R0178-20190726
\textsuperscript{17} https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R1169-20180101
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 holds all permitted claims and their condition for use.

**II.1.4 Radiation**

- **Ionising radiation**: Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation\(^{19}\) - legal base: Articles 31 and 32 of the Euratom Treaty

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.


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.


- **Ultraviolet radiation from sunbeds**: Directive 2014/35/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (Low Voltage Directive).\(^{22}\)

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 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\(^{30}\)

  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


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.

- **Classification, labelling and packaging of chemicals (CLP):** Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures\(^{32}\) - legal base: Article 114 TFEU

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.

- **Biocides:** Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products\(^{33}\) - legal base: Article 114 TFEU

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

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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.

[^34]: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1107-20191214
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\(^\text{37}\).

II.1.8 Specific legislation on exposure to harmful substances in work-related context (various types 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)\(^\text{39}\)

  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)\(^\text{40}\)

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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.


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)).

- **Asbestos:** Directive 2009/148/EC of the European Parliament and of the Council on the protection of workers from the risks related to exposure to asbestos at work

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.

- **Statistics:** Regulation (EC) No 1338/2008 of the European Parliament and of the Council on Community statistics on public health and health and safety at work

- **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

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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.


### II.2 Early detection of cancer

- **Cancer screening**: Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC)

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; the Commission published its second implementation report; and the WHO-IARC published the fourth version of the European Code Against Cancer.

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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.

- **Orphan medicinal products:** Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products\(^{56}\) legal base: Article 114 TFEU, which is particularly relevant for rare cancers.

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;
- 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\(^{57}\), 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 1394/2007 of the European Parliament and of the Council on advanced therapy medicinal products\(^{58}\) 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.

- **Clinical trials:** Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use\(^{59}\), 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 breastfeeding 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.

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- **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\(^{60}\) - 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**: Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices\(^{63}\)

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.

- **In vitro diagnostic (IVD) medical devices**: Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices\(^{64}\)

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

establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027\textsuperscript{68} - 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.\textsuperscript{69}

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

- eHealth network: Commission Implementing Decision 2019/1765 providing the rules for the establishment, the management and the functioning of the network of national

\textsuperscript{68} [Link](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0522&qid=1618231187236)

\textsuperscript{69} [Link](https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2018/0224(COD)&l=en)

‘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)\textsuperscript{71} - 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.

\textsuperscript{70} https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1602154476974&uri=CELEX:32019D1765

\textsuperscript{71} https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A3A02016R0679-20160504