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.

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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...

1 M. Crul, M. Lawler, M. Aapro: The Impact of COVID-19 on Cancer in Europe: The 7-Point Plan to Address the Urgency and Build Back Better - European Cancer Organisation, 2020
https://www.europeancancer.org/component/attachments/?task=download&id=375

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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.²

I.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.

³ 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
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:

- The Commission issued comprehensive guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak (C(2020)2272);
- 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).

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.

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4 See footnote 1
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:

- 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 per 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.

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- **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.

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 policy-makers 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 the 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 the 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)](https://eur-lex.europa.eu/eli/reg/2020/727/oj), 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.