I-Com Study

DESIGNING THE FUTURE EUROPEAN HEALTH UNION?
Scaling-up Ambitions, Powering Resilience

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EXECUTIVE SUMMARY

While the COVID-19 pandemic began posing a major public health threat to EU/EEA countries and the UK, the EU was struggling to play a coordinating role, complementing national policies to help countries in facing common challenges, such as a lack of sufficient healthcare organisation and provision, so that each Member State would be better prepared for the virus's impact on their healthcare systems. Since the beginning, European countries have responded differently to the pandemic depending on their specific needs (number of fatalities, percentage of older people or people infected, etc.), as well as the differences in aspects of its national system and, almost without exception, the country's own interests. A key political lesson of this crisis is that further collaboration is required in Europe to face health challenges such as the COVID-19 pandemic. The President of the European Commission, Ursula von der Leyen, in her first speech on the State of the Union before the European Parliament in Brussels (16 September 2020) announced that with the Italian Presidency of the G20 the Commission will organise a Global Health Summit in Italy to show that Europe is there to protect its citizens. The aim is to build a Health Union as the pandemic is not at its end and recovery is still in its early stages. For this reason, the EU must act with responsibility and unity. To take stock of the proposal for a strengthened European Health Union, announced by the President as a long-term response to the critical issues emerging from the pandemic crisis, this study will focus on the key priorities on the EU health agenda with a focus on the main two which the European Commission will outline by the end of the year - the Cancer Plan and the Pharmaceutical Strategy.

The first chapter offers a reasoned reconnaissance of the bottlenecks and challenges of the EU health response to the COVID-19 pandemic and describes the institutional response since the beginning at the EU level. Through the lessons learned in facing these hard times, the chapter then analyses the task of the Commission in the next five years to constantly improve the quality and sustainability of Member States' health systems. The key priorities to tackle the old and new challenges for healthcare in the European Union are: ensuring the supply of affordable medicines; allowing for the effective implementation of the new regulatory framework on medical devices; making the most of the potential of e-health to provide high-quality healthcare and reduce inequalities by creating a European Health Data Space to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes; fully implementing the European One Health Action Plan against Antimicrobial Resistance; prioritising communication on vaccination and promoting Europe's Beating Cancer Plan to support Member States in improving cancer prevention and care. The priorities of the European Commission for 2019-2024 already represented a new strategic

paradigm, where the European social market economy and technological innovation are closely interconnected and are strongly linked to health. Moreover, in May 2020, in response to COVID-19, which has had a major impact on medical and healthcare staff, patients and health systems in Europe, the European Commission issued a regulatory proposal to the European Parliament and Council to draw up a programme for the Union's action in the field of health for the period 2021-2027, repealing Regulation (EU) No 282/2014 ("EU4Health Programme"). The EU4Health Programme's main aim is to strengthen crisis preparedness and response but, at the same time, it will address other important long-term challenges for health systems such as inequalities in health status among population groups, countries and regions, and access to affordable, preventive and curative healthcare of good quality; the burden from non-communicable diseases, especially cancer, mental health diseases, rare diseases and risks from health determinants; the uneven distribution of health care systems capacity; obstacles to the wide uptake and best use of digital innovations as well their scaling up; the growing health burden from environmental degradation and pollution, in particular, air, water and soil quality, and also from demographic changes. For each health priority, the chapter offers an analysis of the reasons why they are so considered and of the challenges that still need to be faced.

The second chapter focuses on Europe's plan to beat cancer. Starting from the huge burden that cancer poses on our health and social systems, putting pressure on government budgets and negatively impacting the productivity and growth of the economy, the chapter describes and presents the roadmap that foresees the adoption and presentation of the Commission Communication and Action Plan by the end of 2020. Since evidence suggests that there is an urgent need for more effective, accessible and resilient health systems, the Commission has embarked on a common path that will lead to Europe's Beating Cancer Action Plan by the end of the current year. The four pillars of Europe's Beating Cancer Plan are prevention, early diagnosis, treatment and follow-up care. It is thus glaringly clear that the way to beat cancer requires a "health in all policies approach" and involves acknowledging that health must play a key role in policy-making across many sectors. This is the reason for the EBCP proposing actions at every key stage of the disease - prevention (lifestyle, pollution, vaccination), diagnosis, treatment and survivorship.

The third chapter focuses on the EU pharmaceutical strategy. Guaranteeing universal access to safe and affordable medicines that offer all citizens options for the diagnosis, treatment and prevention of diseases is a key principle on which Europe is based. However, the recent health crisis caused by Covid-19 has clearly demonstrated the need to modernise how the EU ensures access to medicines for its population and has highlighted the need for a future-proof and crisis-resistant system to guarantee timely access to high quality, safe and effective medicines under all circumstances. For this, re-establishing pharmaceutical manufacturing in the EU and leveraging the existing EU manufacturing capabilities is essential to reducing vulnerabilities in this value chain,

particularly for generic drugs, and to guarantee medicines to all citizens. Therefore, Europe needs a research and manufacturing infrastructure that delivers the next generation of vaccines and treatments. This involves developing clinical trial networks, biobanks and data-banks, building a European health data space, delivering public-private collaboration mechanisms to accelerate bringing health solutions to patients and encouraging innovative manufacturing. On 1 June 2020, the European Commission published a roadmap for a pharmaceutical strategy for Europe, forecasted to be adopted for the fourth quarter of 2020. The strategy will also inform the newly proposed EU4Health Programme and align with Horizon Europe for research and innovation. The main aim is to create a "future proof" system, which reaps the benefits of digitalisation and promotes innovation especially in areas of unmet needs, such as antimicrobials, medicines for children and medicines for rare diseases. It also intends to reduce the EU's dependency on imports from third-countries.

The last part of the study presents conclusions and policy recommendations for each of the chapters in the study.

1. TOWARDS A EUROPEAN HEALTH UNION

European countries have, since the beginning, adopted different responses to the pandemic. The way each country has responded to the emergency does not only reflect the objective needs of that country (number of fatalities, share of older people or people infected, etc.), but also the differences in the character of its national system and, almost without exception, the country's own interests. A key political lesson of this crisis is that further collaboration is required in Europe to face health challenges such as the COVID-19 pandemic.

Despite having little space for manoeuvre, **the past European Commission mandate made some significant steps forward in terms of health policy**. However, more efforts are needed since Europe must tackle unprecedented challenges affecting people's health besides, and together with, the current pandemic, such as demographic changes, environmental degradation and the rapidly changing world of work. **Hence, implementing a multi-sectoral, holistic and comprehensive approach to health becomes fundamental**.

In the initial Commission President's mission letter nominating the then new Commissioner for Health, she outlined the task of the Commission in the next five years in constantly improving the quality and sustainability of Member States' health systems, and this task has, of course, been strengthened by the advent of the COVID-19 crisis. According to the drafted health agenda of the EC, to do this, actions should be included in two main chapters - promoting and protecting public health and improving food safety and animal and plant health.

The main priorities to be addressed in the first chapter (promoting and protecting public health) are:

- ensuring the supply of affordable medicines;
- allowing for the effective implementation of the new regulatory framework on medical devices;
- making the most of the potential of e-health to provide high-quality healthcare and reduce inequalities by creating a European Health Data Space to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes;
- fully implementing the European One Health Action Plan against Antimicrobial Resistance;
- prioritising communication on vaccination;
- promoting Europe's Beating Cancer Plan to support Member States in improving cancer prevention and care.

The main priorities to be addressed in the second chapter (improving food safety and animal and plant health) are:

- promoting a new 'Farm to Fork' strategy for sustainable food from production to consumption;
- working on protecting plant health and reducing dependency on pesticides in order to deliver on the zero-pollution goal;
- improving consumer information especially on the health and sustainability of food products;
- equipping Europe to prevent and fight against animal diseases that can be transmitted, and enforcing the animal welfare legislation and promoting European standards globally;
- focusing on the implementation and enforcement of the extensive legislation in the areas of food safety and animal and plant health;
- developing a strategy with concrete measures against food fraud.

Thus, first three priorities of the European Commission for 2019-2024 already represented a new strategic paradigm relying on three pillars, where the European social market economy and technological innovation are closely interconnected and strongly linked to health. Thereafter, on May 2020, in response to COVID-19, with its major impact on European medical and healthcare staff, patients and health systems, the European Commission issued a proposal to the European Parliament and of the Council on the establishment of a Programme for the Union's action in the field of health for the period 2021-2027, repealing Regulation (EU) No 282/2014 ("EU4Health Programme"). The EU4Health programme has three general objectives:

1. protecting people in the EU from serious cross-border health threats and improving crisis management capacity;
2. making medicines, medical devices and other crisis relevant products available and affordable and supporting innovation;
3. strengthening health systems and the healthcare workforce, by investing in public health, for instance, through health promotion and disease prevention programmes and improving access to healthcare.

As well as crisis preparedness and response, the EU4Health Programme will address other important long-term challenges for health systems. These include inequalities in health status among population groups, countries and regions, and access to affordable, preventive and curative health care of good quality; the burden from non-communicable diseases, in particular, cancer, mental health, rare diseases and risks from health determinants; the uneven distribution of

healthcare systems capacity; obstacles to the wide uptake and best use of digital innovations as well their scaling up; the growing health burden from environmental degradation and pollution, especially, water and soil quality, and also from demographic changes. Through the EU4Health Programme, the Commission proposes to invest €9.4 billion in strengthening health systems. This is compared to the previous Commission proposal for a health strand under the European Social Fund+ of €413 million. The funding will come in part from the EU budget (€1.7 billion), and partly via external assigned revenues, stemming from the borrowing operations of the Union as set out in the EU Recovery Instrument Regulation (€7.7 billion). There will be no pre-allocation for each of the objectives mentioned in the programme. The distribution will be agreed upon during the implementation of the EU4Health programme. The programme takes into account the lessons learnt and gaps revealed by the crisis to date, **and will put in place structural changes to better prepare the EU for further health challenges.** Once the proposal is adopted by Member States and the European Parliament, the intention is to start launching specific actions under EU4Health as of 1 January 2021.

Access to affordable medicines remains at the top of the list of the health priorities, as well as the implementation of the new regulatory framework for medical devices. These are two key areas in both pharmaceutical and health technology policies which have been returned to the health portfolio. Responsibility for pharmaceuticals and medical devices has returned to DG SANTE, five years after a decision of the Juncker Commission moved them to DG GROW (Directorate for Industry, Enterprises and the internal Market). Today, more than ever, it is clear that the **role that science and new technologies play in developing new solutions is central and needs to be recognised reinforcing what** the Commissioner for Health, Stella Kyriakides, underlined in her answers to the European Parliament[1] at the end of 2019. For this reason, the EU needs to ensure that regulatory frameworks remain up-to-date, fit-for-purpose and with a citizen-centred approach. The "State of Health in the EU Companion Report 2019" stresses that **gaps in the access to healthcare are still very much a reality in the EU** and problems regarding accessibility and the extent to which EU citizens experience them vary enormously. However, standard data does not reveal how differences in covered services and medical goods relate to socio-economic aspects or clinical needs. Several Member States tend to show similar exceptions to their benefit packages, and these exceptions often create gaps in being able to access expensive or experimental treatments.

According to the report, this is the case for **experimental or very expensive new pharmaceuticals that are not systematically covered**, or delayed in terms of their inclusion in the benefit packages.

[1] https://ec.europa.eu/commission/commissioners/sites/comm-cwt2019/files/commissioner_ep_hearings/answers-ep questionnaire-kyriakides_0.pdf

Findings reveal striking differences in the sales and availability of innovative medicines between different Member states and, according to the European Parliament, the problem has been exacerbated by the economic crisis (Fig. 1.1). In 2016, the Council adopted conclusions on strengthening the balance in the EU's pharmaceutical systems[2] and, in 2017, the EU Parliament adopted a resolution on options for improving access to medicines[3] in which it called for national and EU-wide "*measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies*". Moreover, it called on the Commission and the member States "*to foster R&D driven by patients' unmet needs, such as by researching new antimicrobials, coordinating public resources for healthcare research in an effective and efficient manner, and promoting the social responsibility of the pharmaceutical sector*". Given the increasing concerns about shortages of certain medicines, the supply side also requires attention. To this end, the EMA recently issued guidance on the detection and notification of shortages of medicinal products[4], and to face COVID-19, the European Commission has published guidelines for EU Member States with concrete actions for preventing medicine shortages during the pandemic[5]. To build an inclusive and fair system, epidemiology, severity of needs and **outcome-based data** must be factored in. The latter requires a **clear and mutually recognised definition of outcomes** whereby a more holistic approach to measuring access could be implemented, taking into account both the system's cost-effectiveness and the patient's perspective.

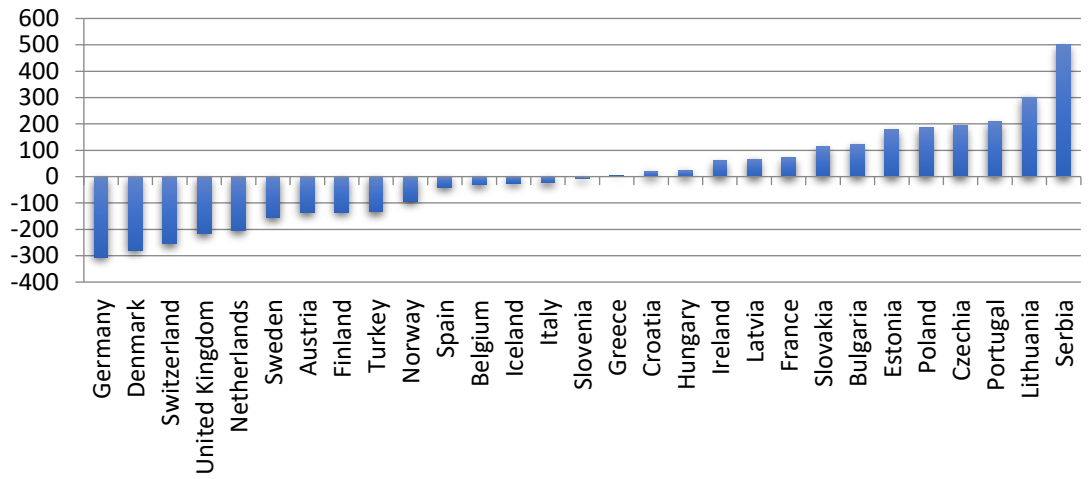
[2] Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States (2016/C 269/06).

[3] Options for improving access to medicines, European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI)).

[4] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf

[5]https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/availability-medicines-during-covid-19-pandemic

Fig. 1.1: Average time between marketing authorisation and patient access for medicines in Europe by country (2018, difference in days number vs EU average)



Source: I-Com elaboration on IQVIA data

New legislation concerning **medical devices and in vitro diagnostic devices** has also been adopted recently. Regulation (EU) 2017/745 and Regulation (EU) 2017/746 set the rules on placing medical and in vitro diagnostic devices on the market and on related clinical investigations. Devices are grouped according to their risk category, each with a specific set of rules. These regulations were a significant step towards strengthening patient safety as they introduced more stringent procedures for conformity assessment and post-marketing surveillance, requiring manufacturers to produce clinical safety data, establish a unique device identification system for the traceability of devices, and provide for the setting up of a European database on medical devices. Their effective implementation should improve patient safety and consolidate the EU's role as a global leader in this field. On 23 April 2020, the Council and the Parliament adopted Regulation 2020/561, amending Regulation (EU) 2017/745 on medical devices regarding application dates of certain of its provisions. This Regulation postpones the date of application for most Medical Devices Regulation provisions by one year – until 26 May 2021 - and enters into force on the day of its publication in the Official Journal of the European Union. According to the regulation this will allow all key players, i.e. Member States, health institutions and economic operators, to give priority to the fight against the ongoing pandemic, forming a key position in the timing of the lifting of confinement measures as Member States return to the road of recovery.

Among the priorities for promoting and protecting public health, there is the effective implementation of the **One Health Action Plan against Antimicrobial Resistance (AMR)**.

Antimicrobial agents are substances that kill or inhibit microorganisms, including bacteria, viruses, fungi and parasites. The use (and misuse) of antimicrobial agents is linked to an increasing prevalence of microorganisms that have developed resistance to such agents, thereby posing a threat to public health. EU-level actions to tackle antimicrobial resistance date back to the late 1990s, while the European One Health Action Plan against Antimicrobial Resistance (AMR)[6] is the latest policy initiative. Adopted in 2017, its main goal is to maintain the possibility of effective treatment of infections by reducing the emergence and spread of AMR and increasing the development and availability of new, effective antimicrobials. Moreover, the action plan highlights the need to set up incentives to boost early research, as well as the development of novel antimicrobials and innovative alternative medicinal products (e.g. vaccines, antibacterial, antifungal, antiviral agents) and diagnostics. It also looks at developing new Health Technology Assessment methodologies and reimbursement reforms to better capture the added value of new antimicrobials, alternatives and diagnostics. The EU Parliament responded to this action plan in a recent resolution[7] and, in 2019, the Council adopted conclusions[8] on the next steps for making the EU a best practice region in combatting AMR. In its resolution, Parliament emphasised its conviction that "*diseases have to be tackled in both people and animals, while also taking into special consideration the food chain and the environment, which can be another source of resistant microorganisms*" and underlined the important role of the Commission in coordinating and monitoring national action plans implemented by Member States and the importance of cross-administrative cooperation.

Health priorities for the Commission, moreover, include the need to prioritise **communication on vaccination**. Obviously, **in fighting the COVID-19 pandemic the focus has been on the EU strategy to ensure that a safe vaccine will be available for all Europeans**. As Europe learns to live with the pandemic, it is imperative that the Member States follow a common vaccination strategy for vaccine deployment and apply evidence-based and proportionate non-pharmaceutical measures to stem infection rates to manageable levels. **The Commission Communication to the European Parliament and Council on preparedness for COVID-19 vaccination strategies and vaccine deployment**[9] (October 2020) reports that, to date, the Commission has entered into agreements with individual vaccine producers on behalf of the Member States, purchasing and/or reserving the right to purchase vaccine doses under Advance Purchase Agreements. Currently there are three contracts that allow the purchase of a vaccine once it has been proven safe and effective -

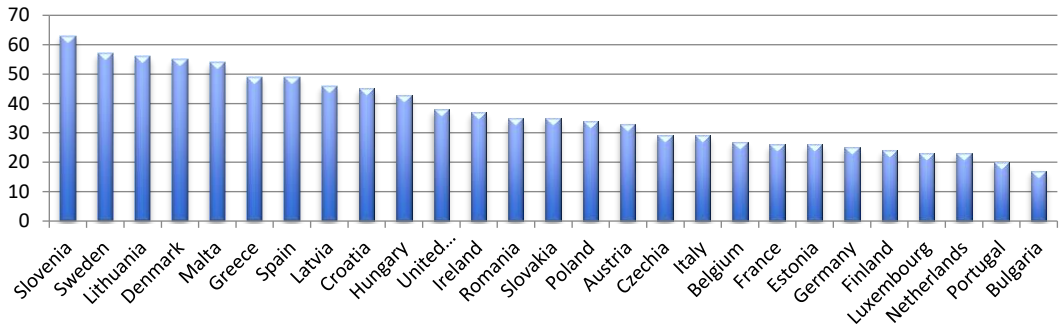
[6] https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf
[7] European Parliament resolution of 13 September 2018 on a European One Health Action Plan against Antimicrobial Resistance (AMR) (2017/2254(INI)).
[8] Council conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance (2019/C 214/01).
[9] https://ec.europa.eu/health/sites/health/files/vaccination/docs/2020_strategies_deployment_en.pdf

namely with Astra Zeneca, Sanofi-GSK and Johnson&Johnson. To date, the Commission continues discussing similar agreements with other vaccine manufacturers. All three contracts approved with vaccine producers include provisions through which Member States may donate or resell vaccine doses to third countries, striving for global solidarity. To overcome the crisis, Europe needs to obtain a broad portfolio of vaccine candidates so as to maximise the chances of quickly developing, manufacturing and deploying a vaccine for all Europeans. The Communication underlines that once one or more COVID-19 vaccines have become available, it is important to ensure that vaccination services are able to deliver and distribute vaccines in an ordered manner, within a given timeframe and in line with a rapidly changing epidemiological situation. **Member States should, therefore, ensure that vaccination services have sufficient resources to carry out their task**, both in terms of skilled workforce for the administration of COVID-19 vaccines and supply of the necessary medical and protective equipment.

Going beyond COVID-19, **vaccination is among the main tools for primary prevention and it is recognised as one of the most cost-effective public health measures available**. However, several EU and neighbouring countries are currently facing unprecedented outbreaks of vaccine-preventable diseases due to insufficient vaccination coverage rates. The waning of public confidence in vaccinations, geographical differences in accessibility and the **rise of disinformation on vaccinations are a cause of concern and a major challenge for public health experts**. Vaccine confidence, the trust in the effectiveness and safety of vaccines and trust in the healthcare system that delivers them, refers to the belief that vaccination serves the best health interests of the public and its constituents. The EU has one of the lowest confidence levels in the safety and effectiveness of vaccines worldwide, as reported by the latest European Commission report "State of vaccine confidence in the EU 2018". The 2019 special Eurobarometer[10] confirms high differences among countries in confidence. The share of individuals responding to the question "Why have you not had any vaccination in the last five years?", reporting the absence of need to be vaccinated, are found below in Figure 1.2.

[10] https://ec.europa.eu/health/sites/health/files/vaccination/docs/20190426_special-eurobarometer-sp488_en.pdf

Fig. 1.2: Share of individuals who don't see the need to be vaccinated in EU 2019, by country (% values, 2019)



Source: Special Eurobarometer 288

For this reason, ensuring equitable access to vaccines for all EU citizens, fighting disinformation, and improving vaccine confidence are objectives shared by the European Commission and EU Member States. In December 2018, the Council adopted a Recommendation to strengthen EU cooperation on vaccine-preventable diseases, an initiative that aims to tackle vaccine hesitancy, improve coordination on vaccine procurement, support research and innovation, and strengthen EU cooperation on vaccine-preventable diseases. The European Commission is reinforcing its support on national vaccination efforts to increase coverage, including through the European Joint Action on Vaccination, co-funded by the EU Health Programme11 with € 3.55 million. The action seeks to increase vaccination coverage in the EU and is coordinated by INSERM (France) involving 20 partners (among them 17 EU countries and 3 non-EU countries). A "Coalition for Vaccination" that involves the European Association of Healthcare Workers and the Students' Association was also convened in spring 2019 to support delivering of accurate information to the public and combating myths.

[11] The Health Programme is a funding tool to support cooperation among EU countries and underpin and develop EU health activities. The legal basis for the Health Programme is agreed on by the European Parliament and the Council for a period of several years.

2. EUROPE'S PLAN TO BEAT CANCER: A COMPREHENSIVE APPROACH TO PREVENTION AND CARE

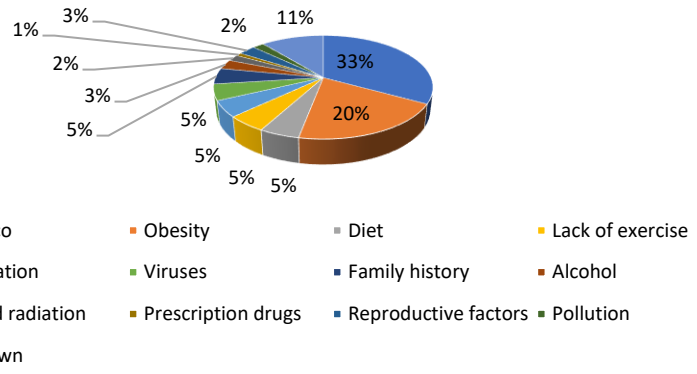
The growing field of implementation science has clearly demonstrated that the cancer burden could be reduced by introducing changes in individual and population behaviours, and by increasing **public health efforts based on robust scientific knowledge** and a **social commitment to change**. The main known risk factors related to cancer are[12]:

- tobacco use
- being overweight or obese
- unhealthy diet with low fruit and vegetable intake
- lack of physical activity
- alcohol use
- sexually transmitted HPV-infection
- hepatitis infection or other carcinogenic infections
- ionizing and ultraviolet radiation
- urban air pollution
- indoor smoke from household use of solid fuels

Preventable cancer risks, including unhealthy lifestyle choices and consequent health outcomes, are particularly prevalent among people of lower socio-economic groups, lower education and limited access to information and health services. Amongst these factors, physical inactivity and tobacco use alone are linked to more than 50% of preventable cancers.

[12] Available from: https://www.cancer.net/navigating-cancer-care/prevention-and-healthy-living/understanding-cancer-risk

Fig. 2.1: Distribution of preventable cancer-related factors



Source: Comparator report on cancer in Europe, IHE 2019

Therefore, reducing cancer morbidity and mortality strongly depends on the cooperation of a variety of stakeholders, including citizens. The way to beat cancer requires a **"health in all policies approach"** and would involve acknowledging that health must play a key role in policymaking across many sectors.

A "health in all policies approach" would involve:

- **Public authorities and national governments intervening to define cross-sectoral strategies and implementing active policies that provide citizens with incentives to choose healthier lifestyles.**

All stakeholders should recognise methods for prevention, such as harm reduction, within health strategies, to address health inequalities and champion social justice. Healthy lifestyles are not only a matter of willingness, but also of **opportunity**. Thus, legislation can deeply impact a population's behaviour, widening the range of opportunities to apply to as many citizens as possible. Though legislation on product prices and labelling might have an impact on consumption choices and habits, induced behavioural changes, particularly in the most at-risk population groups, can have a deeper long-term impact. They result in a permanent effort of the population in adopting sustainable lifestyle choices, and monitored consumption patterns. **These choices can be fostered by incentives supporting less risky alternatives for consumption and lifestyle habits** which, on the one hand, are effective since they help to avoid excessive exposure to cancer-related risk factors and, on the other, allow for greater access to sustainable behaviour opportunity for lower socio-economic groups (i.e. green spaces and areas for physical activity, sustainable mobility intervention, walking paths, school-based awareness campaigns, community-based programmes);

- **Emphasis on the importance of education and information to influence the population's general behaviour and consumption patterns to lower cancer morbidity, and to help patients living with cancer.**

Health professionals should be involved in recommending, monitoring and leading specific lifestyle choices for patients in order to obtain better clinical outcomes and/or lower the occurrence of critical conditions. The objective should be to reach a better quality of life for cancer patients. Education and information campaigns should involve different stakeholders, socio-health professionals and institutions. Their actions should be coherent and within a comprehensive plan to achieve the same final objectives. **The lack of information tends to create confusion on the best choices to follow and risks reducing the effective efforts made by different actors.**

- **Early detection of cancer greatly increases the chances for successful treatment**

There are two major elements of early cancer detection - **education to promote screening participation and early diagnosis.** Health professionals should participate in training and education programmes that encourage research, strengthening their contribution to prevention and early diagnosis and spreading awareness among health workers of cancer warning signs. Health professionals should feel responsible for providing the most up-to-date information to patients on diagnostic procedures and on therapeutic paths to follow. Some Member States have already demonstrated significant reductions in cancer-related mortality through well-organised population-based screening programmes[i]. As reported in the second report on the implementation of the Council Recommendation on cancer screening (2017), most Member States follow the European guidelines to ensure high participation (systematic written invitation of the eligible women with prefixed appointments, functioning screening registries, etc.) and appropriate quality assurance (a team responsible for quality assurance, linkage between the screening and cancer registries, etc.), but there is still room for improvement in many programmes to close the gap between and within Member States.

In the first wave of the European Commission public consultation, the Cancer Plan Roadmap registered a record number of **384 submissions**. Our analysis of the submissions revealed an overarching theme related to specific sectors with a large number of the submissions encouraging the uptake of strategies such as harm reduction. Nearly 20% of all contributions supported the definition of harm reduction plans for alcohol or tobacco. One in every six submissions recommended policies which encourage the use of reduced risk nicotine products by smokers and, at the same time, approximately 15% called for guidelines and provisions on consumption for alcohol products. Just under 5% (25 submissions) highlighted the impact of pollution and chemicals and, similarly, 23 submissions focused on nutrition. The submissions including such suggestions often include more than one risk factor. **It is widely recognised that modifiable risk factors are**

best addressed through cross-sectoral, population-based policies and legislation creating health-enabling living environments. The generation of data on the link between environmental and lifestyle factors and cancer is needed and requires the allocation of sufficient resources to relevant EU agencies in order to take the appropriate risk reduction measures, relative to the direct exposure and exposure due to environmental pollution. This **cross- sectoral strategy requires taking into account public health and social costs as benefice for regulatory action (as avoided costs) during the socio-economic analysis performed.** Prevention is only one of the stages for which Europe's Beating Cancer Plan will propose concrete actions. The plan will deal with bottlenecks existing in early detection and diagnosis, treatment and care and quality of life. For the first, early detection and diagnosis, the plan will propose measures to improve the chance of a better health outcome through early diagnosis which includes increasing the coverage of the target population for cancer screening and increasing the use of digital solutions and technical support to Member States, in line with the priority to create an health data space for Europe. For the second, treatment and care, the plan will propose measures to improve outcomes of cancer care and treatment, including improving the access to high-quality treatment and uptake of new therapies and the definition of measures to ensure the availability and affordability of essential medicines and innovation and research, in line with the forthcoming pharmaceutical strategy for Europe. For the third, the quality of life, the plan will propose measures to ensure the best possible quality of life for cancer patients, survivors and careers, including measures to improve professional re-integration, prevent discrimination and improve the provision of palliative care also through the transfer of best practices.

3. THE EU PHARMACEUTICAL STRATEGY: A NEW FRAMEWORK FOR INNOVATION AND AFFORDABILITY?

The coronavirus pandemic has highlighted the need to ensure affordability, sustainability and security of medicine supply and the need to establish the means to produce medicines within the EU in order to ensure that citizens and hospitals can have access to essential medicines at all times. Moreover, COVID-19 has shown the need for strong IP and incentives to ensure the EU is 'strategically autonomous' for innovative medicines. Furthermore, it has also shown the need for an accelerated digitalisation of healthcare (e.g. increased telemedicine, need for EU health data which is findable, accessible, interoperable, reusable for the tracking of the pandemic spread).

The recent Covid pandemic has highlighted the EU's long-existing structural problems related to the supply of medicines, especially generic drugs, and the dependency on third-country imports for certain essential and critical medicines and ingredients. While Europe has a strong manufacturing footprint, the supply chain still relies heavily on subcontractors to produce pharmaceutical raw materials outside the EU, where labour costs and environmental standards are often lower, with the result that 60 % to 80 % of chemical active ingredients are manufactured outside the EU, mainly in China and India. These two countries reportedly produce 60 % of the world's paracetamol, 90 % of its penicillin and 50 % of its ibuprofen[13].

Instead, the EU's innovative pharmaceutical industry is resilient and not dependent on third countries like China or India[14]. About 70-80% of innovative medicines are now sourced in the EU, however, EU Member States' uncoordinated actions and lack of solidarity in, for example, stockpiling, patient hoarding, export bans etc., place tension on some supplies.

Above all, during the pandemic there have been different factors that have caused medicine shortage[15]:

- **Sudden surge in demand**. Approximately 40% of the diagnosed Covid-19 cases required hospitalisation and demand for medicines (anaesthetics, antibiotics, muscle relaxants, resuscitation medicines and anti-diuretics, respiratory and cardiac medicines, analgesics, anti-clotting medicines) used in intensive care units has markedly increased. However, there is still no specific treatment for Covid-19, but a number of medicines authorised to treat other diseases are now under consideration as a potential treatment (off-label and compassionate

[13] https://www.europarl.europa.eu/doceo/document/A-9-2020-0142_EN.html
[14] https://www.efpia.eu/news-events/the-efpia-view/blog-articles/eu-strategic-resilience-in-pharmaceuticals-global-value-chains-and-innovation/
[15] https://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_BRI(2020)652709

use). The increasing demand for these medicines has threatened their availability for patients using them for the authorised indications, i.e. to treat their chronic or rare illnesses.

- **Dependency on third country imports.** The dependency of the European pharmaceutical industry on third-country imports has been a long-standing issue, which had been recognied as a potential threat to the EU's strategic autonomy already before the pandemic, and has now been exacerbated by the crises.
- **Export bans and national stockpiling in response to the pandemic.** Export bans in supplying third countries, such as the restrictions by India on the export of 26 APIs, including the API and formulations of paracetamol, had a substantial impact on the global supply chain. Export bans were introduced within the EU by the Member States as well, in the anticipation of shortages and to create national stockpiles, hampering the functioning of the internal market.
- **Transport barriers.** The worldwide confinement, which resulted in temporary lockdowns or decreased production capacity in production sites, raw material or API suppliers, had a severe impact on the availability of essential medicines and ingredients. A decrease in air freight capacity and price increases due to the grounding of air transport, border closures within the EU and other transport barriers worsened the situation further, causing delays in the delivery of medicines and ingredients and making their transport expensive.

In order to tackle the pandemic-related medicine shortage, some key actions have been identified[16]:

- **Enhanced cooperation and coordination at EU level**. The Commission issued comprehensive guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak. To respond to the needs of closer cooperation and coordination, the 'EU Executive Steering Group on shortages of medicines caused by major events' was launched. The Steering Group is chaired by the Commission, and made up of representatives of the Commission, HMA, EMA, the chairs of the Coordination Groups for mutual recognition and decentralised procedures, and risk communication specialists. It is working to identify and coordinate EU-wide actions in case of supply shortage risk and ensure consistent and transparent information about the risks and the remedial actions.
- **Monitoring and predicting demand, matching supply and demand.** The European medicines regulatory network is compiling a list of the medicines used for COVID-19 treatment, comprising active substances identified by the national competent authorities as crucial, particularly in ICUs (Intensive Care Units). Moreover, pharmaceutical industry associations have taken steps to develop a forecasting model based on industry data that would help to predict and match demand and supply of medicines used in ICUs.

[16] Ibidem

- **Increasing production capacity**. In the beginning of April 2020, in the wake of an imminent shortage of essential ICU medicines and the export ban on paracetamol from India, Commissioner Kyriakides turned directly to the pharmaceutical companies and asked them to increase production of those medicines. This call was reiterated a few days later in the Commission's guidelines, which called not on the industry but on the Member States to request, facilitate or coordinate joint industry efforts to find effective measures and resources to reduce shortages.
- **Antitrust guidance for securing the supply of hospital medicines.** At the beginning of April 2020, the Commission published a 'Temporary Framework', providing antitrust guidance to companies who wish to cooperate and coordinate their activities temporarily, in order to optimise supply of essential, urgently needed hospital medicines. The Commission is giving a helping hand to companies and trade associations in assessing the legality of their arrangements, and establishing safeguards against longer-term anti-competitive effects. This would normally be up to the companies themselves.
- **Ensuring the free movement of ingredients and medicines into, and within the EU** through temporary easing of the entry conditions for medical goods and the use of temporary admission procedures at the external borders of the EU25.
- **Regulatory flexibility.** To overcome supply chain/manufacturing disruptions, certain regulatory flexibility was allowed. The flexibility concerns the validity of GMP (Good Manufacturing Practice) certificates, which might be extended until the end of 2021, and GMP on-site inspections for new sites, which can be done via distant assessment. Similar flexibility applies to Good Distribution Practice (GDP) certificates and on-site inspections for wholesale authorisations.

Taking into account what has been said so far, returning pharmaceutical manufacturing to the EU and leveraging the existing EU manufacturing capabilities are fundamental to reducing vulnerabilities in the pharmaceutical manufacturing value chain in the EU, particularly for generic drugs, and to guarantee medicines to all citizens. Over the last 15 years, China and India have become highly competitive manufacturers in the global pharmaceutical chain. However, the Covid-19 pandemic has caused a reshuffling across the board It has also exacerbated the risks of drug shortages caused by weaknesses in the supply chain for sourcing generic treatments and active pharmaceutical ingredients. According to EFPIA, however, there is already strong resilience in the European pharmaceutical industry with 77 % of EU imports for all pharmaceutical products sourced from within Europe itself. Only 2.4 % of EU imports of pharmaceutical products come from China and1.3 % from India. Moreover, Europe is the biggest exporter of medicines in the world with a strong history of research and development. **It is critical, therefore, that Europe uses its**

strengths in international trade and innovation to help the region recover and become more resilient through open trade and a strong focus on R&D and innovation.

Hence**, Europe needs a research and manufacturing infrastructure that delivers the next generation of vaccines and treatments**. This means developing clinical trial networks, biobanks and data banks, building a European health data space, delivering public-private collaboration mechanisms to accelerate bringing health solutions to patients and encouraging innovative manufacturing[17].

According to EFPIA (European Federation of Pharmaceutical Industries and Associations), to place the EU at the forefront of pharmaceutical innovation, **Europe needs a world-class IP framework to attract investment in the development of future treatments for the benefit of patients**, including those with rare and pediatric diseases. Supplementary protection certificates and strong IP systems can increase certainty and predictability for innovators and investors alike. Therefore, the market conditions for manufacturers in the European Union need to be improved. This concerns both **reimbursement and pricing rules for prescription medicines, as well as measures to reduce the regulatory burden for all kinds of medicines**. In more concrete terms, the German Medicines Manufacturers' Association believes that specific measures around **regulatory flexibility which have been introduced during the corona-crisis for marketing authorisation procedures[18] should continue.**

Moreover, the European policies, to prevent future shortages due to unforeseen events[19] should:

- support the costs of technology transfer;
- ensure regulatory flexibility (e.g. fast-track approvals), in full compliance with regulatory standards[20];
- increase cooperation among public authorities/national governments on shortages;
- guarantee transparent information exchange among authorities on medicine stocks available in each country.

Finally, the EU should agree on a definition of shortages (supply/demand side), standardised shortage reporting requirements based on patient needs (not national demand), prioritising critical products with high potential impact. The information should be uploaded onto a common portal (single template with harmonised data, incl. from EMVS) to ensure a

[17] https://dcatvci.org/6635-eu-s-pharma-strategy-secure-the-supply-chain-innovation
[18] Ibidem
[19] Ibidem
[20] Ibidem

streamlined and effective alert system. Restrictions that distort carefully calibrated and globally integrated supply chains should be prevented.

POLICY RECOMMENDATIONS

TOWARDS A EUROPEAN HEALTH UNION

- Europe needs to adopt a holistic and integrated approach that goes beyond the subsidiarity principle. EU countries must not be left acting alone in an uncoordinated manner. In turn, this means that **the way the EU institutions understand their work together with the Member States needs to be turned around**;
- **A possible way to face health challenges**, such as the COVID-19 pandemic, **through a collective action would be in creating a European public health authority**, with powers beyond the limited coordination activities carried out by the European Centre for Disease Prevention and Control. It would be able to support the preparation and response capacity for trans-national health emergencies;
- Today, more than ever it is clear that the role that science and new technologies play in developing new solutions is central and needs to be recognised. Gaps in the access to healthcare are still very much a reality in the EU and differences in covered services and medical goods often also relate to socio-economic aspects or clinical needs. **The EU should work to create an inclusive and fair system, where epidemiology, severity of needs and outcome-based data must be factored in.** The last requires a **clear and mutually recognised definition of outcomes to allow Member States to build a fair value – based evaluation of pricing and reimbursement**;
- **The waning of public confidence in vaccinations**, geographical differences in accessibility and the rise of disinformation on vaccinations **are a cause of concern** and a major challenge for public health experts. Ensuring equitable access to vaccines for all EU citizens, means acting at a European level and together with Member States to **fight disinformation and to build national systems able to support effective vaccination strategies and plans**;
- **The importance of elementary health data** relevant for research has been recognised at the European level and highlighted by the high pressure resulting from the COVID-19 crisis, both on the research community and on the NHSs. **The top need is for a complementary and joint action to ensure that research findings and elementary health data can be shared rapidly, openly and effectively**. To create a European Health Data Space, as part of the European Commission health agenda, the Commission should work to develop sector-

specific legislative or non-legislative measures, complementing the horizontal framework of the common data space, and deploy the data infrastructures, tools and computing capacity for the European Health Data Space. **This is the only way to enable the shift towards value-based healthcare models and systems**;

- The Commission is planning to examine the application and functioning of Chapter V of the EU GDPR 2016/679 (GDPR) on the transfer of personal data to third countries or international organisations. **It is desirable that the latter would pave the way for answering the need for a consistent interpretation of the GDPR across Member States**. The implementation of a code of conduct could be a solution to face this challenge helping to facilitate the cross-border sharing of data.

THE EUROPE'S PLAN TO BEAT CANCER: A COMPREHENSIVE APPROACH TO PREVENTION AND CARE

- Cancer could soon surpass cardiovascular diseases as the disease group causing the greatest societal burden and it has already done so in many wealthy countries. **The way to beat cancer requires a "health in all policies approach"** and would involve acknowledging that **health must play a key role in policy-making across many sectors**;
- Preventable cancer risks, including unhealthy lifestyle choices and consequent health outcomes, are particularly prevalent among people of lower socio-economic groups, lower education and limited access to information and health services. **Thus, public authorities and national governments should intervene to define cross-sectoral strategies** and implement active policies that provide citizens with incentives to **choose healthier lifestyles because choices are not only a matter of willingness, but also of opportunity;**
- **Early detection of cancer greatly increases the chances for successful treatment.** There are two major elements of early cancer detection - **education to promote screening participation and early diagnosis**. Some Member States have already demonstrated significant reductions in cancer-related mortality through well-organised population-based screening programmes following the European guidelines to ensure high participation and appropriate quality assurance. However, **there is still room for improvement in many programmes to close the gap between and within Member States and Europe should be able to lead in achieving this objective**.

THE EU PHARMACEUTICAL PILLARS IN A POST-COVID WORLD

- Europe needs a **research and manufacturing infrastructure** that delivers the next generation of vaccines and treatments;
- **Europe needs a world-class IP framework to attract investment in the development of future treatments for the benefit of patients**;
- **The market conditions for manufacturers in the European Union need to be improved**. Above all, specific measures around regulatory flexibility which have been introduced during the corona-crisis with regards to marketing authorisation procedures should be considered;
- **The cooperation among public authorities/national governments on shortages should be increased** and the EU should be able to guarantee transparent information exchange among authorities on medicine stocks available in each country;
- **Bringing innovative health solutions to patients should be a top priority.** Developing clinical trial networks, biobanks and databanks, building a European health data space, delivering public-private collaboration mechanisms should be prioritised in order to **accelerate the process towards this objective and in order to support and encourage innovative manufacturing.**

[i] Cancer screening in the European Union (2017). Report on the implementation of the Council Recommendation on cancer screening. Available from: https://ec.europa.eu/health/sites/health/files/major_chronic_diseases/docs/2017_cancerscreening_2ndreportimplementation_en.pdf