POLICY BRIEF

TOWARDS A EUROPEAN HEALTH UNION
Lessons learned, future challenges

Policy Brief
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Abstract

The Covid-19 has spread across Europe, and disproportionately hit older and more fragile people, showing a clear social gradient in correlated deaths. Generally speaking, the pandemic showed that a lack of investment in health systems, while saving money in the short term, can have devastating effects on the economy and society in the long term. Moreover, it has highlighted that other health emergencies will occur in the future, especially concerning the increasing burden of non-communicable diseases which will require placing the patient at the centre of health policies and the uptake of new innovations in treatment. Consequently, health expenditure should be regarded as an investment for our societies, rather than a cost, avoiding health budgets being cut as a consequence of economic recession. The EU's institutional response has been mainly (though not exclusively) led by the European Commission, and through European Council member meetings. The European Parliament and European Central Bank have also played important roles. A number of collaborative EU-level initiatives have helped alleviate supply constraints and support a more coordinated response across countries. However, the EU struggled to play a coordinating role, complementing national policies to help countries in facing common challenges. Therefore, the European Commission declared its commitment to building a strong European Health Union, where all EU countries prepare and respond together to health crises, with available, affordable and innovative medical supplies, and where countries work together to improve prevention, treatment and aftercare for diseases such as cancer. The key initiatives to build a European Health Union include crisis preparedness and response measures, a Pharmaceutical Strategy for Europe and the European Plan to Beat Cancer and this policy brief will present them with their strength and weaknesses.

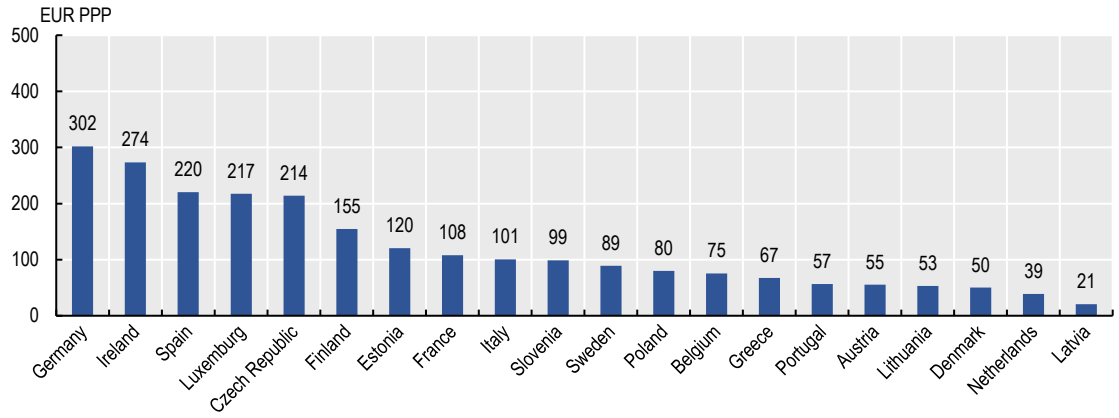
1. A strong European Health Union?

The Covid-19 has spread across Europe, and disproportionately **hit older and more fragile people, showing a clear social gradient** in correlated deaths. **Countries that had been better prepared** and acted quickly to reduce the spread of the virus through the rapid scaling-up of testing, tracking and tracing strategies, **were more able to avoid the more stringent and costly containment and mitigation measures**. Meanwhile, policies to temporarily increase hospital beds and equipment have helped deal with the surges in demand, however, the most significant, though indirect, help was provided by reinforcing local healthcare, particularly home assistance.

Furthermore, many non Covid-19 patients were unable to access needed care during the peak of the pandemic in spring 2020, and the reductions in prevention and control also followed into the next months. People with emergency health needs have sometimes struggled to receive timely acute care, and those with chronic health conditions have faced disruptions to their routine treatment. **The pandemic has, therefore, put an immense strain on European countries**, testing the resilience of every country's health and economic systems, together with the **ability of the European Commission to develop a coordinated set of responses to what is still a common threat**.

Generally speaking, the pandemic showed that a **lack of investment in health systems, while saving money in the short term, can have devastating effects on the economy and society** in the long term. Moreover, it has highlighted that **other health emergencies will occur in the future**, especially concerning the increasing burden of non-communicable diseases which will require placing the patient at the centre of health policies and the uptake of new innovations in treatment. Consequently, health **expenditure should be regarded as an investment for our societies, rather than a cost, avoiding health budgets being cut as a consequence of economic recession**. The central governments of the European Member States increased their health spending in response to the health emergency during 2020 (Fig. 1). As well, the EU has approved the extraordinary Next Generation EU (NGEU) programme, better known as the Recovery Fund. It is a special fund aimed at financing economic recovery in the coming years, with the issuance of European bonds that **will serve to support projects and structural reforms established by the Recovery Plan (reforms and investment) in each of the 27 EU Member States**. In total, the forecasted sum is **€ 750 billion**, made up of €390 billion in grants and €360 billion in loans, divided according to the different needs of the Member States most affected by Covid-19.

Fig. 1 Central government additional Covid-19 health spending commitments per capita, 2020



Source: OECD member country governments

According to the OECD (2020), **the pandemic introduced a new concept of resilience**, acknowledging that massive disruptions can and will happen, and it is essential that core systems must be able to **recover and adapt**. This new approach to resilience should focus on "the ability of a system to **anticipate, absorb, recover from, and adapt** to a wide array of systemic threats."

The EU's institutional response has been mainly (though not exclusively) led by the European Commission, and through European Council member meetings. The European Parliament and European Central Bank have also played important roles.

The EU public health response has mainly involved:

- direct financial support for procurement programmes to support healthcare systems;
- support for research in treatments and vaccines;
- medical guidance for Member States;
- coordinating the supply and manufacturing of Personal Protective Equipment (PPE).

A number of collaborative EU-level initiatives have helped alleviate supply constraints and support a more coordinated response across countries. Notable actions include:

- **Joint procurement.** The European Commission has launched several voluntary Joint Procurement procedures since February 2020. These are based on Article 5 of Decision

1082/2013 on cross-border health threats[1], as well as on the Joint Procurement Agreement (JPA) with participation open to all EU and EEA Member States;

- **Seven international tenders** launched to address or prevent shortages of medical countermeasures relevant for Covid-19. The European Commission helped countries identify and select suppliers, and negotiate contracts, enabling them to purchase essential products under the same conditions;
- **Clearing house**[2]. The European Commission set up a temporary clearing house to facilitate matching supply and demand between manufacturers and MSs. It uses a centralised platform that pools data on trade flows, production capacity in third countries, together with logistical, technical and regulatory bottlenecks;
- **Enhanced monitoring**. The European Medicines Agency, together with the pharmaceutical industry and EU MSs, launched a fast-track monitoring system to help anticipate drug shortages. This reinforced a single contact point for national medicine agencies (SPOC) and the launch of an industry single point of contact (i-SPOC);
- **Strategic stockpiling**. The EU reinforced and strengthened components of its disaster risk management by upgrading the EU Civil Protection Mechanism[3]. The latest element introduced is RescEU, established in March 2020 as a common reserve of medical equipment managed autonomously by the European Commission;
- **Manufacturing capacity**. Although Europe has a strong manufacturing footprint, the supply chain still relies heavily on subcontractors to produce pharmaceutical raw materials outside the EU borders. The European Commission's new pharmaceutical strategy[4] emphasises policies to increase the manufacturing capacity for certain critical medicines, active pharmaceutical ingredients and raw materials within Europe;
- **Trade policies**: regulating exports and liberalising imports. A temporary EU-wide export authorisation scheme for personal protection equipment (PPE) set out conditions for their export during the very first wave of the epidemic. In April 2020, customs duties and VAT were waived on imported medical devices and PPE from non-EU origins. Moreover, the EMA published guidance on regulatory expectations and flexibility during Covid-19, where MSs may "grant full or partial exemption to certain labelling and packaging requirements" for crucial medicines used for Covid-19[5];

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013D1082&from=EN
[2] https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/emergency-support-instrument/covid-19-clearing-house-medical-equipment_en
[3] https://ec.europa.eu/echo/what/civil-protection/mechanism_en
[4] https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2173
[5] Article 63(3) of Directive 2001/83/EC

- **Vaccines**. The EU Vaccine Strategy[6] outlines how the European Commission intends to accelerate the development and availability of Covid-19 vaccines. Its main objectives are to secure the production of vaccines within the EU; to ensure their availability for its MSs through Advance Purchase Agreements with vaccine producers; and to adapt EU rules to accelerate the development, authorisation and availability of vaccines while maintaining safety standards.

However, the EU struggled 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 was better prepared for the healthcare challenges posed by the virus. **European countries have since the beginning adopted different responses** to the same pandemic. Indeed, while most federal states have an authority or an agency with such a remit, and responsibilities on global health and epidemic intelligence, the equivalent does not exist for the EU. In the latter, **responsibilities are decentralised to MSs**, which only began sharing information after the **European Centre for Disease Prevention and Control (ECDC) was established in 2005[7], with limited functions** and not being involved in public health decision making. **During the last few weeks, we have still witnessed European MSs confusing information, communications and decisions about the vaccination campaign** concerning the monitoring of the safety of one of the Covid-19 vaccines. **All of this has created great damage in terms of public confidence, and curbed the vaccination campaign**. The EMA participation was messy, and information leaked to the press did not help. Thus, **the key political lesson from this crisis is that further collaboration is required in Europe to face health challenges** and, fortunately, the EU seems to have learnt the lesson, even if **the foreseen and proposed actions still need to be established.**

"*We cannot wait for the end of the pandemic to repair and prepare for the future. We will build the foundations of a stronger European Health Union in which 27 countries work together to detect, prepare and respond collectively*". So declared Ursula von der Leyen, President of the European Commission, speaking at the World Health Summit (25 October 2020). **Therefore, the European Commission is committed to building a strong European Health Union**, where all EU countries prepare and respond together to health crises, with available, affordable and innovative medical supplies, and where countries work together to improve prevention, treatment and aftercare for diseases such as cancer. The European Health Union should better protect the health of its citizens, equip the EU and its MSs to better prevent and address future pandemics and improve the resilience of Europe's health systems.

[6] https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1103
[7] https://www.ecdc.europa.eu/en/about-uswhat-we-do/ecdcs-mission

The key initiatives to build a European Health Union include **crisis preparedness and response measures, a Pharmaceutical Strategy for Europe and the European Plan to Beat Cancer**.

2. Crisis preparedness and response measures

Early lessons learnt from the pandemic have shown **that the current system has not been able to ensure an optimal response at EU level**. The current health security arrangements, established by Decision No 1082/2013/EU on serious cross-border threats to health[8], provide a limited legal framework for EU level coordination, based essentially on the Early Warning and Response System (EWRS) and the exchange of information and cooperation within the Health Security Committee.

Due to **unpreparedness combined with the gradual time–spatial transmission** of the virus, Phase 1 of the epidemic in the EU was initially characterised by regulatory variations (Fig. 2) across MSs, but then was promptly replaced by a **spontaneous regulatory convergence**. It is worth noting that this convergence among EU MSs' national responses occurred spontaneously, **with no direct role played by the EU and its cross-border health emergency coordination mechanisms**.

The key lessons learned during the health emergency, include the **need to increase and improve capacities for surveillance, preparedness, early warning, risk assessment and response as well as the operation of the key EU structures and mechanisms** thus reinforcing both the health response of the EU agencies, and international cooperation. Answering to the lesson learned requires to **propose a stronger and more comprehensive health security framework** for the Union, in order to prepare and respond to health crises while setting out the main elements of the future Health Emergency Preparedness and Response Authority (HERA).

The question is: how these instruments can be prepared to work?

The EU proposal thus includes the extension of the mandate of the ECDC to support the Commission and Member States in the following areas:

- prevention of communicable diseases and specific health issues, e.g., antimicrobial resistance, vaccination and biosecurity;
- preparedness and response planning;

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013D1082&from=EN

- reporting and auditing epidemiological surveillance via integrated, digital systems enabling real-time surveillance;
- provision of non-binding recommendations for risk management;
- coordination of new networks including EU reference laboratories

At the same time the EU understood that industries need to partner up with institutions for better collaboration, and to **avoid shortages and increase capacities of production**. That is the reason why EMA is the second EU agency whose role and operation need to be reinforced. In this context it is important to have monitoring and reporting procedures, and to develop IT tools to check on supplies chain in order to prevent major crisis from escalating. Moreover. it is essential to establish list of critical medicines and monitor supply and demand through the close collaboration between member states and industry. Moreover, the EU will establish an Emergency Task Force that will be built as a membership to include various Agency committees and working groups, the Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMD(h)), and the Clinical Trials, Coordination and Advisory Group (CTAG)).

The European Commission proceeded with a **Proposal for a Regulation on Serious Cross-border Health Threats** repealing Decision 1082/2013/EU[9], in order to create a more robust mandate for coordination at EU-level. It:

- sets out a **comprehensive legislative framework to govern action at Union level** on preparedness, surveillance, risk assessment, and early warning and responses;
- enhances the Union's **guidance in the adoption of common measures at EU level** to face a future cross-border health threat.

The regulation applies to threats of biological origin (communicable diseases, antimicrobial resistance and biotoxins), threats of chemical origin, threats of environmental and unknown origin, and events which may constitute public health emergencies of international concern under the International Health Regulations (IHR), provided that they fall under one of the previously listed categories.

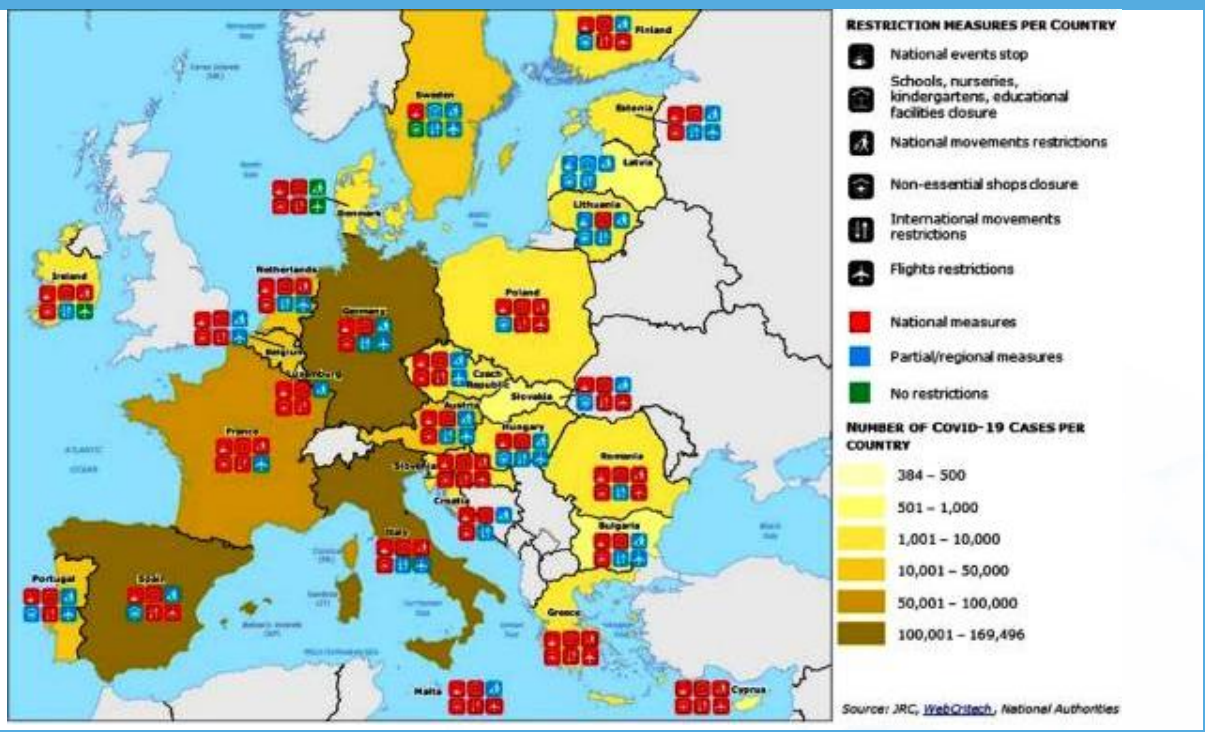
The main operative consequences would be the creation of an EU health crisis and pandemic preparedness plan, complemented by national plans and transparent reporting of capacities, strengthened and integrated surveillance systems, enhanced risk assessment for health threats, increased power to enforce a coordinated response at EU level through the Health

[9] https://ec.europa.eu/info/sites/info/files/proposal-regulation-cross-border-threats-health_en.pdf

Security Committee, and an improved mechanism for recognition of and response to public health emergencies.

Moreover, it provides for the strengthening of the EU's key public health agencies - the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA).

Fig. 2 EU, Covid-19 restriction measures during Phase 1 (April 2020)



Source: JRC

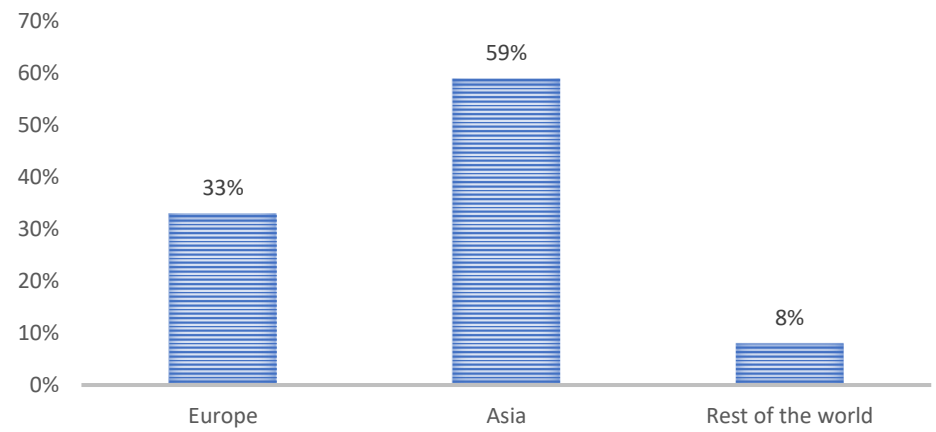
The European Commission and the ECDC will regularly test and audit pandemic preparedness plans at EU and national levels, and **report results to the MSs and European Parliament**, while MSs will be required to improve their reporting of health system indicators. **What is still not clear, is the possible effect on MSs of the preparedness evaluation conducted by the agency**. However, the proposal is accompanied by two further proposals to extend the mandate of the EMA and of the ECDC[10]. The **package of three proposals** should be discussed during the **next conference of the Council of the European Union in June 2021**. Its implementation will be part of the next 2020-2027 Multiannual Financial Framework.

[10] https://ec.europa.eu/info/sites/info/files/proposal-mandate-european-medicines-agency_en.pdf
https://ec.europa.eu/info/sites/info/files/proposal-mandate-european-centre-disease-prevention-control_en.pdf

3. The Pharmaceutical Strategy

The pandemic caused by the SARS-CoV-2 virus clearly demonstrated the need to **revise how the Union supplies medicines to its population**, as well as highlighting the importance of establishing the conditions and means to produce medicines within the EU, **guaranteeing accessibility, sustainability and safety**. Returning the **production of pharmaceutical raw materials to Europe is one of the cornerstones of this strategy**, as is the need to increase innovation in the areas of unmet needs. Indeed, although Europe has a strong manufacturing footprint, the **supply chain still relies heavily on subcontractors** to produce pharmaceutical raw materials outside the EU. The result is that between 60% and 80% of the active chemical ingredients are produced outside Europe, mainly in China and India.

Fig. 3: Geographical allocation of active principle producers (% value, 2020)



Source: Certificate Database, European Directorate for the Quality of Medicine & Healthcare

Other factors connected with the emergency have also contributed to the shortage of medicines in Europe, jeopardising the management of the health emergency. First of all, there was the sudden increase in demand for some medicines, especially in intensive care units. In addition, the population reacted to the pandemic by cramming stocks of non-prescription pain relievers. Consequently, the growing demand for all these medicines threatened their availability for patients who take them regularly to control chronic and / or rare diseases.

At the same time, the supply side suffered from export bans together with the building up of stocks of medicines at national level, the reduction in production capacity, and the closure of suppliers of raw materials / active pharmaceutical substances. Logistical problems and difficulties in cross-border transport further affected the availability of drugs, as well as the development of new therapies against Covid-19.

On 1 June 2020, the European Commission began working on this problem, publishing a roadmap for drawing up a European Pharmaceutical Strategy and launching a public consultation. The aim was to promote competitiveness, the ability to innovate and the sustainability of the EU pharmaceutical industry. On **25 November 2020, the Commission published the final document of the Pharmaceutical Strategy for Europe**[11], an initiative in line with the new Industrial Strategy for Europe and the priorities outlined in the European Green Deal, with the European Cancer Plan and the European Digital Strategy.

Specifically, the strategy is divided into four objectives as below.

Fig. 4: The Pharmaceutical Strategy objectives

Objectives	Description
1	Provide patients with access to affordable medicines and address unmet medical needs.
2	Promote the competitiveness, innovation capacity and sustainability of the EU pharmaceutical industry and the production of high quality, safe, effective and greener medicines.
3	Strengthen emergency preparedness and response mechanisms and address the issue of security of supply.
4	Ensure a solid position of the EU on the world stage by promoting high standards in terms of quality, efficacy and safety.

Source: European Commission

The main initiatives of the strategy include:

- **the revision of basic pharmaceutical legislation** to be adapted to future needs and encourage innovation;
- **the creation of an EU authority for preparedness and response** to health emergencies;
- the **revision of the regulations on medicinal products** for paediatric use and rare diseases;
- the **launch of an open and constructive dialogue between all those involved in pharmaceutical production and public authorities**, to identify the fragility of the global supply chain and define strategic options to strengthen the continuity and safety of the supply in the EU;

[11] https://eur-lex.europa.eu/legal-content/IT/TXT/HTML/?uri=CELEX:52020DC0761&from=EN

- **collaboration between national authorities on pricing, payment and procurement policies** to increase the sustainability of health systems;
- the creation of a **robust digital infrastructure**, including a proposal for a European health data space;
- **support for research and innovation**, mainly through Horizon 2020 and EU4Health;
- **actions to promote innovative approaches to European research and development and public procurement**, regarding antimicrobials and their alternatives, and measures to restrict and optimise their use.

The new proposed European authority, HERA (Health Emergency Response Authority) on the model of Barda, the US authority for research and development in the biomedical field, **should also be a reference point for programming,** knowing and evaluating the upcoming innovation in order to reap the benefits of innovation and deploy tools to support market access. **The authority will be set up within a year, but the first investments that led to the creation of the so-called HERA Incubator**[12] have already been allocated. The incubator is an initial plan that the Commission will exploit to work with researchers, biotech companies, manufacturers and public authorities, **to detect new Covid-19 variants, provide incentives to develop vaccines (new and adapted), speed up the approval process, and ensure the increase of production capacity in Europe**. Presented on February 17 by the European Commission, the incubator is de facto a plan for preparing for biodefense based on a strong public-private partnership model, and it should become the basis for the long-term response to health emergencies.

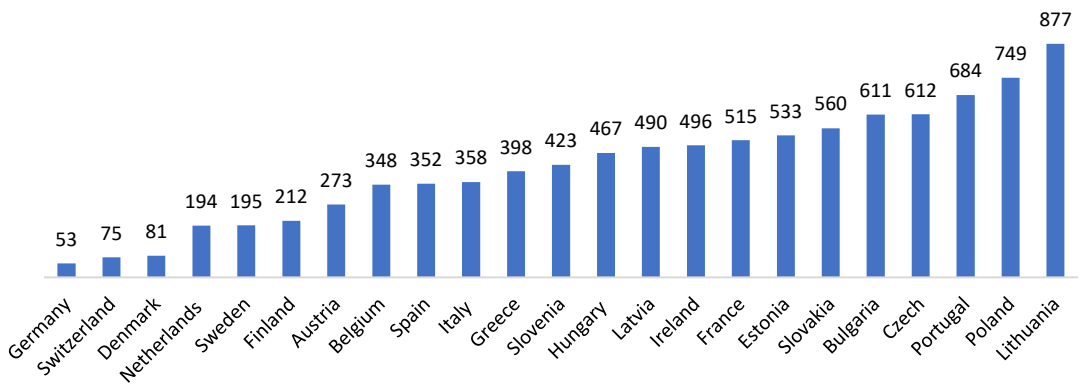
Bringing the production of pharmaceutical raw materials back to Europe is the cornerstone of this strategy, requiring the design of **an adequate industrial policy, and the creation and preservation of incentives. The latter obviously also depends on, but not only, the definition of the price negotiation by MSs**. An interesting example is France, which is preparing a pricing strategy for pharmaceuticals, that guarantees a higher price when they come entirely from French territory. This aspect of the negotiations has not been considered to date, while the evaluation often focuses only on economic convenience.

In general, some risks may be related to some of the proposals contained in the strategy, depending on how the proposals will be implemented through actions. These are partly related to the multi-year duration of the review process, and partly to the possible erosion of patent rights. The strategy specifically plans an impact assessment for some changes to the European regulations concerning medicines for rare diseases (Regulation No. 141/200) and

[12] https://ec.europa.eu/commission/presscorner/detail/en/fs_21_650

paediatric medicines (Regulation No. 1901/2006), and to investigate the effectiveness of the incentives introduced by the two regulations. Both[13] support research and development and, according to the scientific literature, have brought clinical benefits. Furthermore, many small-medium companies have approached the orphan drug market, albeit still immature, using the relevant regulatory paths. Consequently, a **fear is that a revision of the legislation could undermine the level of innovation in disease treatments, without actually creating added value in terms of access**. Here, it **is worth mentioning that patient access to medicines still varies greatly amongst MSs** (Fig. 5), and that the commitment to reducing these differences could result in both **equity in access for citizens and the willingness to innovate for firms**.

Fig. 5: Median time to availability for all new medicines (2015-2018), days



Fonte: EFPIA

In this context the immediate target for Europe, of course, is to ensure that the production of vaccines is speeded up and that it respects the agreements, the contracts and the expected deliveries. In this moment data are still coming from contractors and subcontractors, and the EU is making steps forward, **the objective is to have these medicines developed in Europe also with a view to future production capacity**. **The medium/long term objective is instead to overcome the fragmentation of the health ecosystem also by an industrial point of view**. The main challenges to be addressed are the **supply chain vulnerabilities, health care capacities constraints, and fragmentation**. As far as the supply chain is concerned the EU need to consider also skill shortages, and pay and working condition which prevent the skilled staff from staying in the long run. Moreover**, public buyers are still awarding contracts mainly basing on the best bidder**, with the smallest price and this contributes **to reducing market concentration and the number of suppliers in the EU**.

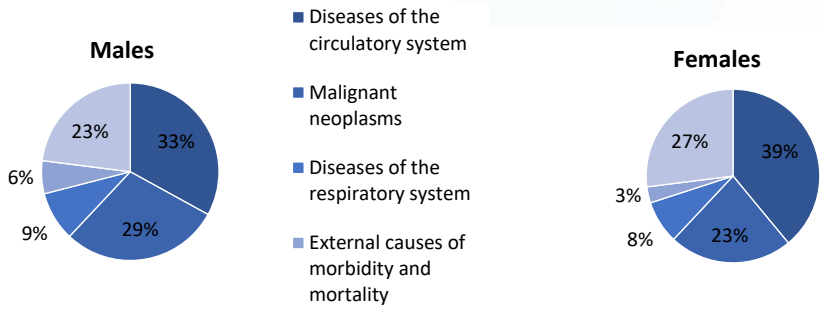
[13] Oriol Solà-Morales, Journal of Market Access & Health Policy, "Has OMP legislation been successful? Yes, though the orphan drug market remains immature" (2019)

Thus, while working on the industrial side the EU also need to work in order to **increase capacity building, and the digital upskilling of employers working in the health sector while intervening to leverage the health data potential**, which is still underdeveloped, and underused. That is why one of the corollary initiatives of the pharmaceutical strategy are the European Health data space and Eu4health and, of course **it is a matter of time**. The ambition is to prepare a reform for the pharma strategy packet by the end of 2022.

4. Europe's Beating Cancer Plan

Since **cancer is the second leading cause of mortality in EU countries after cardiovascular diseases**, accounting for 29% of all deaths among males and 23% among females across all EU Member States, improving prevention and care is vital. 40% of cancer cases in the EU could be prevented but only 3% of health budgets are spent on health promotion and disease prevention[14]. Moreover, a **number of non-communicable diseases share common risk factors and their prevention and control** would benefit most citizens.

Fig. 6: Main causes of mortality among women and men in EU



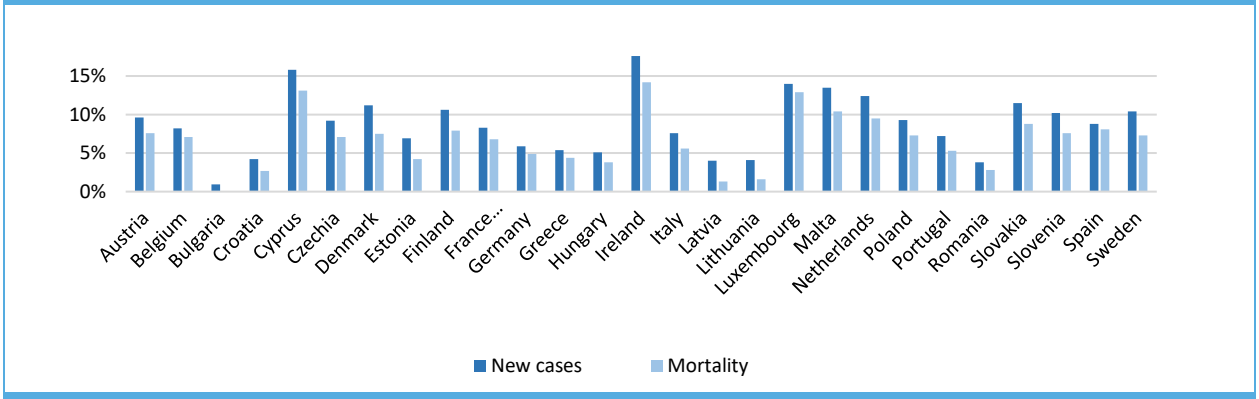
Source: Eurostat

The disease burden of cancer (total number of DALYs) has increased and **malignant neoplasms cause the second-greatest share of DALYs, increasing from 19% to 20%** of the total in the last fifteen years. Cancer could soon surpass cardiovascular diseases as the disease group causing the greatest societal burden, having already done so in many wealthy countries. Moreover**, we expect that** Covid-19 will create in the very near future a "**cancer epidemic" due to the worsening in screening, monitoring and following therapy among target population groups and cancer patients.**

[14] Europe's Beating Cancer plan - Let's strive for more.

The IARC (International Agency for Research on Cancer) estimates there will be a substantial growth in new cases and mortality among European countries in the next five years (Fig. 7).

Fig. 7: Predictions for all cancers, new cases and mortality change (%) in 2025 vs 2020 per country



Source: IARC

Europe's Beating Cancer Plan was launched on World Cancer Day on 4 February 2020, in an event in the European Parliament in Brussels, supported by the MEPs Against Cancer Interest Group. The mission letter to the Health Commissioner Stella Kyriakides defined **the four pillars of Europe's Beating Cancer Plan - prevention, early diagnosis, treatment and follow-up care**. The plan is linked to other priorities of the new Commission and has the support of the MEPs, Member States and stakeholders who work together with the Commission to improve cancer prevention and care in Europe. Speaking in the European Parliament, the Commissioner gave an indication of what the plan could focus on, specifying a horizontal approach addressing key determinants, such as tobacco consumption, alcohol abuse, physical exercise and healthy diets, as part of a prevention-focused strategy. On 4 February 2020, the European Commission opened a public consultation on the plan (12 weeks and closing on 21 May 2020) inviting all interested individuals or organisations to share their views and experiences to feed into a European cancer plan putting European citizens at the centre. **The plan was then adopted on 3 February 2021**[15]. **The actions and flagship initiatives finally included in the plan cover and tackle the entire pathway of the disease -** prevention, diagnosis, treatment and quality of patients and survivors.

[15] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL. Europe's Beating Cancer Plan. Brussels 3/2/2021.

Europe's Beating Cancer Plan will focus on research and innovation, tap into the potential that digitalisation and new technologies offer, and mobilise financial tools to support MSs. With its policy objectives, supported by ten flagship initiatives and multiple supporting actions, the Cancer Plan will help MSs turn the tide against cancer. It will enable expertise and resources to be shared across the EU supporting countries, regions and cities with less knowledge and capabilities. It will help researchers to exchange findings in the EU and access crucial health data on the potential causes of cancer and its promising treatments. Medical staff and hospitals will be able to tap into a wealth of shared information. Ultimately, it will ensure that patients across the EU can benefit from better care and treatment.

Making the most of data and digitalisation in cancer prevention and care is one of the key issues of the plan, and the Commission underlines that the digital transformation can bring significant benefits for the health sector. As much as 30% of the world's stored data is currently produced by health systems, but **the health sector lags behind in exploiting this potential and making information out of data.** Cancer care is one of the major disease areas that will benefit from the European Digital Strategy, the Commission says, thanks to better exploitation of real-world data and using powerful tools such as Artificial Intelligence and high-performance computing. **The European Health Data Space (EHDS) will enable cancer patients to securely access and share their health data in an integrated format** in the electronic health records between healthcare providers and across borders in the EU. The Commission will pursue work with Member States on a common exchange format for electronic health records and to tackle data security, privacy and interoperability. **The Commission will establish the EU Cancer Plan Implementation Group**, to align actions and policies across the European Commission and other EU institutions. **It will work closely with the European Parliament committees** that deal with cancer-related issues; Member States (through the Steering Group on Health Promotion, Disease Prevention and the Management of Non-Communicable Diseases); the Cancer Mission Board functioning as a scientific advisory group; and a stakeholder contact group, mainly involving patient groups, established under the Commission's Health Policy Platform. The Commission will meet with representatives of these institutions and stakeholder groups at regular intervals, at least twice per year, and the Cancer Plan will be monitored through **an implementation roadmap and progress indicators**.

5. Conclusions

Nowadays, still living under the threat of the health emergency, **the pivotal issue is clearly the Commission's proposal for a regulation on serious cross border threats**, which dates to November 2020. The proposal, beyond a communication outlining the scope of the future Health Emergency and Preparedness Response Authority (HERA), includes two other proposals pursuing to reinforce the mandate of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA). These proposals are meant to **improve European resilience to health crisis and were seen as a first steps towards a European health union**.

The Commission's initiative should enjoy broad support, mainly because of the widely recognised necessity **to reinforce the existing structure of the ECDC** in different areas: crisis preparedness and response planning, epidemiological surveillance, prevention of communicable diseases, creation of an efficient system for automated contact tracing, and coordination among previous and new networks. **As far as EMA is concerned**, improving **monitoring and reporting procedures to avoid shortages of critical medicines, and to developing IT tools to check on supply chains to prevent major crisis from escalating**, are indeed the main points that require a **quick grounding**. In this context **industries need to partner up with institutions**, for a better collaboration.

The Commission needs to focus on a second important mission, beyond the immediate one of ensuring that the production and distribution of vaccines is speeded up and that agreements are respects. Indeed, **in the medium to long term, the European Health ecosystem will need to be reconsidered**. As for now indeed, the ecosystem appears to be fractured: besides several big players there are around 500.000 smaller health related firms, of which 99% are small and medium-sized enterprises (SMEs). **The improving the competitiveness of enterprises, with special emphasis on SMEs, is instead essential to a genuinely thriving EU market**. In this sense, the main challenges to be addressed are the **supply chain vulnerabilities, the health care capacities constrain, and the build in fragmentation of the system**. As recent events have revealed, health data and information play a central role in this context and will become increasingly important. Therefore, **the creation of a European Health Data Space (EHDS) must remain one of the main priorities for the Commission and should be developed** in a complementary way, **hand in hand with other initiatives to build a strong European Health Union**. A better access to health data would **improve both research and development and health systems and policies**.

Lastly, member states should consider to **recognise the benefit deriving from joint procurement and cross border joint procurement**, namely the procedure through which two or more contracting authorities from different Member States (MSs) are jointly purchasing supplies or services through one tendering procedure. **This instrument could represent an interesting tool in the near future, according to the experience of the recent past**. The potential advantages deriving from it, would be administrative, financial and competency related, as such different authorities could share best practices, expertise and competences.