THE EUROPEAN FILES

May-June 2021 - n°66

TOWARDS A EUROPEAN HEALTH UNION

BUILDING A RESILIENT EUROPEAN HEALTH SYSTEM


The European Investment Bank
INVESTMENT FOR A MORE EFFECTIVE, SAFE AND AFFORDABLE HEALTHCARE
Thanks to EIB investments in 2020, more than **1.5 billion people worldwide will benefit from improved healthcare services** in the coming years.
© GettyImages
The European Investment Bank is the European Union's bank and the world's biggest multilateral lender.
From small businesses to massive infrastructure projects, we back investments that reduce healthcare inequalities.
www.eib.org/health
European Investment Bank
The EU bank

EDITORIAL

TOWARDS A EUROPEAN HEALTH UNION
BUILDING A RESILIENT EUROPEAN HEALTH SYSTEM

Health is not an exclusive competence of the EU but the responsibility of each Member State. The European Union has a role of coordination and support of national actions to guarantee an effective health protection and safety policy to European citizens.

The COVID crisis that we have been experiencing for more than a year, has revealed gaps in preparedness and emergency responses to health threats and has highlighted need for stronger and more efficient coordination of the European countries but also globally.

Governance and preparedness are essential in times of crisis. It is up to EU legislators to evolve the already existing structures such as the EMA and ECDC in order to strengthen their capacity to protect and promote human (and animal) health more efficiently. In addition, the European Commission proposes the creation of a European Health Emergency Response and Preparedness Authority (HERA) to address health threats in a faster, more comprehensive and coordinated manner.

Strong EU's national health systems are crucial and can be achieved through private and public investment. Investment is notably needed for a rapid digital transformation of healthcare with a robust digital infrastructure.

To meet these challenges, the Commission adopted a Pharmaceutical Strategy for Europe last November. The objective of the Strategy is twofold: to ensure the security and diversification of supply sources across value chain and to strengthen the competitiveness and innovation of the European pharmaceutical industry.

Strategic cooperation among the Member States remains the cornerstone of the construction of a Europe of Health. This entails information sharing, identification of best practices, in-depth evaluation of innovative medicinal products and treatments and above all, procurement practices that ensure timely and equitable access to affordable innovative medicines.

A Europe of Health also means ensuring that the regulatory framework for pharmaceuticals and medical technologies meets the needs of EU patients and health systems, while enabling the EU to remain a global industrial leader.

These initiatives are an opportunity for the EU to take the first steps towards a Health Union. Its success will depend on the commitment and ability to collaborate of all actors in the pharmaceutical value chain and, more importantly, on the Member States' willingness to create an effective European Health Union.

This edition of the European Files addresses all of these points through articles by various European leaders and experts, as well as contributions by high level executives from the health and pharmaceutical industry in Europe.

Editor-in-Chief
LAURENT ULMANN

Management: The European Files / Les Dossiers Européens - 19 rue Lincoln, 1180 Brussels
www.europeanfiles.eu - ISSN 1636-6085 - **email:** ulmann@europeanfiles.eu
Publication Director and Editor-in-Chief: Laurent ULMANN
Layout & printing: Drifosett Printing - www.drifosett.com

TABLE OF CONTENTS

TOWARDS A EUROPEAN HEALTH UNION
BUILDING A RESILIENT EUROPEAN HEALTH SYSTEM

A **Health Union** to **prepare Europe** for **health threats** across borders

MARGARITIS SCHINAS

European Commission Vice-President in charge of promoting our European Way of life

The coronavirus pandemic, unprecedented in depth, intensity and extent, has cost the lives of millions of human beings. And it is not over yet. It has caused immense human suffering, pushed health systems to their limits, and also inflicted deep social and economic costs both in the European Union and around the world. It has fundamentally changed the course of the world as we knew it.

The measures implemented to contain the pandemic have been effective in reducing the infections and save lives, but have also had a huge impact on people's livelihoods, their jobs and their freedoms.

Solidarity has been real and tangible since the beginning of this tragedy. Healthcare workers were at the forefront, working day and night to take care of COVID-19 patients. EU Member States switched from unilateral measures to supporting each other, by receiving for instance COVID-19 patients from neighboring countries, and by sending both healthcare professionals and key medical equipment where they were most needed across the Union. The emergence of a solid cooperation on health matters at the EU level is indisputable.

The EU's agencies competent in this field, the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) played and continue to play a key role in the response to the COVID-19 pandemic. On the one hand, the ECDC continuously provided risk assessments and scientific advice based on the epidemiological spread of the virus to guide decision making. On the other hand, the EMA has streamlined its assessment procedures to allow a more rapid and flexible assessment of COVID-19 vaccines and treatments.

Despite all these consequent efforts, the experience of the current pandemic taught us several broad lessons. The first is the primacy of securing and protecting the health of our citizens, and by extension the importance of having healthcare systems that are efficient, resilient, and well-resourced. The second is the strong interdependence of the Member States of the EU – both in terms of health and economies. We cannot overcome this crisis unless we respond with unity and coordination. The third lesson is about the need for the EU to develop an open strategic autonomy; we should never again experience shortages of medicines or basic health equipment.

In order to pursue efficiently the fight of the COVID-19 pandemic and to anticipate future health emergencies, we need to equip the EU to better prevent, protect and manage health crises. We need to have a reinforced framework of coordination at the European level. This means reinforcing and complementing the existing structures and mechanisms.

It is specifically in this context that the European Commission announced the objective to build a stronger European Health Union.

A strong European Health Union will not only protect our health. It will also protect our way of life, our economies and our model of society.

Where our health is in danger, our economies are in danger. By building a stronger Health Union, we will contribute to a more resilient EU internal market and sustained economic recovery for all, leaving no one behind.

Following up on its commitment, the Commission adopted in November 2020 a legislative package laying down the first building blocks of the European Health Union.

This package, currently under discussion by EU co-legislators, extends the role of the EMA to serve as central hub for scientific excellence, provides to the agency both the ability to assess supply capacity and to monitor shortages of crucial medicines during a crisis. It also strengthens the mandate of the ECDC to provide hands-on support through epidemiological surveillance and scientific recommendations for appropriate health measures to deal with health crisis. Finally, it includes a Regulation to improve preparedness and response to serious cross-border threats.

What a Health Union also needs, is a facilitated access to medicines. In this view, we have adopted a new Pharmaceutical Strategy in late November last year that has three main objectives: ensure accessibility and affordability of safe and effective medicines and innovative treatments; harness the competitiveness and innovation capacity of European pharmaceutical industry, and ensure Europe's open strategic autonomy with strong supply chains that can withstand drastic change and are resilient to disruption.

By now, we are fully implementing the EU Vaccines Strategy. This Strategy is a concrete example of the power of European collaboration and of European solidarity in action. Vaccines are available for all EU countries, at the same time, on the same conditions. Simultaneously, the EU is at the forefront of deliveries of vaccines to the rest of the world, which amount to more than 200 million doses, as many as the doses amount that have been delivered to the Europeans. This massive distribution exercise of vaccines and vaccination definitely allows us to see the light at the end of the tunnel.

However, they will not eliminate the disease, and therapeutics will still be needed on the long run. Recently, on 6 May 2021, we adopted a COVID-19 therapeutics Strategy to support the development and availability of COVID-19 therapeutics, including for the treatment of the long-term effects of COVID-19 infection. Our goal is to have at least three new therapeutics to treat COVID-19 authorised by October 2021, and possibly two more by end of the year.

A Health Union is not only about pandemics, it is also about improving the daily life of people. And in this view, fighting cancer remains a key battle to win. In February of this year, we adopted our Beating Cancer Plan. The COVID-19 pandemic interrupted cancer treatment, delayed screening, and affected access to medicines, exposing patients to greater risks. The EU Cancer Plan re-focuses our efforts with actions across the entire disease pathway – prevention, detection, diagnosis and life after cancer- aimed at strengthening partnerships, building links between fields, and putting patients at its core.

This year still, we will present further proposals to complete the Health Union under construction. This will include the creation of a Health Emergency Preparedness and Response Authority (HERA) that is meant to address gaps in foresight, including demand/supply dimensions, with better EU preparedness and response to serious cross-border health threats, by enabling rapid availability, access and distribution of needed countermeasures.

In addition, we will launch the European Health Data Space. Using digitalisation to its full potential and offering secure access to health data will benefit health research and decision-making and improve healthcare delivery.

In order to put money where our mouth is, these initiatives will be supported financially by the largest allocation to health ever in the EU budget - amounting to 5.1 billion EUR - under the umbrella of the new self-standing EU4Health programme. These resources come in addition to those allocated to health from other sources, notably from EU's research budget, such as Horizon.

The Commission is encouraging Member States to use the generous resources they will benefit from via the Recovery and Resilience Facility to invest in their national healthcare systems, addressing in this way structural weaknesses displayed by the COVID-19 pandemic.

All these proposals and efforts are within the remits of the Treaty, fully respecting the competences of the Member States. However, they still fall short to address the high expectations of EU citizens for more Europe in health.

Looking towards the future now, the freshly launched Conference on the Future of Europe, with its emphasis on outreach to citizens and its aim to create a forum to address their concerns and priorities, provides an optimal platform to ignite discussions on the evolution of the EU's role on health in the future.

Additionally, the Global Health Summit scheduled on 21 May 2021 in Italy will allow the EU to steer the worldwide reflection on how to strengthen global health security in the "age of pandemics".

The coronavirus has touched every aspect of our personal, professional, social and economic life. We urgently need to build a strong European Health Union to increase our resilience to cross-border health threats and provide all European citizens with the high level of public health they expect and deserve. It is our shared and urgent responsibility to take forward these measures quickly and thoroughly, and to overcome the fragmentation and gaps in instruments, information, and mind-sets, which will make us collectively more resilient, and consequently, will allow us to protect and promote our European Way of Life.

Credits/Copyright: Portuguese Government Portal

Reinforcing our cooperation at **EU level** to further **strengthen** our **health systems**

MARTA **TEMIDO**

Minister for Health, Portugal

2021PORTUGAL.EU

The past year has highlighted Europe's struggles in institutionalized cooperation in the field of health. As a result, our health systems suffered under the weight of the pandemic. Indeed, when the first cases of infection by SARS-CoV-2 reached European hospitals and families, coordination attempts were faulty. The existent infrastructure and agencies could not work quickly enough to assist Member States adequately in the height of the crisis. Later on, Europe did come together to provide relief to Member States which had been disproportionately hit by the virus. European solidarity was truly on display in these moments, for instance through the mobilization of emergency medical support teams and critical medical devices and equipment to several Member States whose health systems were at breaking point.

However, these relief actions relied mostly on *ad hoc* mechanisms and did not fix the underlying problem: lack of institutional coordination to prevent and rapidly assist Member States in moments of serious health threats.

Due to the challenges faced by Member States from the onset of the COVID-19 pandemic, the plan to build a true European Health Union arose as a top priority in the European legislative agenda. As of May 2021, it is no longer simply a plan. Significant advances have been made by the Council of the European Union on the proposals set forth by the Commission in late 2020, to strengthen the mandates of the European Centre for Disease Prevention and Control (ECDC) and of the European Medicines Agency (EMA). Alongside these legislative proposals, the ongoing revision of Decision 1082/2013 on serious cross-border health threats has also made noteworthy strides.

When these legislative proposals are approved, Member States can expect to benefit from comprehensive platforms devoted to information sharing on multiple levels. Through the extension of the mandates of these key European Agencies, and with the support of the infrastructure reform brought by the revision of the EU's current framework for handling serious cross-border health threats, Member States will fully make use of the best European expertise in the field of health.

The full length of the new competences granted to the ECDC and the EMA will enable these agencies to assist Member States the form of continuous, integrated monitoring of health challenges. Recommendations on what measures to adopt in order to control an outbreak, such as targeted advice on the supply of medical devices in moments of crisis, will also play a key role in the integrated approach sought by the establishment of a European Health Union.

The setup of the Health Emergency Preparedness and Response Authority (HERA), tasked with providing a dedicated structure to support the development, manufacturing, and deployment of medical products during a health crisis will also play an important role in strengthening our collective response to health threats. Its adoption by the Commission, scheduled for the third quarter of 2021, will be a crucial milestone in the pursuance of the abovementioned goals.

Finally, as we move forward with our plan to build a more resilient Europe in the field of Health, we must broaden our focus to include non-communicable diseases – which hold the higher levels of mortality among European countries. In that sense, it is essential to underline the importance of Europe's Beating Cancer Plan, approved by the Commission earlier this year. One of the key aspects of this ambitious plan is a modern approach to dealing with cancer, by investing in technological development, research and innovation at service of patient-centred prevention and care. Investing in research will be instrumental in delivering improved health outcomes for cancer patients.

As the ongoing pandemic highlighted, collaboration and strong research networks were essential to the innovation required to respond to this healthcare crisis and deliver new and repurposed medicines to tackle this disease. Such a reinforced cooperation will enable Europe to maintain high quality cancer care and research even during an adverse event as this one.

Finally, Europe should invest in increased cooperation between Member States and EU Institutions in order to remain a crucial actor in the international setting. A strong, robust and resilient European Union will naturally be able to forge increasingly relevant partnerships with third countries and provide assistance through effective channels. In fact, as Europe rebuilds itself after the effects of the pandemic, our collective focus must be on ensuring access to COVID-19 vaccination across the globe.

Let there be no doubt: an increase in European solidarity and cooperation in the field of health will result in stronger, more resilient health systems – which are and will continue to be one of the essential features of the European Social Model, in which we believe and are tasked with protecting.

Providing continuing support to health systems

OLIVIER VÉRAN

Minister for Solidarity and Health, France

The health crisis has shed light on both the global resilience of health systems and the need for support in all areas of care: primary care, mental health, and social services.

At the throes of the crisis, EU Member States showed a great deal of solidarity, notably by taking in patients from other countries in their intensive care unis. They also realised that several tools were lacking in order to make close cooperation a reality: insufficiently interoperable information systems, fragmented research and innovation support programmes lacking critical mass, health security agencies not adequately equipped to respond to the magnitude of the crisis, etc.

In light of this, the need to intensify the construction of a Europe of health became apparent in a bid to provide responses worthy of the issues at stake and to take swifter action, in a spirit of solidarity and collective security. Europe is determined to learn from the crisis, even if it is not yet over.

This closer cooperation between national health policies at EU level has already been fleshed out, in particular by the new EU4Health programme with a budget of €5.1 billion, but also by the "Europe of Health" package, the pharmaceutical strategy and the creation of a digital health data space.

The European Union must act where it brings real added value, and health security is one of the areas where more Europe could make us stronger as a whole.

With the draft regulations on cross-border threats and on the revision of the ECDC and the EMA, the European Union is on the verge of endowing itself with a legislative arsenal that will enable it to face future health crises more effectively and operationally. The EU is able to act quickly. And France welcomes the "HERA incubator" initiative put forth by the European Commission. We will capitalise on the experience gained from this programme to facilitate the setting up of the new European Health Emergency Preparedness and Response Authority, which will provide the EU with more structural tools to anticipate and tackle future pandemics.

However, while increasing health security at European level is an essential first step, it is still insufficient to fully deal with the legacy of the Covid-19 crisis.

We also need to address the impact of the crisis on health systems, both at European and national level. Actually, the cost of improving the fight against health security threats is only a fraction of the costs incurred through epidemics.

Alongside these European initiatives, we must also rethink the provision of care at territorial level, by ensuring continuous patient care between cities, hospitals, and medico-social establishments. These investments are necessary for the day-to-day operation of health care services, but also to support the modernisation and transformation of the health care system to ensure its sustainability for the benefit of our populations.

With this in mind, the French government has launched a consultation of the players of the health system within the framework of the so-called "Ségur of Health", the conclusions of which resulted in the adoption of a plan to boost investment totalling €19 billion.

These investments, partially financed by the European Recovery Facility, will enable better management of future pandemics by ensuring increased performance of the various working tools. The European Union has supported and continues to support each of the 27 Member States to help bring about these major developments in health.

The implementation of structural reforms seeks to improve the working conditions of caregivers and to put patients back at the very core of the healthcare system, as well as to address attrition of health professionals, improve medical attractiveness, and revitalise the provision of care and, more generally, the economic fabric throughout the country.

A €9 billion investment plan for hospitals will help to support projects aiming at breaking players free from their silos and, in particular, fostering city-hospital cooperation in the regions, especially when medical demography has been eroded. It will focus on all areas of health and will be a lever for innovation and improve the quality and safety of patient care, by streamlining the care pathway and links between all health care actors.

Investment in health care will depend largely on the regional level and on the involvement of territories and their elected representatives in the decision-making process.

With the emergence of the Europe of health, we, the countries of the UE, will be able to benefit from cooperative mechanisms with a magnified impact that will increase the resilience of our health systems, while respecting our particular features.

Minimizing risks related to pandemics to better protect communities

HANS KLUGE
WHO Europe Regional Director

Pandemics are unpredictable but recurring events that have severe consequences on human health, well-being and livelihoods.

COVID-19 is an example of a pandemic that has inflicted unprecedented damage on an unimaginable scale. It has and still is, claiming millions of lives, and placing a heavy toll on communities, health workers, health systems, economies and societies. The repercussions will be felt for years to come. The pandemic has also stalled our collective progress towards the Sustainable Development Goals.

In the WHO European Region, some 54 million COVID-19 cases and 1.1 million deaths have been reported to date. The pandemic has had a severe impact on economic development in the 53 countries in the WHO Region. In the European Union, the unemployment rate has increased significantly and gross domestic product in 2020 dropped by 7.4%.

But the impact of the virus has also hit communities unequally, with the more affluent parts of the population suffering less, in terms of the economic effects and health outcomes. COVID-19 has compounded inequities.

The pandemic offers several lessons: some of them timely, but none of them can we afford to ignore. It has highlighted the need for preparedness, including the use of innovative early warning systems that allow for early identification and prompt response, as well as for clearly-defined command-and-control emergency response mechanisms, at sub-national, national, regional and global levels.

WHO recognizes the interdependence of health emergency preparedness, health system strengthening and essential public health functions. We provide guidance and coordinate action to overcome challenges and minimize risks in pandemic responses. This includes addressing inequities with the aim of leaving no one behind.

The International Health Regulations (IHR) 2005 are what WHO bases its work on. They play a critical role in strengthening, developing and maintaining country capacity to respond effectively to public health risks and emergencies of international concern. The IHR are a legally binding instrument of international law that create rights and obligations for countries, requiring them to establish and maintain core capacities for surveillance, risk assessment and responses. It is then WHO's role to coordinate the implementation of the IHR and support countries in building capacity. The health emergency we currently face stresses an urgent need to revisit the Regulations – and WHO has already started consultations with its members to that end.

In the WHO European Region, our roadmap until 2025, is the European Programme of Work, "United Action for Better Health", which prioritizes protecting people against health emergencies. The Programme focuses heavily on learning the lessons of COVID-19, in order to improve WHO's governance and operational management of emergency responses. Going forward, we place particular focus on immunization. This is one of four flagships of our Programme of work – vital both today and in the future, to help prevent and decrease the risks of infectious diseases.

Looking ahead, the Pan-European Commission on Health and Sustainable Development, established last year, is another source of inspiration, identifying ways to better protect communities. It is an independent, interdisciplinary group of leaders, tasked with rethinking policy priorities in the light of pandemics. The Commissioners write that "previously, calls for spending on many of the thing things that would have stopped this pandemic in its tracks, or greatly mitigated its impact, have been rejected," and then call for drastically increased investment of e.g. governments and development banks in early warning and response systems, and measures to reduce threats. Among its recommendations is to establish a Global Health Board at the G20 level, modelled on the Financial Stability Board launched in the wake of the global financial crisis. This could then evolve into a Global Public Good Board. The Commission also calls for the concept of One Health to be fully operationalized; demanding a stronger focus on addressing the interdependence of human, animal and environmental health. The Commission's findings and recommendations will be made public in September 2021.

WHO works with partners on multisectoral coordination and efforts to combat health threats, using the One Health approach. In April 2021, this commitment culminated in the establishment of a tripartite Regional One Health Coordination Mechanism for Europe and Central Asia. Through this mechanism, FAO, OIE and WHO provide leadership and direction, convene stakeholders and partners and coordinate support across the Region.

The current pandemic has made a strong case for Universal Health Coverage to help health systems and populations alike become more resilient. This crisis has also provided us with a strong argument for multilateralism: a judicious response to a global threat. Rethinking policy priorities beyond health policies is pivotal, and so is acknowledging the interconnectedness of sectors, stakeholders and countries.

It is relatively simple. To minimize risks and protect communities from future pandemics and public health emergencies - we must act globally and learn our lessons. Health security threats will continue to occur in ways that will challenge even the most advanced health systems. What may prove more complicated is to collectively shoulder responsibility and implement the many lessons learned from COVID-19 - to break the cycle of events that allowed this pandemic to happen in the first place.

Enhancing co-operation to create better health policies for safer and healthier lives

FRANCESCA COLOMBO
Head - OECD Health Division

The COVID-19 pandemic has shown how the world was unprepared to deal with a pandemic of the scale and intensity we have seen over the past year. Health systems, even in most advanced economies, were caught by surprise. Now, as political attention turns to how to improve future preparedness for health emergencies, deepening international co-operation has a huge role to play. Many reviews have been launched to learn lessons for the future, emphasising the need to strengthen the existing international health architecture. Better mechanisms for improving the early detection of new emerging diseases, particularly at the animal-human interface, are badly needed. Past health crises -- such as SARS, H1N1, MERS and Ebola – also demonstrated the critical importance of sharing timely information, both between and within countries. Yet despite the rapid sharing of data on the viral genome, enabling the rapid development of testing kits and vaccines, there has been a need to better co-ordinate across countries actions to flatten the curve of the pandemic, be it containment measures and travel restrictions.

We should also learn from the way different health systems responded to the crisis. Consensus is growing that countries need to invest more in making health systems more resilient for the future. On average across the OECD, an estimated additional 1.5% of GDP in core investments would be necessary both to strengthen the foundations of health systems – through investing in prevention to tackle health risk factors and addressing factors that make people vulnerable such as poverty and inequality – and to build capacity to maintain high quality health services for all in time of crisis. These would be investments in the economy, with a very positive rate of return. International collaboration can help steer policy development through sharing of evidence on what works, economic analyses to support investment cases, and improved co-ordination of policies and their outcomes.

Stronger international co-operation will help reinforce the health workforce. The pandemic has shown the terrific dedication of staff working against the odds to save lives. However, health worker shortages are the most significant limiting factor in addressing health emergencies and maintaining health services for all. While countries need to expand their national training capacities, shortages of health workers cannot be solved by domestic measures alone. Across the OECD, nearly one in four doctors was born abroad and one fifth were trained abroad, with similarly high proportions of nurses. With an estimated global shortfall of 18 million health workers by 2030, there is a need for a global response to the global health worker shortage. International co-operation is key to avoiding poaching of health workers across countries, which further weakens fragile health systems. The *OECD-WHO-ILO International Platform on Health Worker Mobility* can help advance our understanding of health workforce mobility and support dialogue on policy approaches to better and more ethically manage international health worker migration.

Developing harmonised approaches to health data governance is another important area for international co-operation. At present, health lags far behind other sectors of the economy in being able to harness data held in different databases. Over the course of the pandemic, despite a few, clear cases illustrating how effective data integration improves pandemic responses (such as in South Korea), there have been numerous cases of decisions made with incomplete or no data, and of many systems being unable to report data in real time. In 2017 OECD countries adopted an OECD Council Recommendation on Health Data Governance, which set out key principles for realising the dual goals of protecting privacy and data security, and making data accessible for surveillance, monitoring, clinical optimisation and research. Ongoing monitoring by OECD of progress in developing national health data governance, to enable data to be safely shared and accessed within and across countries, will provide impetus for countries to put health data to work and as a result, be better prepared to respond to future health crises.

One of the key lessons of the international response to COVID-19 relates to the supply of medical goods. In the early days of the pandemic, shortages of personal protective equipment, ventilators, and therapeutics were exacerbated by export bans. This highlighted the vulnerability of medical supply chains arising from the concentration of production capacity and sources of materials necessary for the manufacturing of certain products. Besides helping to shed light on this vulnerability, international collaboration should support identifying how best to adapt health, trade and industrial policies to ensure reliable and diversified global medical supply chains.

Finally, advances in genomics and the rapid sharing of sequencing data helped the development of COVID-19 vaccines in record time. The COVAX facility was established, with substantial European and other funding, to help support access to COVID-19 vaccines in developing countries. However, as of early May richer countries still held the vast majority of vaccine supplies. Not only is this inequitable, it is also short-sighted. Mutations of the virus, especially in those countries where the virus is spreading rapidly in the absence of effective vaccination, risk the spread of further variants for which existing vaccines offer reduced protection. Enhancing international co-operation to eliminate barriers that hinder the expansion of global supply and distribution of vaccines has never been more critical to save lives and support economic recovery.

EMA shapes up for its post-pandemic role

EMER COOKE

Executive Director for the European Medicines Agency.

These are exciting and challenging times. The public health emergency has brought medicines regulation into the public spotlight. Many had not even heard of the European Medicines Agency until recently or were not aware of what we did, but today I could have a wide-ranging discussion about the challenges of vaccine development and authorisation in any corner shop throughout the EU. When the unprecedented global crisis hit last year, EMA geared up into crisis mode. The Agency immediately re-prioritised its activities to support the fight against COVID-19 in the EU.

Pandemic prompted quick action

Now as ever, EMA's role is to evaluate the safety, quality and efficacy of the medicines and the vaccines that are used in Europe on a daily basis. The outbreak of the global pandemic brought to the fore how critical this role is for the protection of public health. When the pandemic first hit, there were many issues that needed to be addressed urgently in a coordinated manner across the EU. EMA rose to the challenge and worked with national authorities to deal with shortages of urgently needed intensive care unit medicines caused by both sudden disruptions to global supply chains, as well as the impact of lockdowns on clinical trials and pharmaceutical manufacturing. And most importantly, EMA reached out to developers of COVID-19 medicines and vaccines to help them speed up their development programmes. The Agency has given scientific advice on the development of 80 vaccines and therapeutics and interacted with developers on a total of 250 COVID-19 treatments and vaccines since the beginning of the pandemic.

To quickly address all urgent issues, EMA set up its COVID-19 pandemic Task Force as a new agile infrastructure, that facilitates the decision-making by EMA's scientific committees. In its work to counter the pandemic, EMA was guided by lessons learnt from the H1N1 pandemic in 2009. Processes were adapted to be as efficient as possible to review new medicines and vaccines. Under the rolling review procedure, new data is assessed as it is submitted rather than only once the developer can present all data and studies, as is normally the condition for a review by EMA. Once the formal marketing application is submitted, most data has now already been reviewed by the Agency's experts. These rolling reviews of evidence from clinical trials and other studies have speeded up the regulatory assessments considerably, which is critical in a crisis situation.

The rolling review allowed the Agency to recommend approval of four vaccines for use against COVID-19 in record time: Comirnaty by Pfizer/BioNTech, Vaxzevria by AstraZeneca, Moderna and Janssen. A number of other vaccines are under rolling review to broaden the choice for European citizens in countering the pandemic.

It was a historic scientific achievement to have a vaccine developed and authorised against a new disease in less than a year! In terms of therapeutics, one medicine (Veklury) is authorised on a conditional basis and assessments are ongoing for other treatments including with monoclonal antibodies, antivirals and immunomodulators, but more work is needed to achieve a real breakthrough for patients who have contracted the disease. Many new and old therapeutics are studied for the treatment of COVID. Given the promising new therapeutics currently in the pipeline, the aim is to possibly authorise another five medicines to treat COVID-19 by the end of this year.

Vaccine safety monitoring crucial

The monitoring of authorised vaccines is a big part of EMA's responsibility going forward. When millions of people receive vaccines as they are being rolled out in vaccination campaigns across the EU, rare events can occur that were not seen in the clinical trials. The role of EMA's safety monitoring is to rapidly detect and analyse any possible risks and their impact on the benefit/risk profile of the vaccine.

As with all medicines, vaccines are continuously supervised and controlled. All side effects must be reported to the regulatory authorities in the EU and in addition, for

COVID-19 vaccines companies have to provide EMA with more frequent monthly safety updates.

Suspected side effects from ongoing vaccinations are continuously reported. Regulatory authorities assess all potential safety concerns to determine if there is a link to the vaccines. EMA also pursues independent safety monitoring of the COVID-19 vaccines – an early prospective safety study in eight countries has begun and a larger prospective safety study, funded by the European Commission and coordinated in liaison with the European Centre for Disease Prevention and Control, ECDC, will start later in the year. The aim is to complement the data received from pharmacovigilance reports as a continuation of the large randomised clinical trials usually necessary for authorisation. EMA is also working closely with ECDC in monitoring the effectiveness of the COVID-19 vaccines.

Transparency about our scientific reviews is a top priority for EMA and within the Agency we are taking exceptional measures to ensure that the EU countries and the public have all the necessary information to safely roll out vaccinations. The publication of our assessment reports has been speeded up in order to provide an overview of the submitted data and the full rationale behind our recommendation for authorisation. The clinical data that has been submitted as part of the marketing application is also published. Once the Agency has granted a product marketing authorisation, it is valid in all EU countries at the same time.

A new dawn for medicines' regulation

The crisis has brought medicines' regulation into the spotlight – before, many EU citizens were not even aware of the regulatory body at European level. EMA is an example of a real EU success story because it demonstrates the value of working together and relying on each others' expertise. The Agency pools the expertise within Europe to respond to patient and public health needs. Patient groups are involved in many committees in order to evaluate what is needed from a patient perspective.

As the Agency completes its 26 years of service, it has become central to the von der Leyen Commission's push for a European Health Union. The pandemic response prompted a review of the Agency's role. The legislative proposal puts several of the structures and processes that EMA has established during the COVID-19 pandemic onto a permanent footing, which is an acknowledgement by the European Commission that EMA's response to the current crisis has been effective.

Moving beyond the current crisis, proactive engagement with the public is more essential than ever. There is a perception that EMA is under enhanced political scrutiny, but the sole driver for the Agency is to serve the European public. More vaccines are needed to cover the needs, in particular in the global context where many people are still waiting to be protected from the virus. But, the progress on COVID-19 vaccine roll-out in the EU member states has been incredible; Europe as a whole is doing a remarkable job on joint procurement, evaluation and roll-out of these vaccines.

Emer Cooke was appointed as the new Executive Director of the European Medicines Agency on 16 November 2020. She also holds the role of Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) for a term of two years. Ms. Cooke served as the Director for all medical product-related regulatory activities at the World Health Organization from 2016-2020, where she led the WHO's global work on the regulation of health technologies.

© European Commission

Creating a **safer** and **healthier Europe** by strengthening **ECDC'S** mandate

ANDREA AMMON
ECDC Director

The ongoing COVID-19 pandemic offers an important opportunity to learn lessons as to how countries - and international organisations - could be better prepared to deal with future outbreaks. Serious threats to health are inherently cross-border and lessons learnt so far from this pandemic underline the importance of strong international cooperation and coordination with partners at EU- and global level.

A legislative proposal by the European Commission aims to reinforce ECDC's capacity to support preparedness, surveillance, risk assessment, and early warning and response mechanisms, to help countries face future cross-border health threats. In parallel, a proposal for a new Regulation on serious cross-border threats has been announced, which would create a more robust mandate for ECDC when coordinating with the Commission and EU agencies.

These proposals would strengthen ECDC's capabilities in areas where it is already active, such as reinforcing surveillance systems through digitalisation. Preparedness and response activities would also be strengthened - for example, assisting Member States in developing preparedness plans against future epidemics. The new mandate would also enable ECDC to issue non-binding recommendations to Member States in relation to risk management.

Furthermore, the Centre's contribution to EU's international cooperation and global health security preparedness would be reinforced through the intensification and expansion of its collaboration with international partners and third countries. This would help them to strengthen their capabilities for implementation of the International Health Regulations (IHR).

In addition to boosting its existing activities, ECDC would move into a number of new areas:

- Setting-up an EU-level platform for the post-authorisation monitoring of vaccine safety and effectiveness, hosted jointly by EMA and ECDC;
- Creating an 'EU Health Task Force' to support countries in strengthening preparedness and be able to intervene rapidly in a health crisis at the request of an affected country;
- Coordinating a new network of EU reference laboratories for public health and a network of national services supporting transfusion, transplantation, and medically-assisted reproduction.

The full extent and the practical implementation of the proposed tasks and responsibilities are still under internal review, subject to the final agreement of the Member States and the European Parliament. Some of the key areas in the proposal will require substantial additional human and financial resources – for example, the reinforcement of surveillance systems (rapid digitalisation and integration), preparedness, training, and the Early Warning and Response System (EWRS).

Health system strengthening and capacity building in areas such as behavioural science, health economics and crisis management are key components to work on during the periods in-between pandemics and outbreaks. Although the focus is now on the current crisis, it is important not to neglect other issues, such as the spread of antimicrobial resistance and ensuring the continuity of immunisation programmes.

ECDC welcomes the European Commission proposals to amend its mandate and establish a new Regulation on serious cross-border threats to health to improve the EU health security framework. These initiatives would reinforce ECDC's role and capabilities in many key areas, ultimately creating a safer and healthier Europe that would be better prepared to deal with existing and future health threats.

The ECDC building in Stockholm, Sweden

Transparency as a strength - the **EU administration's** role in **health policy**

EMILY O'REILLY
European Ombudsman

The EU has a somewhat limited role in health policy - a fact often repeated at the start of the COVID-19 pandemic. However, the first lesson of the pandemic was that the intricacies of the EU division of powers matter neither to the border-crossing virus nor to citizens. In times of crisis, people simply want to know that public administrations are dealing efficiently and transparently with the problem before them.

The second lesson of the pandemic was that a lot of health-related decision making is - or at least can be - done at the EU level, involving the EU institutions and Member States together. In addition to decisions on the safety of vaccines; there were decisions on vaccine and personal protective equipment procurement, as well as on a major EU recovery fund.

From the outset, it was clear that a transnational crisis of this scale would severely test the capacity of the EU institutions. It was also clear that transparency and accountability would have to be the bedrock of any response in order to ensure public trust.

It is of course hard for the public to understand why vaccine contracts with global pharmaceutical companies - one of which had a damaging public dispute with the Commission - were not proactively published last year. It is also difficult to explain the reluctance to name the seven Member States involved in negotiating the contracts alongside the Commission. This led to the Commission alone being criticised about vaccine procurement in the EU - while the role of national governments in shaping and approving the contracts was rarely mentioned. This is not just about attributing responsibility, it is also about avoiding creating doubt among already anxious citizens about what kind of decisions are being taken.

The EU has two frontline agencies for public health issues: the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC). My office examined the work of both in 2020 as both as part of general monitoring of how key EU institutions dealt with COVID-19. In reply, EMA, which has had a centre-stage role in the EU's response to the crisis, explained it would maintain the accountability procedures it has in place in 'normal' times - essentially ensuring that the vaccine approval process is as independent and objective as possible. My proactive work in this area reflects the fact that agencies working in areas related to health have to do the utmost to prevent any perception that they are not working in the public interest. It is not enough for EU bodies - particularly those working in highly sensitive areas - to have internal rules on ethics, they must be seen to be implementing them. And I welcome the positive steps in terms of transparency by EMA.

My inquiry into the ECDC - set up in 2004 in the aftermath of the SARS outbreak to help to co-ordinate the EU response to a future and much more serious epidemic - was broader. This reflected reasonable expectations, given its title and mandate, that it would have a major role in any response to the pandemic. The reality was quite different however. The agency - small in terms of staff and budget - has little capacity to act independently and is entirely reliant on the good will of national authorities to get the data it needs to properly do its task of assessing and monitoring any disease.

This structural weakness came to the fore in 2020 when the ECDC was unable to properly carry out its mandate because it did not have access to the data it needed. All three of its main sources for information - an early warning system and a surveillance system to which national authorities provide data, and surveys carried out by the ECDC itself - proved to be inadequate.

A survey in spring 2020 on laboratory shortages, for example, resulted in only 9 of 30 national authorities responding. Similarly, there were large discrepancies between the number of COVID-19 cases reported to the surveillance database and the much higher numbers revealed by the ECDC's own epidemic intelligence screening. The inquiry also revealed other shortcomings related to how the ECDC presented the data it received - early on in the pandemic advice on wearing facemasks was changed with little explanation as to why, while certain surveys of member state capacity to deal with the crisis were published while others were not. Meanwhile, despite the pandemic being an issue of overwhelming importance to people, the agency's communication with the outside world tended to be geared only towards health experts and not the general public.

While the ECDC can make some improvements by itself - such as being more transparent and enabling greater public scrutiny of its data and assessments - ultimately it is up to EU legislators to reflect on its mandate. Without specific new powers to ensure the completeness and quality of the data it receives from national authorities, the ECDC cannot effectively fulfil its role of pan-European disease prevention and control.

Crises bring unprecedented levels of public scrutiny to governments and institutions. Decisions that may previously have been routine take on a new significance - in health crises they can have life and death consequences. The COVID-19 pandemic has been called the crisis of the century, and continues to have profound social, economic and financial consequences across the globe. In the EU it has prompted debate on creating a 'health union'. Whatever changes are made to the EU's role in health policy, the ability of EU institutions and agencies to act effectively will only ever be as strong as the trust the public accords them.

When in a **pandemic**, call on your **development bank**

THOMAS ÖSTROS

Vice-President, European Investment Bank

"Few natural hazards threaten more loss of life, economic disruption, and social disorder than large-scale disease outbreaks. An influenza pandemic could infect billions, kill millions, and reduce global economic output by trillions of dollars." These words from a 2019 World Health Organisation (WHO) report on Pandemic Preparedness Financing turned out to be visionary. The report found that investing in pandemic preparedness would protect societies and economies from significant losses. But it also pointed out that progress in creating and financing preparedness systems had been slow in non-crisis times – something that became painfully clear at the outbreak of the coronavirus pandemic.

When we think of pandemic preparedness, banks do not immediately come to mind. But the work of international financial institutions, such as the European Investment Bank Group, plays a crucial role in mitigating the economic impact of a pandemic and the ensuing public health crisis. For example, the European Investment Bank, the EU bank, is instrumental in providing a safety net for small and medium-sized firms affected by the crisis through the establishment of the European Guarantee Fund. The fund is tapping nearly €25 billion in guarantees from participating EU countries to provide loans, guarantees, equity financing and other financial instruments to bolster mostly small or mid-sized companies. The European Investment Bank is also an important financier of COVID-19 emergency measures and projects around the world. We have approved or are in the process of approving more than €11 billion in such financing since the start of the pandemic. These investments strengthen healthcare systems and services, support innovative life science companies in developing vaccines, tests or cures for the coronavirus and help fund global initiatives like COVAX, which provides equitable access to COVID-19 vaccines for people in low- and middle-income countries.

Financial groups like the European Investment Bank Group also help fill the market gaps inherent in public health care systems. Free markets sometimes struggle to allocate resources efficiently or take into account the social benefits garnered from certain investments. This creates market distortions, which arise when private investors fail to recover the costs of their investment despite generating an overall economic benefit for society. These gaps can result in a lack of resources for health care services, with serious consequences for individuals and communities alike. The European Investment Bank intervenes to plug these gaps, using financial instruments such as project investment loans, project financing, investment programmes and framework loans. When Spain was badly hit by the first COVID-19 wave, we provided €600 million to help the region of Madrid increase the capacity of its hospitals, intensive care units and emergency services. Earlier this year, we topped up our loan with another €200

million to support the region's vaccination programme and help it buy medical supplies and protective equipment.

The EIB Group doesn't just provide money. We also have a depth of technical expertise that can help design projects in a way that ensures their success. Thanks to a diverse and highly skilled team of doctors, natural scientists and health care professionals, the bank can check the financial viability and technical feasibility of financing proposals for projects. This expertise is particularly valuable for life science or innovative firms that traditionally have difficulty attracting private funding because their products are in the early stage. Risk aversion can significantly slow down innovation. BioNTech, the first producer of a successful COVID-19 vaccine in the western world, is a case in point. The company received European Investment Bank financing twice, €50 million for their cancer research in 2019 and another €100 million when it became clear that their mRNA technology had the potential to help prevent COVID-19.

The European Investment Bank was actively involved in vaccine research, development and manufacturing before the pandemic, working with global players such as the European Commission, the World Health Organization, the Coalition for Epidemic Preparedness Innovations, and the Global Alliance for Vaccines and Immunizations. BioNTech wasn't the only COVID-19 vaccine developer to receive our support. Curevac, another German mRNA pioneer, and the French immuno-oncology company OSE Immunotherapeutics also received loans from us.

In general, the pandemic resulted in record amounts of financing being raised last year for innovative biotech firms in the European Union. But the picture is deceptive. A 2018 study from InnovFin Advisory, one of our advisory services, anticipated a funding shortfall of €30 billion to €40 billion from 2017-2021 for life sciences companies in four representative European regions alone (Bavaria in Germany, Catalonia in Spain, Poland, and South East England). For decades, funding for European biotechnology firms was significantly lower than for their US peers. The average US company received five times more financing. Needless to say, this lack of funding hampers the development of a sector that is uniquely positioned to create value for our society and which lays the foundation for universal health and prosperity.

The EIB Group is in a strong position to help attract funding for health projects, particularly in the biotech sector. We have a toolbox of financial instruments that allow us to provide the financing start-up firms need to develop ground-breaking health solutions. Those financial instruments include equity financing, venture debt and classical debt financing as well as sovereign loans and guarantees. In many ways, our job is to identify the market failures that are holding back innovation and advancement and then to implement the financial tool that best manages risk and unlocks public and private funds.

In short, this is the role banks can play in pandemic preparedness and in addressing the world's major health concerns. And this is the role we, at the EIB, are strongly committed to play. In the end, providing funding for innovative health care solutions and novel pharmaceuticals, such as vaccines, protects all of us against future crises.

Towards a European Health Emergency Plan

VÉRONIQUE TRILLET-LENOIR

MEP (Renew Europe, France), Member of the ENVI Committee, Rapporteur for the European Parliament on the Regulation on serious cross-border threats to health

The COVID-19 pandemic has once again exposed the fragility of the European Union when it comes to public health.

Faced with this life-size test, our national health systems proved overwhelmed. This powerlessness led to our governments initially applying national protection measures as a reflex action.

However, this initial protectionist attitude soon gave way to enhanced European solidarity and coordination.

We are undeniably stronger together, but we still need to activate the available tools to respond to health emergencies of such magnitude. Adopted as and when health crises occur, these instruments do exist and are used side by side or in combination; however, reactive and efficient coordinated EU level action is lacking. The legislative package "Building the European Health Union" published on 11 November last, shows the European Commission's commitment to bringing coherence to our health crisis anticipation, preparedness, and response mechanisms.

This is a very good start, but we can go further. The regulation on serious cross-border health threats must become a European Health Emergency Plan.

As a hub for crisis management, this legislation will coordinate existing and future European health instruments, legislation, and agencies.

As a Rapporteur of the European Parliament, I fully support the new set of proposals put forward by the European Commission under this new regulation.

Several of these measures were strongly supported by the European Parliament's resolutions an updated Early Warning and Response System (EWRS), the auditing and stress testing of the national plans, the joint procurement of medical products, the training and mobility of health care professionals and, last but not least, stronger European health agencies.

Beyond these essential measures, I also warmly welcome the taking into account of climate-related threats, the building of a European network of reference laboratories and the possible introduction of an exclusive "European Union" clause in grouped purchasing contracts, which would put an end to national orders interfering with previous Community orders.

In some respects, I am convinced that the European Union could do even better.

Promoting solidarity in the European Union and beyond

The COVID-19 crisis has shown that no single country can tackle a global pandemic on its own.

Our priority must be to ensure "health solidarity" by reducing health inequalities between and within Member States. Every European must have the opportunity to enjoy the same level of protection against health threats and have access to the same health care and treatments regardless of the country they live in.

And our values of solidarity for fair and universal coverage of quality health services must also be promoted beyond our European borders: a strengthened cooperation with third countries in the exchange of knowledge and best practices on threat preparedness and response is essential. To this end, a robust, sustainable, and effective partnership should be established with international organisations and third countries, particularly in Africa.

Coordination at international community level is a major catalyst for all European actions as regards prevention, preparedness, and response to health hazards. That is why, in my report, I put a very strong emphasis on the need for international cooperation, supporting notably the development of an international treaty on pandemics to facilitate the implementation of the International Health Regulations.

Improved operational coordination at European level

The European Union must draw lessons from the crisis and seize this opportunity to establish an effective system to coordinate the European response to future threats of all kinds posed to public health.

The cross sectoral approach "Health in All Policies" must shape our entire crisis anticipation and management framework, whatever the nature of the crisis. The European Union must be prepared to respond to new pandemics or to any kind of environmental or chemical threats. This is why I am working to broaden the scope and instruments of the legislative proposal beyond the communicable diseases. The involvement of the various health agencies in the risk assessment of a threat is perfectly in line with this approach.

The fight against COVID-19 has revealed strengths and shortcomings in the European Centre for Disease Prevention and Control (ECDC) workings, in particular issues related to gaining rapid access to comparable data. We need to support Member States to ensure data collection and transmission in times of health emergencies. The data provided will enable the ECDC to carry out epidemiological surveillance at Union level. This surveillance could also be extended to the impact of communicable diseases on non-communicable diseases and population groups at risk. In line with its recommendations to Member States and health professionals, the ECDC could extend its communication to European citizens by establishing a portal providing verified information. This tool would further enhance the fight against disinformation.

Ensuring access to health products in Europe

The COVID-19 crisis has highlighted a long-standing observation: the European Union has become dependent on medical products. To address this dependency issue, a common approach is urgently needed.

The availability of medical supplies, the risks of shortages and the estimated production capacities for these products will need to be assessed in the context of the European and national crisis preparedness and response plans and their audits.

The European Union is stronger when it negotiates with the industry with one voice on behalf of all Member States. Grouped purchasing of medical products must be facilitated. This collective bargaining aims to ensure equal access for every European citizen at the same time.

The European Medicines Agency (EMA) plays a key role in health crisis preparedness and management and, as such, it should be given a much more prominent role than set out by the Commission in its legislative proposal. Its responsibility in marketing authorisation, in continuous risk assessment of medicines and management of shortages, should put the Agency on par with all other European agencies involved in the assessment of health risks.

Building inclusive health governance

This enhanced crisis preparedness and management system must be based on inclusive health governance.

The strengthening of the Health Security Committee and its working groups, the greater involvement of all European agencies and the establishment of the Advisory Committee on public health emergencies are steps in the right direction.

The COVID-19 crisis has also revealed that the European citizens wanted more transparency and participation in the decision-making process.

Hence, I am proposing that the European Parliament is given an observer role in the Health Safety Committee and that representatives of civil society, an important role in the Advisory Committee.

Beyond the decision-making aspect, the EU should involve all health authorities in the implementation of European and national crisis preparedness and response plans. These plans should foster greater cross-border health cooperation through interregional crisis anticipation planning.

Including regional and local authorities in this process will allow Member States to mobilise funding in a proportionate fashion according to their needs, notably facilitating partnerships in border regions with a view to sharing facilities as well as infrastructure and staff costs.

This legislative proposal, along with those on the revision of the EMA and the ECDC mandates, are the first steps towards a true European Health Union.

With a budget of 5.1 billion euro for the 2021-2027 period, the European Health Programme, EU4Health, finally gives us the means to prioritise coherence and efficiency in our health policy. Let us not miss this opportunity! The European people would not forgive us.

A **pharmaceutical strategy** for **Europe** to promote health security

SANDRA GALINA

Director General - DG SANTE, European Commission

Europe has always been a frontrunner in universal health, a global leader in healthcare research & development and a major trading partner in pharmaceuticals and medical technologies. However, the landscape is evolving rapidly. Digital transformation, scientific breakthroughs, globalisation, health system sustainability are some of the drivers bringing fast changes. Europe must lead the digital and sustainability transition and foster innovation for unmet medical needs. This includes ensuring that the current regulatory framework on pharmaceuticals and medical technologies meets EU patients' and health systems' needs, while allowing the EU to remain a global industrial leader.

To tackle these emerging challenges, the Commission adopted ,on 25 November 2020, a Pharmaceutical Strategy for Europe[1] to ensure that the European Union has sustainable access to affordable medicines and that the European pharmaceutical industry remains an innovator and world leader. The Strategy is a building block of the "European Health Union" put forward by President Von der Leyen, in her September State of the Union speech, reinforcing the EU's resilience for cross-border health threats[2].

The current COVID-19 pandemic is a daily reminder of the importance of health and a policy framework for medicines that delivers on a consistent basis. The crisis itself did not give rise to completely new problems, but it has highlighted existing ones as well as flaws in the system that can have grave consequences in a crisis setting. The crisis has taught us that we need to deal with such threats in a faster, more comprehensive and coordinated manner. It demonstrates the need to have a future-proof and crisis-resistant system to ensure access to safe, quality and efficacious medicines under all circumstances.

The impact of COVID-19 on the supply of medicines in the EU, in particular in stocks of intensive care unit medicines or increased demand of certain medicines, has shown the importance of anticipating, monitoring and managing the risk of shortages in a crisis, especially for critical medicines. Several existing tools and mechanisms such as advance purchase agreements, stockpiling, data pooling have been, and keep on being, reinforced through the crisis, and should be further operational permanently. Governance and preparedness become ever more relevant as part of a crisis-resistant system. A reinforced role of the European Medicines Agency (EMA) and the European Health Emergency preparedness and Response Authority (HERA), as proposed by the European Commission last autumn, will be instrumental. The EU has proven its benefit in coordinating, identifying potential treatments, diagnostics and vaccines, and alerting and mitigating shortages of essential medicines. The European Health Union package, announced on 11 November, will further reinforce EMA's mandate to effectively monitor and mitigate shortages. This will include a digital platform for reporting information regarding available stocks and shortages of medicines and medical devices. Inter-agency collaboration (between EMA, and other EU and national Agencies) is crucial for knowledge exchange and crisis management. HERA, on the other hand, will anticipate threats and enable technologies and countermeasures through investment in

1 COM/2020/761 final

2 COM/2020/724 final

public private partnerships. The Commission will adopt its proposal for this new Agency in the second half of this year.

The challenge of shortages is not only present at times of crisis. The Pharmaceutical Strategy commits to analyse the complex root causes of shortages and propose solutions. As a first concrete step, the Commission launched, on 26 February, a structured dialogue in cooperation with actors of the pharmaceutical supply chain to address potential vulnerabilities of the functioning of the global supply chain. The supply chains for many medicines are indeed long and the causes for shortages complex, therefore requiring holistic answers. Under the Pharmaceutical Strategy, the Commission will map the manufacturing capacity in the EU, analyse the root causes of shortages, as well as identify active pharmaceutical ingredients and the products that are critical from the point of view of public health and vulnerable from the point of view of supply. Such evidence-based assessment, to be notably discussed with the industry, will allow evaluating if the current framework is fit for purpose, and provide potential solutions to address the issue and design the system in a way that it is less prone to shortages.

The pharmaceutical strategy is not only a response to the issues highlighted by the COVID-19 crisis, but also a response to the need for creating a strong and future-proof pharmaceutical legislative framework.

COVID-19 has highlighted the need for a framework that enables innovation to develop therapeutics and vaccines. Besides, new generations of medicinal products, such as combinations of pharmaceuticals and medical devices, are testing our legislation. Our ambition is to develop a lasting legislative framework that benefits from digitalisation and reduces regulatory burden while continuing to ensure the quality and safety of medicines. The evaluation and revision of the EU pharmaceuticals legislation will consider how to make best use of new methods of evidence generation and assessment, such as artificial intelligence, the analysis of big and real world data to support the development, authorisation and use of medicines. A conducive regulatory environment through the planned creation of a European Health Data Space will support these transformations. Regulatory flexibility and "platform technologies" could benefit high quality, coordinated clinical trials supported by an EU-wide clinical trials network. Combined with simplification and streamlining of our regulatory processes, such changes will lead to overall better coherence and make the EU system more appealing.

The Pharmaceutical Strategy for Europe seeks to strike the right balance between market protection and data exclusivity that guarantee a return on investment for companies and the need to ensure that the resulting medicinal products are available across the EU. This system of 'incentives and obligations', as we call it, is a key part of the revision of the general EU pharmaceuticals legislation. The notion of 'unmet medical needs' is pivotal in that sense as it could define the areas where innovation could receive additional support. The ongoing review of medicines for rare diseases and for children under the Strategy contributes to our thinking.

Antimicrobial resistance (AMR) is another major threat, identified as such for many years, since it decreases our ability to treat infectious diseases. It is a multifactorial and global issue, with serious health and economic ramifications. The strategy will tackle the issue in two ways: measures to reduce their use and ensure appropriate use of antimicrobials, and measures to incentivise the development of new classes of antimicrobials.

The Strategy includes a sustainable dimension as it links with the Green Deal and sustainability goals. It aims, among others; to strengthen the environmental risk assessment of medicines and address the environmental challenges, in particular to address the AMR also from this angle.

Finally, the Strategy also ensures a strong EU voice globally, for which the ongoing cooperation with international partners at multilateral and bilateral level is key.

I want to stress that the Strategy sets out a long-term vision. 2021 marks the beginning of a process that will ensure the EU's pharmaceutical policy delivers and serves public health in an economically, environmentally and socially sustainable manner. Its success will depend on the commitment and contribution of all actors in the pharmaceutical value chain to build common ownership, and ultimately to contribute to the building of the European Health Union.

© Sanofi Pasteur

A new **public-private** collaborative approach for **stronger European pandemic** preparedness

THOMAS TRIOMPHE

Executive Vice President, Sanofi Pasteur, the vaccines division of Sanofi

In Europe's efforts to tackle COVID-19, the public health community came together to share its expertise and resources at a pace never seen before. While we collectively responded to the immediate crisis, we also began to lay foundations for what could be a new public health model for European pandemic preparedness and response in the future.

These new levels of public-private collaboration can become the path forward for bringing breakthrough science into standard medical practice in record time and at massive scale. By acting on key lessons learned in the last 18 months, including some of those outlined here, Europe can become the world leader in healthcare innovation and public health preparedness as a single and strong European Health Union.

A. Greater public-private collaboration to equip Europe for future health emergencies

COVID-19 brought the importance of the political power of the EU to the forefront of public attention. The European Commission acted on behalf of Member States to secure the block's supplies of COVID-19 vaccines for all EU residents. And most recently, Europe's leadership has announced the ambition to create a dedicated public-health emergency preparedness authority to better equip the continent and permit EU leadership of global health solutions.

The HERA Incubator

The future Health Emergency Preparedness and Response Authority (HERA), or the "European BARDA" will allow our region to be in a better position to compete for resources and innovative solutions when it comes to pandemic responses.

Initial work on the HERA incubator underway is encouraging, bringing together science, industry and public authorities to address ongoing public health needs out of the current crisis. This includes plans to invest in European capacity for the development and manufacturing of vaccines adapted to COVID-19 variants while working with scientific experts to look at the course of COVID-19 epidemiology over the long term. This is just the beginning.

The benefits of such a centralized and organized body designed specifically to the pandemic preparedness purpose could also extend beyond the continents' borders, by increasing the region's ability to contribute to answering global health needs as well as its own.

End-to-End collaboration

To unleash the full potential of HERA, Europe can enable new models of long-term, end-to-end collaboration between public and private sectors for fast, effective and equitable crisis response. Increased collaboration could cover all the stages of medicinal products' lifecycles, ranging from advanced stage research and clinical development to product manufacturing and procurement.

HERA could also play a key role in providing financial mechanisms that enable faster drug development and approval. These could include enhancing Europe's ability to pool resources and provide at-scale funding possibilities for the development and manufacturing of new vaccines or treatments that no Member State could achieve alone.

EU countries' preparedness and response plans

Complementary to HERA, the EU is best positioned to establish a Union-wide framework for national health crisis and pandemic planning. Such plans could be established by Member States' governments

© Sanofi Pasteur – Jean Fotso

and include comprehensive dynamics of pandemic preparedness including templates for diagnosis, vaccination and/or treatment deployment, re-allocation of healthcare infrastructures, management of supplies and logistics, and sourcing and training of more healthcare professionals.

B. **Paving the way to a European Health Union**

Beyond preparing for the next pandemic, I believe the broader EU ecosystem can evolve to foster faster, more seamless, equitable and therefore robust public health care for all Europeans.

Fostering EU strategic autonomy for improved health competitiveness

The COVID-19 pandemic has highlighted Health as a strategic sector. Strategic dependencies have been identified, as Europe lags other regions in bringing innovations and medical measures to the populations. There is absolutely no reason why the European Union could not become a world leader in the creation and delivery of innovative health sciences and technologies. Recent initiatives such as the EU industrial strategy are heading in the right direction, but this will need to be accompanied by short- and long-term steps to achieve an ambitious European Health Union.

In the short term, we can seek to foster EU-based industrial capabilities on key molecules and bioproduction, investments as valuable as the continent's green and digital transformations. This will require sometimes strategic decisions at both the Commission and country levels.

In the long run, we'll need to step-up our process for innovation in strategic fields such as mRNA technologies, gene cell therapies, and personalized medicines to embrace change in the healthcare paradigm, one that is led by smart, powerful new technologies.

Setting-up European data systems and surveillance

The current crisis has revealed the power of data and the urgent need to finally push forward a cutting-edge health data ecosystem. Data is clearly an essential asset in the improved management of public health both generally and in a crisis context. We can note several examples of this, from essential track-and trace digital tools to follow the spread of a virus in a population, to sophisticated real-time epidemiological data sets which scientists develop and share to more quickly understand a new disease.

And indeed, big data powered by artificial intelligence could already today help government decision makers and pharmaceutical companies to predict and anticipate epidemiological changes (i.e. emerging variants), against which they can adapt their solutions.

Extending EU agencies' mandates

The EU has recently proposed new regulation on Serious Cross-Border Health Threats that could equip countries with greater response mechanisms for future public health crises. We should go further by also reinforcing the role of EU health agencies in this context, namely, the ECDC and EMA.

The COVID-19 pandemic has shown the important role that the ECDC can play in risk assessments, surveillance, analysis of epidemiological information and recommendations for actions to prevent and control communicable diseases. We also saw that dialogue between EU agencies and the pharmaceutical industry was key to getting to initial support for pandemic response shared across Member States, including fast-tracking of essential new medicines and sourcing and supplying more existing medicines in the face of rapid and unexpected shifts in demand.

In conclusion, Europe can further strengthen and formalize its regulatory ecosystem in ways that make it predictable, adaptable, and enabling of globally competitive solutions.

On the journey ahead, we need to continue the dialogue on pandemic preparedness, starting with HERA and continuing with broader end-to-end collaboration across EC-level government, national governments and industrial partners. These are the foundations on which a great, resilient, and innovation-driven European Health Union can be built in the future, one that best protects the lives of the people of Europe and beyond.

Since the start of the fight against COVID-19, Sanofi has been engaged in a partnership effort in the research of two vaccine candidates. The first vaccine candidate, developed with GlaxoSmithKline (GSK), is an adjuvanted recombinant protein vaccine and the second is an mRNA candidate vaccine developed in collaboration with Translate Bio.

While the company's utmost priority remains to advance these two COVID-19 vaccine programs, Sanofi has also stepped forward to support increased supply of three other companies' approved vaccines to help bring and keep the pandemic under control as quickly as possible.

Affordable medicines for all EU citizens

NICOLAE ȘTEFĂNUȚĂ

MEP (Renew Europe, Romania), Member of the BUDG and ENVI Committees, European Parliament

The city of Padua in Europe is considered as the birthplace of modern medicine, but for all its medical prowess, Europe now stands more divided than ever, when it comes to health equity for all its citizens.

Whereas in many areas like economy or rights and liberties the EU is synonymous with solidarity, in terms of health we continue to stand divided.

There is still a persisting "Iron Curtain" with regards to health services, separating East from West, and although patients across Europe suffer from the same types of illness, they rarely have access to the same treatment options.

Ensuring equal access to affordable medicine for all EU citizens is not an easy task, and there are several big obstacles we need to overcome such as speeding the process of authorization of novel treatments, reducing frequencies of medical scarcity, improving medicine pricing mechanism and securing proper health infrastructure in all Member States.

Access to novel medicine is hindered by difficulties of market penetration of novel treatment due in part to unharmonized regulations in different Member States. This puts innovative companies in the position of seeking 27 market authorizations for the same product, making populous countries more attractive for industry to first seek authorization than less populous ones, which have a delay of up to 3 to 4 years in terms of medicine availability.

Digitalization and standardization of data required for market authorization across different A centralized approach to market authorization for novel medicines like the one used for the market authorization of the COVID-19 vaccine could go a long way to speeding up the process of placing invaluable and much needed medicines on the market and making them widely available for patients across the Union with life threatening conditions.

Member States can drastically reduce the bureaucratic burden behind the application process for authorization in 27 different countries thus ensuring that medicines become available at around the same time across the whole Union.

Fighting medicines scarcity is yet another major factor to health inequality and the rise of unmet medical needs. Some of the main causes for medicine shortages are disruptions in the supply chain due to "black swan" events like the COVID-19 pandemic or due to market practices such as market viability of efficient but low value medicine, or to parallel trade, which causes an outflow of essential medicine and manufacturing problems.

Securing access to medicine is of strategic importance and investing in a homegrown pharmaceutical industry as well as relocating production sites from third countries and diversifying supply chains so that critical disruptions are less probable are actions that we, in the European Parliament, want to see implemented.

Treatment adherence for patients fighting with life threatening diseases is crucial and we need to make sure that the burden of living with an illness is not increased due to unreliable access to necessary medication.

The lack of a comprehensive medical infrastructure is a problem that plagues mostly Eastern Member States, where investment in health infrastructure has been minimal in the past 30 years and where isolated rural communities lack reliable access to hospital and ambulatory specialist care.

Lack of access to healthcare means late diagnosis which in some cases translate to bad prognostics limiting treatment options or even putting patients in a situation where no treatment is available. Even when treatment is possible, adherence to it for long periods of time, especially for chronic diseases, might be almost close to impossible for patients living in these rural communities, preventable deaths rates being much higher in Eastern countries than in Western ones.

High medicine pricing is one of the driving factors for unmet medical needs due to high costs that neither patients, nor health insurances can afford to pay. In the past couple of years, the cost of novel anticancerous drugs has increased annually on average between 9 to 21 per cent. In a study published in the Journal of Oncology Practice by Ronok Saluja et al., the predicted main incremental anticancer drug cost increased from $30,447 in 2006 to $161,141 in 2015 (more than fivefold).

This trend is worrying since clinical benefits of these new medications did not improve at such a dramatical pace, sparking questions on the motives behind such increase in pricing.

When it comes to medicines pricing negotiations, there is a huge asymmetry between governments and the pharmaceutical industry, which clearly favors the latter, in terms of access to commercial information, the real costs of research and development and the cost of production. Furthermore, Member States compete to outbid one another in order to secure essential medicine and less powerful economies in Europe are finding it increasingly harder to finance in a sustainable way the expense on medicines.

Common Joint Procurement of innovative and orphan medicines, which tends to have higher costs, could be our answer to level the playing field with regards to price negotiation all the while ensuring equal access to medicine for all citizens regardless of the economic might of their native country.

We have seen this Joint Procurement mechanism in action during the purchasing of COVID-19 vaccines, without which today we would live in a Europe divided between those that have the vaccine and those that have not.

The future Europe of Health needs to be built on the need to secure equal and equitable access to treatment for all European citizens regardless of their nationality, putting patients above national political interests.

A **forward-looking public private collaboration** to fit with a new **vaccine** era

SIBILIA QUILICI

Executive Director, Vaccines Europe

History has a habit of accelerating at moments of crisis. The current pandemic is no exception. It has taken us to a crossroads in vaccine science and is a pivotal moment for European decision-makers. Europe has been the home of vaccine innovation and production for decades. In our fast-changing world, we need to think hard about how we work together to strengthen Europe's leading role in immunisation.

So, what's new? Let's start with technology. Vaccines made using mRNA technologies are the most impactful breakthrough of the pandemic. However, far from being an overnight success, the story of mRNA can be traced back decades and is marked by evolution rather than revolution. It is a story of investment and innovation which, catalysed by the crisis, has taken us to the start of a new era of discovery. Beyond COVID-19, the pipeline of new products and platforms shows real promise in a variety of disease areas.

These innovations create opportunities but also demand a fresh approach. At the heart of this is the spirit of partnership that delivered the safe and effective tools we need to exit our current crisis. It would be a mistake to draw a line under these unprecedented collaborations. Rather than thinking of it as a unified response to a sudden threat, we should view it as the blueprint for future successes.

Technologies are not the only things that are changing. There is a growing focus on the role of life-course immunisation and resilient health systems to protect population health. Existing vaccines for adolescents and adults against HPV, influenza, pneumococcal disease and shingles have real untapped potential to support these efforts, while researchers are working towards their next breakthroughs that could deliver new tools.

Vaccines Europe and its member companies are making a strong contribution to this common goal and we stand ready to do more. By driving scientific advances and engaging with others to translate this into national immunisation programmes, the industry is a vital resource in the EU's quest to reduce the impact of the infectious diseases we know today – and the ones that may emerge tomorrow.

Collaboration is key

To build on Europe's strong heritage in vaccine development and production, it is important that we foster a supportive environment. The European Health Union package[1], along with the European Pharmaceutical Strategy[2], could underpin a concerted effort to position the EU at the heart of the transformation that is under way.

For Vaccines Europe, collaboration is key. The challenges we are facing as a society are far too complex to tackle in silos: none of us can do this alone. We all need to work together to set objectives and find ways to deliver new innovations, in an early, timely and transparent way. We are calling for EU institutions, such as the European Centre for Disease Prevention & Control (ECDC), to establish regular dialogue with non-governmental actors, including vaccine manufacturers and developers, in an appropriate and structured way.

The vaccine ecosystem is far from simple. Indeed, as biological products, vaccines are considerably more challenging to produce than pharmaceuticals or industrial products. Regulating vaccines and distributing them through global supplies chains can be equally complicated.

We envisage intensified collaboration between industry and authorities at each step of the journey from the laboratory to the citizen. Outdated views of our industry are a barrier to closer cooperation. Over the past decade, the EFPIA Code of Practice[3] and Disclosure policies have raised standards across the sector, ensuring that company interactions with health professionals, healthcare organisations, and patient organisations respect the most stringent principles of professionalism and responsibility.

What is needed now are permanent ways to engage. We welcome proposals to reinforce the mandates of the ECDC[4] and European Medicines Agency (EMA)[5]. Regular, transparent, structured exchanges will all actors – including private ones – should be built into these fresh mandates.

1 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions "*Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats*", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0724&from=EN, Accessed on 18 May 2021.

2 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions "Pharmaceutical Strategy for Europe", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761&from=EN, Accessed on 18 May 2021.

3 EFPIA Code of Practice, https://www.efpia.eu/media/554677/efpia_codes_a5_v3-2021_sm.pdf, Accessed on 18 May 2021.

4 Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020PC0726&from=EN,

5 Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020PC0725&from=EN, Accessed on 18 May 2021.

Models for public-private interactions can be found at the Paul Ehrlich Institut in Germany, Public Health England in the UK, the US Centers for Disease Control and Prevention (CDC), and WHO's Scientific Advisory Group of Experts (SAGE) which advises on immunisation policies. In each case, these reputable public bodies enjoy the benefits of multi-stakeholder input without compromising their independence. Where there's a will, there's a way.

Step 1: Vaccine R&D

One of the most promising elements of the EU response to the pandemic has been the move to establish the European Health Emergency Preparedness and Response Authority (HERA). Modelled on the US Biomedical Advanced Research and Development Authority (BARDA), this public-private partnership is designed to equip Europe to prevent and fight emerging health threats. To be successful, HERA must collaborate closely with agencies, academia and industry, providing support for early-stage research through to licensure and manufacture.

Again, there are models of non-competitive public-private partnerships on which to draw. The Innovation Medicines Initiative (IMI) is a strong example of close cooperation for more than a decade, which delivered real results. Its successor, the Innovative Health Initiative (IHI)[6], will take this collaborative model to the next level. This is reflected in the European Commission's efforts to provide harmonised rules for efficient, flexible and ethical partnerships.

Step 2: Vaccines' regulatory approval

The record-breaking development and approval of several safe and effective vaccines against COVID-19 was only possible because research-based pharmaceutical companies and regulators stood shoulder to shoulder. Without cutting corners or compromising on safety, they streamlined a complex process to ensure trials were designed to answer regulators' questions and data was reviewed early. The European Medicines Agency's rolling reviews of vaccines are a case in point, while its active role in informing the public has raised its profile and supported vaccine confidence.

Step 3: Vaccines' production and supply

Anticipating vaccine demand is essential to ensuring adequate supplies. As seen during the flu vaccination campaigns in autumn/winter 2020[7], sudden surges in demand can leave citizens unprotected – even where supply has increased year-on-year. The nature of biological products is such that the tap cannot quickly be turned on further in a matter of weeks or months. Production decisions are made months – and sometimes years – in advance where additional manufacturing capacity must be built to meet demand.

That was a somewhat unique situation, but there are other factors – such as changes to vaccine recommendations – that can stimulate demand. Again, the solution is early and continuous dialogue between manufacturers and health authorities to better anticipate changes. Strengthening Europe's capacity to manufacture vaccines also brings clear benefits in terms of pandemic preparedness.

Step 4: The launch of a vaccine and inclusion in vaccination programmes

Health Technology Assessment (HTA) bodies and National Immunization Technical Advisory Groups (NITAGs) can play a key role in ensuring citizens have prompt access to vaccines that have been given the green light by regulators. National HTA bodies could step up their work on horizon scanning, early collaboration with vaccine developers, and HTA reviews. Meanwhile, engagement with NITAGs who recommend vaccines for their populations needs to occur early in the process, and information exchanged so that approved innovations can be available to those most in need.

Appropriate policies are needed to improve transparency, collaboration and coordination between decision-makers at national levels to ensure timely access to vaccines. National efforts are not enough – the EU can add real value here. By achieving greater consensus on standards and methodologies across Europe, more balanced and transparent evaluations can be conducted with greater efficiency and predictability. This will support broader access to new vaccines, helping to reduce inequities between Member States.

Step 5: Monitoring safety and effectiveness

We welcome the recent move by the EMA and ECDC to join forces to strengthen post-marketing monitoring of the safety, effectiveness and impact of COVID-19 vaccines[8]. Vaccines Europe is keen to engage in this initiative. Dialogue between industry experts and EU institutions can ensure efficient use of resources and state-of-the-art know-how.

Together, through the proposed new vaccine monitoring platform, we can devise ways to avoid duplication of effort in conducting phase IV studies that would align with EMA and ECDC requirements.

Engagement between EMA, ECDC and vaccine developers adds real value and synergies for the common good. We are already connecting with the EMA, ECDC and the COVIDRIVE Consortium[9] to identify synergies between requirements set out by the EMA and ECDC.

A lesson learned from the IMI Drive project[10] is that it is best to have all parties at the table. That project, which included 17 public and private partners and was supported by Member States, aimed to streamline post-marketing influenza vaccine effectiveness studies. Although the governance model was designed to safeguard the integrity of this work, and an independent scientific committee was established, the current ECDC mandate constrained its participation. This was a missed opportunity to ensure synergies and reduce duplication.

Conclusions

Vaccines are complex biological products delivering unique value in health and that are in no way comparable to other pharmaceuticals. They evolve across their lifecycle within a complex ecosystem, composed of multiple interconnected components and involving a community of public and private stakeholders that interact with one another and with the environment.

Close collaboration is key to ensure the ecosystem is balanced and Europe needs robust mechanisms for public-private engagement on vaccines. The fruitful partnerships that were the key to tackling the pandemic should be a role model for the future.

Not doing so would leave barriers to our ability to deliver value to citizens and patients.

The vaccine industry stands ready to build successful and sustainable collaborations for the benefit of public health.

6 https://ec.europa.eu/commission/presscorner/detail/en/ip_21_702, Accessed on 18 May 2021.

7 Joint statement on influenza season 2020-2021 and COVID-19 pandemic, https://www.vaccineseurope.eu/wp-content/uploads/2020/10/Statement-on-influenza-season-2020-2021-and-COVID-19-pandemic_October-2020.pdf, Accessed on 18 May 2021.

8 https://www.ema.europa.eu/en/news/ema-ecdc-join-forces-enhanced-post-marketing-monitoring-covid-19-vaccines-europe, Accessed on 18 May 2021.

9 https://www.drive-eu.org/index.php/2021/03/02/tenders-20212022/, Accessed on 18 May 2021.

10 https://www.drive-eu.org/index.php/project/what-is-drive/, Accessed on 18 May 2021.

Role-Players: The importance of patients in co-designing **Europe's future health systems**

MARCO **GRECO**

President, European Patients' Forum (EPF)

Pandemics have played a significant role in shaping human history throughout the ages. Few people reading this today will remember outbreaks on this scale, but history demonstrates that while devastating, the current COVID-19 pandemic is not without precedent. However, despite history's warnings, it still caught us off-guard and unprepared.

Having ravaged many countries socially and economically, healthcare systems across the world are still working tirelessly to contain the impact on people, despite the inefficient and inadequate available resources and systems organisation. Ultimately, COVID-19 has shone a harsh light on the unsustainability and known weakness of our healthcare systems and highlighted once again the importance of a stronger European public health policy designed to meet the needs of Europeans, beyond the pandemic.

Before this bombshell struck our daily lives and placed us in isolation, Europe was dealing with the significant challenge of delivering care for patients with serious, non-communicable diseases, and we still are. The impact on patients with such chronic conditions has not disappeared despite the pressing need to eliminate COVID-19. While the situation has improved 18 months on, many patients are still facing added uncertainties and concern for their lives as their anxiety grows around how long COVID-19 will continue to negatively impact their access to care for their conditions.

As the leading voice of patient organisations in Europe, we have collaborated with our members and patient advocacy groups across the continent to understand the patient perspective on the impact of the pandemic. The detrimental effects of the pandemic on timely access to treatment is confirmed by our findings with almost half of patients having faced treatment delay and many experiencing treatment discontinuation. Another important challenge faced by over a third of patients was the lack of clear information and communication from national authorities and healthcare providers on the availability and accessibility of healthcare services and treatments during the pandemic. Since March 2020, we have continually called for improved and more timely access to healthcare for patients, not hindered by misinformation or other barriers.

The pandemic saw Europe initially unready and quite fragmented on a communication level, but overall the EU reaction has been positive, and showed increased collaboration between member states and with EU institutions. EPF, with many other patient and civil society organisations, worked to provide as much clarity as possible during the pandemic with the respective communities. For instance, we established a cooperation with the European Medicines Agency (EMA) to promote and run public webinars on the COVID-19 vaccines, set up a dedicated resource center on our website and launched weekly newsletters to our members with information about ongoing studies.

With social media nowadays, it is much more difficult to deliver a scientifically checked message, while it takes 10% of the time for someone to produce fake news. The importance of clear, timely and accessible public health communications has never been more pertinent in our lifetime. While there must be an impetus to increase health literacy at a grassroots level, we can ameliorate current conditions by establishing clear communication channels between patients and their healthcare professionals.

Clear communication goes hand-in-hand with technology. We have learned from the past 18 months that that the uptake of technology can indeed be timely, when there is collective effort of motivation and mobilisation from all parties, so we must not remain complacent. We still have not seen a systematic collection or sharing of "best practice" alternative access solutions such as virtual consultations, automatic prescription renewals etc. This is an important area where the European Commission can support Member States, with the involvement of patient organisations. Digital transformation is already underway but to bring real value and true innovation, Europe's future digital health tools and systems should start from patients' priorities and be co-developed with patients.

The proposal of a European Health Union lays out important building blocks to enhance European resilience towards future health crises, increasing preparedness, monitoring and emergency responsiveness. From the patients' perspective, the current proposal should be considered as a starting point to build better healthcare for the benefits of all Europeans. The project for an impactful EU Health Union should go beyond crisis preparedness and cross-border threats. A true EU Health Union should be built on a wider structure, equipped with the right resources and instruments to address systemic challenges that affected patients during the pandemic such as access to quality care and treatment, miscommunication, and the digital transformation of healthcare.

Our vision is a Europe where patient organisations are valued partners in creating equitable, person-centered, accessible, and sustainable healthcare systems. To enable patient organisations to play this role effectively and independently, co-production needs to be built into all EU-level health-related initiatives. The EU absolutely cannot miss this opportunity to learn from the COVID-19 crisis and listen to European citizens and patients to build a European Health Union founded on their needs. Pandemics may have again demonstrated again their significant role in shaping human history but now it is time for patients to play their role in shaping the future of healthcare in Europe.

Mental Health – a **pandemic** we can prepare for

MARIA WALSH

MEP, EPP Group, Fine Gael Party (Ireland), Co-chair MEP Alliance for Mental Health

Mental health does not exist in isolation. Therefore, its management and treatment cannot be considered in isolation. Mental ill-health impacts every aspect of a person's life: education, employment, personal relationships, consumption behaviour, access to healthcare and social services. By not approaching mental health as a holistic priority area, we risk creating a two-tier society where only those privileged few who are in a position to manage their mental health effectively are able to thrive and those who are not able to manage their mental health are left behind. It is only by making mental health a priority in every area of policymaking that we can offer real solutions to people's real problems.

Mental ill-health presents a major challenge to the well-being of our society, and the strength of our economy. It hinders and can destroy lives, traps people in poverty and prevents our countries from harnessing the talents and potential of hundreds of thousands of people. I have seen this first hand. Within a 20 to 30 mile radius of the small village where I live in Ireland, 20 people have died by suicide in the last decade. While we are making slow progress in policymaking that can affect real change on the ground, we have to think laterally, across sectors and policy areas to find holistic solutions for Europeans' whole lives.

European governments are slowly responding to citizens' needs for effective mental health care within their healthcare systems. But little thought or action has been given to preventative or integrated care within other sectors. Recent research from Koa Health in the UK has shown that mental health is not a "cultural priority" for 43% of employers. This admission came despite 56% of organisations witnessing a rise in demand for mental health support from their staff.

The COVID-19 pandemic has shown us a glaring need to reflect on how we develop policy relating to mental health. The European Commission, for example, has granted €33 million under Horizon 2020 to fund research on behavioural, social and economic impacts of the outbreak response. One of the funded projects, RESPOND, aims to identify vulnerable groups affected by the pandemic and evaluate its impact on mental health and well-being. We must capitalise on the current momentum. This is why we have started a call for a dedicated 'EU Year of Good Mental Health', to raise awareness of all aspects of mental health policy, encourage debate in our Institutions and in our Member States and, change the prevailing attitudes towards mental health across the EU.

This EU Year of Good Mental Health would send a strong commitment and political signal from the EU institutions and member governments that mental health will be taken into consideration in future policymaking. Taking the words from Commissioner Kyriakides to ensure 'mental health is threaded across many policies'. We must make mental health everyone's business.

At European level, more and more politicians and leaders are putting Europeans' mental health at the heart of policy areas that would not have previously considered mental health within their remit. The employment directive on the Right to Disconnect is an excellent example of a modern solution. This policy spans the areas of employment, technology, economy, civil liberties, and health. This is how we should be tackling mental health policy: with cross-sectoral input, private and public cooperation, and innovative ideas that benefit more than just the social and healthcare sectors.

We have a unique opportunity to adjust our policies for the 'new normal'. Some things will never return to the way they were, like the nature of work. It is essential that all EU policymakers, including us MEPs, look at our future policy work through this lens. We need to rethink our current policies if we are going to solve the mental health crisis that the pandemic has triggered. Even more than treatment or preventative healthcare, we need policies that tackle the root causes of mental ill-health: poverty, deprivation, discrimination, unemployment, lack of educational opportunities. These are the biggest determinants of our mental ill-health.

We, as policymakers, must remain accountable on mental health and bring real-life solutions to our citizens within a health programme that considers mental health as important as physical health. The primary objective for my work on mental health within the European Parliament, is calling for the development of a comprehensive and proactive EU Mental Health Strategy, taking into account the cross-sectoral impacts of different policies on mental health. By doing so, the EU can improve the lives of millions of Europeans – inclusive of those affected by mental ill-health, their families, and the services and supports who care for both. Contributing to a stronger economy, social cohesion and sustainable development.

Without mental health we cannot have a solid health base. Mental health does not see borders, or a person's skin colour, or orientation or gender. It does not see where one community starts and ends. It is our citizens that are at risk if we don't get this right. Mental health is everyone's business.

How to further engage **European citizens** to improve the **health system** and make it more **resilient** and **efficient**

MARIANO VOTTA

Responsible EU Affairs at Cittadinanzattiva, Director Active Citizenship Network

The WHO has defined community engagement as "a process of developing relationships that enable stakeholders to work together to address health related issues and promote well being to achieve positive health impact and outcomes"[1], and it underlines the "Community and civil society engagement" as a pillar of its "Global Action Plan for Healthy Lives and Well-being for All"[2].

Twenty years ago, in the process of defining the European Charter of Patients' Rights – drafted by Active Citizenship Network together with organizations from 15 EU countries –, the right to participate in policymaking in the area of health[3] was emphasized as a right of active citizenship.

More generally, across the world, it is strongly believed that there is a clear added value in strengthening cooperation among all relevant public and private actors at local, national & European level, including health authorities, healthcare professional, the Scientific Society & Academia, the industry, research and innovation centers, providers, and the media.

For Active Citizenship Network, the EU branch of the Italian NGO Cittadinanzattiva, a civil society organization that works to reduce inequalities, protect patients' rights and promote civic participation in the policy-making process at all levels, there are three major pre-conditions that need to be underlined when considering citizens' involvement for improving the health system: a long term strategy instead of a spot initiative; an approach of "General Interest", because it is only by protecting the general interest that particular interests are also safeguarded; and the need to guarantee a leading role to the people, the communities, intermediate bodies such as Patients' Advocacy groups (PAGs), citizens organizations involved in healthcare issues and, more generally, all actors that promote health as a common good. This is crucial now more than ever, in order to better address the consequences of the Covid-19 outbreak. Consequently, we have decided to devote the 15th European Patients' Rights Day[4] (planned 5 & 6 May 2021)[5] to show and discuss good examples of citizens' engagement in health policies in this particular historical moment.

The above-mentioned statements contradict the unfortunate reality that there is no record of citizens' involvement in the "Proposal for a regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU"[6]. In this regard, Cittadinanzattiva/Active Citizenship Network welcomes the European Commission's proposal for a stronger and more comprehensive legal framework to react rapidly and trigger the implementation of preparedness and response measures to cross-border threats to health across the EU. However, the proposal reveals a serious gap which proves as completely unjustified in light of the lessons that we should have learnt from

1 WHO: "WHO community engagement framework for quality, people-centred and resilient health services", https://apps.who.int/iris/bitstream/handle/10665/259280/WHO-HIS-SDS-2017.15-eng.pdf.

2 WHO: "Stronger Collaboration, Better Health: The Global Action Plan for Healthy Lives and Well-being for All", www.who.int/initiatives/sdg3-global-action-plan.

3 Active Citizenship Network: "European Charter of Patients' Rights": www.activecitizenship.net/files/patients_rights/charter-of-rights/sites-which-host-the-charter/EUROPEAN_COMMISSION.pdf.

4 Active Citizenship Network: "European Patients' Rights Day 2021": www.activecitizenship.net/patients-rights/projects/382-european-patients-rights-day-2021.html.

5 To join the conference titled "The role of civic society and Patients Advocacy Groups for more resilient Health Care Systems. Lessons learned toward a European Health Union), please register here: https://zoom.us/webinar/register/WN_DS86m3cqSkGmTZ0oa9EgiA.

6 EU Commission: "Serious cross-border health threats – stronger, more comprehensive rules": https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12795-Serious-cross-border-health-threats-stronger-more-comprehensive-rules.

the pandemic: in the document there is no reference to the role and involvement of actors of the civil society and Patient Advocacy Groups (PAGs) that could be engaged in the management of serious cross-border threats to health, in support of the institutions, and for the benefit of local communities.

An action managed by the EU Commission, such as the one described in the Proposal for Regulations of the European Parliament and of the Council on serious cross-border threats to health, in compliance with the path indicated by the President of the European Commission towards building the European Health Union, cannot fail to directly address the European population as well. The European institutions must feel the need of "ferrying" European citizens towards this necessary awareness (i.e., in terms of global health and its main threats, a "one health approach", etc.), which is fundamental to build the European Health Union, announced by President von der Leyen in her State of the Union address on 11 November 2020.

PAGs and civic society organizations play an important role in bringing out the needs of particular populations and specific categories of patients, who must therefore be recipients of priority attention, as well as receive timely information from competent health authorities. Authorities that should benefit from the aforementioned associations to disseminate specific information necessary to ensure, for example, the essential continuity of care for patients in need.

Because of the COVID-19 pandemic, 20 years of progress in terms of prevention were put at risk when screening and vaccination services were delayed or suspended during the pandemic, with inevitable consequences on the health of many individuals. To limit these "indirect" effects of the pandemic, it is crucial to make up for the time lost in terms of prevention as soon as possible, which requires a strong investment also in information & citizens' empowerment, an essential element of any long-term strategy to make the health system more resilient and efficient.

Improving patient survival and quality of life through an effective European Health Union

ANTONELLA CARDONE

Director, European Cancer Patient Coalition (ECPC)

Over the past decade, the number of cancer survivors has increased substantially, and with an ageing European population and increasingly effective cancer therapies, the number of survivors is only projected to rise. Yet, cancer survivorship can be a lifelong struggle and almost all EU countries lack adequate policies to ensure rehabilitation and smooth reintegration of cancer survivors into social and professional life. The end of cancer treatment does not signal the end of cancer care. In this survivorship phase, patients' wellbeing must be considered, not only long-term physical effects of treatment, but also psychological, social, and economic needs.

Cancer survivorships consist of three main pillars: medical or clinical aspects, socio-economic aspects, and legal and political aspects. Each of these pillars has a series of challenges that need to be addressed.

The first pillar includes medical and clinical aspects. Cancer-related complications and comorbidities add a significant burden on patients across Europe and are in many cases fatal. There is a need to alleviate this burden through better risk assessment and treatment as cancer-related complications and comorbidities have an impact on quality of life, cancer treatment and its efficacy as well as survivorship. An important matter that needs further consideration is that In Europe cancer survivorship research is usually not integrated into activities related to cancer although it should be an inherent aspect. Furthermore, there is a lack of data intelligence to prioritize cancer survivorship research, thus, robust data should be used to identify the existing research gaps in survivorship. When prioritizing the cancer survivorship agenda, survivors' needs must be reflected and be the focus. However, it is important to state that this should be carried out with an integrated approach as research needs to be done in cooperation with all partners involved (including international collaboration). Research must be both inter-disciplinary and patient-centred and it needs to include assessment of the wellbeing of cancer survivors. Research programmes in the field of cancer survivorship ought to be not only patient-centred but also age-adapted to meet the need of children, adolescents, and adult survivors. A European Cancer Survivorship Research Plan should be developed to share best practices, promote research and innovation, and support the 70:35 vision (an average of 70% survival is to be achieved in Europe by 2035). Research activities in palliative care should also be promoted.

Regarding the second pillar, socio-economic aspects present challenges related to inequalities, Quality of Life, and support. One of the main challenges is the lack of knowledge on social determinant of cancer inequalities which have an impact on cancer survivorship (specially in Central and Eastern Europe). So, analyses should be conducted in order to examine the impact, address patients' needs and inequalities more broadly. We also lack data concerning the economic burden of cancer for survivors so the implementation of economic evaluations should be considered, and new research tools would examine the QoL of cancer survivors. The absence of data on the impact and cost effectiveness of interventions for cancer survivors is one of the challenges. To this end, cancer survivorship research should be integrated into all National Cancer Control Plans (NCCP) in which caregivers and family members should also be contemplated. Overall, there is lack of support for cancer survivorship research at European level and social issues are usually not combined within cancer survivorship research. Research on social issues should be implemented to attain greater stability considering patients' health needs and work and social needs.

Lastly, the third pillar includes the legal and political aspects. It is important to emphasize the promotion of studies on legal aspects of discrimination for cancer survivors as well as the analysis of legal provisions stimulating essential elements such as reintegration, quality, and social inclusion. In this regard, the Right to Be Forgotten needs to be highlighted: once the cure of cancer is declared, patients should be back to their lives, as other people of similar age and socio-demographic characteristics with no cancer diagnosis. Moreover, the above-mentioned European Cancer Survivorship Research Plan should be incorporated to the European Cancer Mission with the 70:35 vision. Research programmes should define the existing stigmas linked to cancer to advocate for a change so that survivorship is at the centre of the stage. Cancer survivors have the right to return to normal life and therefore guidelines on the way survivorship is organized ought to be developed, good practices need to be promoted and patients must be and feel empowered.

Health inequalities in the European Health Union

DR MILKA SOKOLOVIĆ

Director General
European Public Health Alliance (EPHA)

Due to their restricted access to basic rights, the COVID-19 crisis has disproportionately hit vulnerable population groups. Existing socio-economic disadvantage and greater exposure to unemployment, poverty and poor health has been only exacerbated by the pandemic[1], leading to higher mortality rates and risks of complications from increased prevalence of co-morbidities,[2] emphasizing once again the disastrous impact of health inequalities. Nevertheless, despite the evidence demonstrating the greater public health and socio-economic impacts on vulnerable groups, health inequalities have received insufficient attention from policy makers. The issue remains under-addressed in major EU policies aiming to mitigate the effects of the pandemic on European societies and economies, which threatens to leave long-term consequences on health equity and social fairness across the EU.

Reacting to the severity of COVID-19 crisis, and aiming to strengthen coordination between European countries in the context of cross-border health threats, the European Commission has launched a proposal for a European Health Union. The initiative seeks to support Member States through specific policy and financial mechanisms, to positively impact access to essential health and prevention services, medical supplies, and treatment of non-communicable diseases, showing a notable political will to ensure better protection of people's health. It does not, however, seem to allocate sufficient investment in health inequalities despite their systemic and cross-border character, spurring the development of a growing public health challenge.[3] Examples include a missed opportunity to invest in equitable distribution of COVID-19 vaccines, and to seriously address the needs of disproportionately affected communities, along with the structural barriers that they face (beyond the exclusion from national vaccine deployment strategies).

Systemic health disparities impacting the quality of life of entire communities remain a severe obstacle for the achievement of the proposed European Health Union's objectives. The exclusion of these communities from primary healthcare services and national and European crisis response strategies has already generated a heavy burden on national economies[4], and in the absence of comprehensive European initiatives, will only continue to hamper the resilience and capacity of our healthcare systems. Consistently addressing health inequalities in major European policies would be in line with principle 16 of the European Pillar of Social Rights[5], and would help lessen the societal, public health, and economic burden.

The European Health Union should look holistically at the resilience of public health systems, and advance integrated policy measures prioritising health equity in EU and national policies. Better developed information, vaccine, and healthcare delivery channels should be identified to address the needs of marginalised populations in global health emergency preparedness and response planning. Making tackling health inequalities one of the top political priorities of the European Health Union is a key prerequisite for achieving its main aims – reinforcing health systems, ensuring their resilience, and building EU preparedness for upcoming health crises.

1 https://ec.europa.eu/health/sites/default/files/state/docs/2020_healthatglance_rep_en.pdf

2 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00949-1/fulltext

3 https://epha.org/wp-content/uploads/2019/12/epha-health-inequalities-a-public-health-challenge-for-european-policy-makers.pdf

4 https://fra.europa.eu/en/publication/2015/cost-exclusion-healthcare-case-migrants-irregular-situation

5 https://ec.europa.eu/commission/presscorner/detail/en/ip_21_820

© Humphrey Muleba on Unsplash

Prevention is the best cure - A plead for a **European health union** to **solve medicine shortages**

JAN HUITEMA

MEP, (Renew Europe Group/Netherlands), Member of the Committee on the Environment, Public Health and Food Safety

The Covid-19 pandemic made it painfully clear that shortages of medicines are heavily connected to the EU-Asian trade: 80% of the raw materials needed to create our active pharmaceutical ingredients (APIs) come from China and India. The current health crisis uncovered a problem that several European member states already identified. If we look at the Netherlands, but also in other European countries, we see a clear indication of rising shortages in medicines: official reports from the government body showcase that the number of shortages almost doubled every year since 2017. We are not only receiving alarming reports regarding shortages of everyday drugs such as paracetamol, but also for birth control pills, medicines to support the thyroid, several antibiotics and an inhibitor against Parkinson.

At this moment, the Dutch government is doing everything within its power to increase its supply in medicines. The scaling up of the 'iron stock supply', as they call it, from three to five months could redress 85% of all the medicine shortages. Yet, this is not a structural solution and this stock supply could lead to shortages elsewhere in the European Union. As always, prevention remains the best cure. How can we ensure that these shortages don't evolve in the first place? The dependency on third countries for the delivery of raw materials and the ongoing shortages, require a proactive European approach.

The pharmaceutical strategy, released by the European Commission in November last year, is a first starting point and could be considered as a next step towards closer European cooperation on public health. One of the objectives of the Pharmaceutical Strategy is to improve affordability, access and availability of medicines in Europe. At the heart of this agenda lays the diversification of the sources of supply for essential medicines and APIs and the reinforcement of manufacturing capacity within the EU, where possible. Action is required, given the trend where production of APIs and essential medicines is gradually moving outside of the European borders, exposing Europe's issue of supply dependence once more. This debate is highly necessary to ensure the manufacturing resilience of the pharmaceutical industry within the European Union.

Although the reasons for Europe's loss of manufacturing capacity are numerous, it is strategically important to identify and address each one of them. The

pharmaceutical strategy underlines the need to have a good understanding of the current supply situation and its impact on the availability of medicines in the EU, as well as the need for clear policy directions to support a sustainable, predictable and flexible environment to secure supply of high quality medicines in Europe.

On top of the resilience of the manufacturing capacity, there is also a need to invest in and expand the innovation capacity of the European Union. This is the second pillar of the pharmaceutical strategy and is necessary to support the development of high quality, safe, effective and greener medicines. Expertise and research, development and innovation are the core strengths of European companies and should be kept at the heart of the industrial competitiveness of the EU.

To solve the problem of medicine shortages, the pharmaceutical strategy alone will not be sufficient. We are also in desperate need to know of the results of the long-awaited study that the Commission is launching later this year to map out the main issues of medicine shortages. What is the scale of the problem of medicine shortages and how can we detect - and prevent - the vulnerabilities in the international supply chain?

Currently, several member states have a different approach when it comes to the definition of medicine shortages. France puts a drug on the shortlist when the delivery has a delay of 72 hours, while the Netherlands report a shortage when there is uncertainty of delivery after 14 days. The different approaches make it nearly impossible to enable a well-functioning system to deal with medicine shortages. Furthermore, these different approaches disable the capacity to make a correct estimation of the size of the problem in the shortages of drugs. Together with my liberal colleagues in the European Parliament, we are calling for a clear-cut definition European-wide.

Not only do we welcome a uniform definition, we need to monitor the supply chain more closely and improve our knowledge and insights in its vulnerable connections by creating a stronger European monitoring mechanism. It is not rocket science what we need: we already have the European Medicines Agency (EMA), why not reinforce its capacities? As our responsible European Agency, EMA already possesses the expertise and the intelligence to perform this duty. The only thing the agency lacks is the mandate.

This reinforced role of the EMA would be helpful in developing an understanding of our interdependency within the international value chain. At this moment, manufacturers of medicines are not obliged to render information on (potential) obstacles within their production process, or even the location where the manufacturing is taking place. This way, it is nearly impossible to track where our medicines are coming from. This enforced monitoring system could improve the transparency within the international value chain of the drug production.

Together with the European Agency, the European Parliament is ready to become a proactive voice within the debate on medicine shortages, but it is up to the member states to establish a European Health Union. Our patients demand resolute action and more transparency; it is now up to us, the policy makers, to deliver.

Note: **On 22nd June 10h-12h, Renew Europe is hosting an open webinar Manufacturing Resilience in Europe- Availability of Medicine. More information can be asked via** jan.huitema@europarl.europa.eu**.**

ANDERS SCHIERMER

Vaccines Policy & Patient Engagement Director, Mid Europe, MSD

The **European Health Union**: Why a Shared Vision for **Immunization beyond pandemic** times is needed

With discussions ongoing regarding the creation of a European Health Union, it is time to put routine immunization and other preventative services at the forefront of the pandemic recovery and post-pandemic European health systems. Immunization has a key role to play to protect EU citizens, now and in the future; vaccines are one of the most cost-effective public health interventions providing proven social and economic returns across all stages of life at both the individual and societal level.[1] Apart from safe water, no other public health intervention has had a greater effect on overall mortality reduction and population health than vaccines.[2]

In response to the impact of the pandemic, EU Commission President Von der Leyen called on Europe to build a European Health Union in her 2020 State of the Union address. Efforts are underway to update and reinforce the mandates of the ECDC and EMA and create a new European Health Emergency Response Authority (HERA).

Investing in prevention including immunization can have a positive impact on the overall healthcare budget and, as seen with the COVID19 pandemic, on the economy and societal well-being. The public health impact of vaccination strengthens and sustains health systems, directly and indirectly. On average, EU member states spend less than 3% of their health budgets on prevention and less than 0.5% on immunization.[3] Underinvestment in immunization programs leads to gaps in the fully reimbursed public immunization schedule and is one of the drivers of falling vaccination coverage rates. EU member states provide varying levels of access to vaccines through publicly funded programmes, particularly when it comes to adolescent and adult vaccines. Fewer countries achieved 95% coverage of the second dose of the measles vaccine each year between 2007-2017 leading to an increased number of cases and outbreaks across the region.[4] Flu vaccination coverage rates across member states are well below the EU Council's recommended 75% target, costing EU27 countries an estimated €190 to €226 million annually.[5] Vaccination is an investment, with wider benefits that accrue across a lifetime. For example, every €1 invested in adult vaccination starting at age 50 would yield €4.02 of future economic revenue for the government over the lifetime of the person[6]. Immunization budgets need to be dynamic, integrating demographics and new vaccines that may become available.

As the COVID-19 pandemic has made painfully clear, member states are all vulnerable to communicable disease outbreaks and cannot solve common challenges in silos. A more coordinated approach to strengthening and financing immunization programs that can deliver for EU citizens is needed.

The European Commission and the ECDC in particular can play this role of greater coordination and support to member states encouraging more sustainable and smarter immunization financing and other important public health programs with cross-border implications. Immunization financing decisions lie at the level of member states, however, as stated in Article 6 TFEU, the EU has a limited, supplementary competence in the area of the protection and improvement of human health. This competence enables the EU to adopt "actions to support, coordinate or supplement the actions of the member states". This support and coordination could be strengthened by:

1. **Establishing shared definitions:** Provide guidance for member states on what a sustainable and strong immunization program should entail. Establish a shared vision for national/regional preventative services that deliver efficiently as part of resilient health systems.

1 World Health Organization. 2015. How to present the wider societal benefits of immunization. Copenhagen: WHO Regional office for Europe 2015. Accessed April 2021. Available at: www.euro.who.int/__data/assets/pdf_file/0020/281522/How-present-wider-societal-benefits-immunization-.pdf?ua=1.; Ozawa S, Clark S, Portnoy A, et al. Return on investment from childhood immunization in low- and middle-income countries,2011–20. Health Aff. 2016;35(2):199-207.

2 Pollard, AJ. 2007. "Childhood immunization: what is the future?" Arch Dis Child, vol 92:426-433.

3 Gmeinder, M., D. Morgan, and M. Mueller. 2017. "How much do OECD countries spend on prevention?" OECD Health Working Papers, No. 101. Paris: OECD Publishing. dx.doi.org/10.1787/f19e803c-en.
Pascaline Faivre, Goran Benčina, Rosanne Campbell, Sibilia Quilici, Nicolas Dauby, Goran Tešović, Paolo Bonanni & Rosybel Drury (2021): "Immunization funding across 28 European countries", Expert Review of Vaccines, https://doi.org/10.1080/14760584.2021.1905257

4 ECDC Coverage reports. Accessed May 2021. Available at: www.ecdc.europa.eu/en/all-topics-z/immunisation-and-vaccines/vaccination-coverage.; WHO. 2019. "Measles – European Region". Emergencies preparedness, response. Accessed May 2021. Available at: www.who.int/csr/don/06-may-2019-measles-euro/en/.

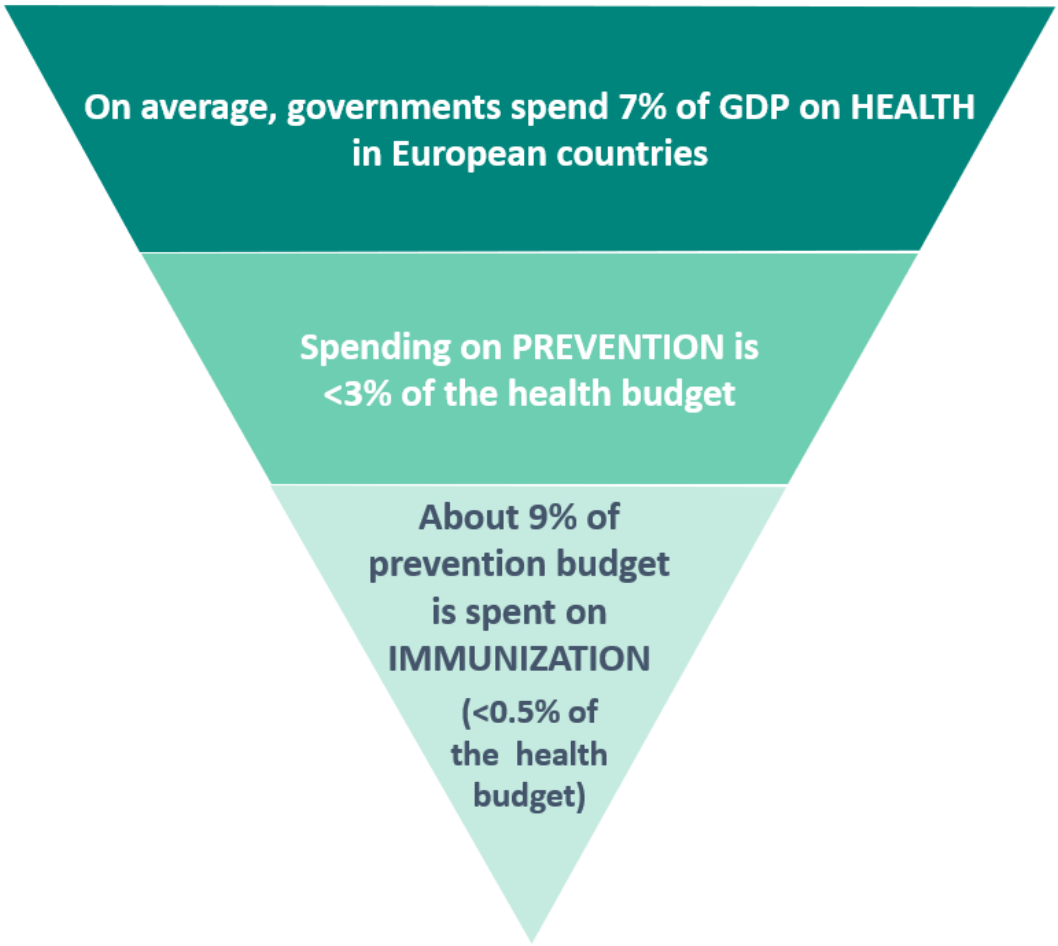
5 Preaud E, Durand L, Macabeo B, Farkas N, Sloesen B, Palache A, Shupo F, Samson SI, & Vaccines Europe influenza working group. 2014. "Annual public health and economic benefits of seasonal influenza vaccination: a European estimate". BMC public health, vol 14(813). doi.org/10.1186/1471-2458-14-813.

6 Supporting Active Ageing Through Immunisation. Adultvaccination: a key component of healthy ageing. The benefits of life-course immunisation in Europe. Supporting Active Ageing Through Immunisation; 2018

2. **Collecting and sharing information on vaccine coverage rates across the life-course:** There is currently no structured approach to tracking vaccine coverage rates at EU level. Though studies are done to track changes in coverage for certain vaccines, the data collected cannot be easily comparable. Efficient surveillance systems and detailed monitoring of vaccine coverage are vital to predict the risk of vaccines preventable diseases outbreaks. The revision of the mandate of the ECDC is an opportunity to improve the monitoring of vaccination coverage by member states, develop initiatives and tools to expand vaccination coverage across Europe and improving the quality and availability of data.

3. **Provide funding for structural investments:** like the EU4Health programme, the Recovery and Resilience Facility (RRF) and others mentioned in recent policy documents such as Europe's Beating Cancer Plan, EU funded instruments constitute an important step in accompanying structural changes at national level, in particular when aimed at strengthening prevention systems structures. The European Semester process could be the vehicle to encourage prevention in member states, building on the RRF spending now aligned with the country specific recommendations.

As the EU is putting resources together to recover and learn from the COVID19 pandemic, there is an opportunity to look at how sustainable immunization programs in a post-pandemic era could help deliver on the objective we are setting collectively: building a stronger and more resilient union, and a healthier and prosperous society.



SUSANNE **KEITEL**

Director at European Directorate for the Quality of Medicines & HealthCare (EDQM)

Guaranteeing access to **quality medicines** and healthcare to **strengthen** the **health** system in **Europe**

Access to quality healthcare is one of the fundamental rights protected by the Council of Europe, which has entrusted its activities in this area to the European Directorate for the Quality of Medicines & HealthCare (EDQM). With multicultural staff and experts drawn from all over Europe, the EDQM works to support health systems at national and European level and enhance the protection of patients by providing legally binding quality standards in the form of the European Pharmacopoeia (Ph. Eur.), which comprises strict quality standards for the production and control of medicines. The Ph. Eur. was one of the first building blocks in the edifice of European health co-operation. Today, 39 European countries plus the EU collaborate and co-ordinate their efforts in the implementation of Ph. Eur. standards in their territories.

As part of its pharmacopoeial activities, the EDQM also establishes and produces the physical reference standards necessary to confirm – through testing – that these quality requirements for medicines are met. These reference standards are essential to ensuring both the quality and availability of medicines for patients in every country that applies the Ph. Eur., in Europe and beyond. Furthermore, a rigorous procedure verifying and attesting the quality of active pharmaceutical ingredients, the Certification of Suitability to the Ph. Eur. Monographs (CEP), has been in place since 1994, contributing to health protection and facilitating marketing authorisations not only in Europe, but further afield.

Quality assurance in medicines stands on deep foundations, such as the analytical competence of the European Network of Official Medicines Control Laboratories (OMCLs), which was set up to ensure the quality of medicines on the market and brings together more than 70 official laboratories in 43 countries, and seven non-European partner laboratories. Impartial and independent, the network facilitates the pooling of resources and information on the latest technologies to save public money and share expertise and best practices. Its work gives participating states the support they need to monitor the quality of medicines at national level.

The scope of the EDQM's mission has progressively increased since its creation in 1964, extending to cover healthcare, standards for substances of human origin (SoHO), the fight against falsified medical products and consumer protection issues, such as cosmetics and food contact materials. Today, the EDQM's remit also encompasses the definition of standards upholding the principles of good pharmaceutical care, i.e. that medicines, in addition to being of good quality, are also administered correctly; co-ordinating the European Network of Official Cosmetics Control Laboratories (OCCLs) to help enforce European regulations; and elaborating harmonised measures to ensure the safety of materials and articles for food contact, supplementing EU and national legislation.

The COVID-19 pandemic has been a real stress-test for Europe's health systems, as illustrated by efforts to develop and distribute vaccines. But the EDQM has contributed to ensuring the timely release of newly authorised COVID-19 vaccines to the market thanks to the work of its Network for Official Control Authority Batch Release (OCABR) acting as the cornerstone in the mandatory mutual recognition of official control authority batch release for human vaccines. The EDQM also conducted critical work on viral vectored vaccines by defining control strategies for these new products.

In times of crisis, the EDQM can leverage expert networks to bring new contributions and perspectives that will anticipate the needs of professionals and manufacturers in the medicines sector. By attracting and relying upon the best experts from all over the world and taking part in a number of joint programmes, co-operation activities and networks, the EDQM strengthens its positive impact, increases its reach and allows for agile and rapid responses.

Moreover, it is widely recognised that the financial burden of protecting patient and consumer health is becoming increasingly onerous. Activities run exclusively at national level – without sharing of resources and experience – tend to be more expensive. The advantage of networking in this context is evident, since member states participating in the EDQM's work can make the best use of limited resources. By providing legal frameworks founded in fundamental human rights, by sharing scientific excellence, technical expertise and know-how, and by co-ordinating surveillance activities, the EDQM therefore supports national authorities in delivering the best possible healthcare to their citizens.

At the forefront of standard-setting for the quality control of medicines and their safe use since 1964, the EDQM has helped shape the European regulatory system, building upon successive partnerships and joint programmes between the Council of Europe, the EU and their respective member states.

Everyone today is acutely aware that the demand for health and pharmaceutical standards that are consistent at European and global level has become increasingly important to safeguarding quality and improving access to medicines and good quality healthcare. Having harmonised approaches and policies in establishing these standards can greatly contribute to achieving this goal, in addition to guaranteeing that fundamental rights remain deeply enshrined in health policies in Europe.

Resilience and the need for a **continuum** of **responsibility** in the **pharma industry**: The **French experience** of Single Points of Contact

CARINE WOLF-THAL

President of the National Council French Chamber of Pharmacists – Ordre national des pharmaciens

FRÉDÉRIC BASSI

President of the Council of Industrial Pharmacists French Chamber of Pharmacists – Ordre national des pharmaciens

In its *Pharmaceutical Strategy for Europe*, the European Commission called for enhancing the resilience and security of supply chains, launching a structured dialogue and a series of consultations in order to come up with practical and reliable solutions. The COVID-19 crisis indeed put the spotlight on long-lasting issues affecting the medicines supply chain, including medicines shortages and the high toll they take on patient chances. The crisis sped up the implementation of solutions at EU level, with the EMA-led SPOC and iSPOC pilots. It was also a test for national regulatory systems.

In the French case, the specific organisation of the chain proved very useful, especially its time-tested network of **Single Points of Contacts in the pharmaceutical industry: Chief Pharmaceutical Officers, or CPOs (*pharmaciens responsables/PR*)**. As the regulator for the pharmacy profession in France (implementing art. 52 of Directive 2001/83/EC on QP duties control), the Chamber of Pharmacists registers CPOs. As an institution tasked by law to promote public health and safety of care, we believe sharing this national good practice could be a useful input to European deliberations preparing upcoming legislative proposals. While detailed organisations should be adapted to national realities according to the subsidiarity principle, the basic concept of single points of contact at industry level might be of interest throughout Europe.

The French experience: a single, central, reliable and efficient point of contact for health authorities

Every pharmaceutical company in France has a Chief Pharmaceutical Officer (CPO) as part of its managers, supervising delegate CPOs to cover each of the company's structures. By law, the CPO is personally responsible for the compliance of all pharmaceutical activities falling within the scope of the company, in all civil, criminal and disciplinary matters. This means CPOs supervise **quality and safety** (covering R&D, manufacturing authorisation and quality, unique identifiers, pharmacovigilance, batch monitoring and recall/withdrawal), as well as **information** (including marketing authorisation submission and updates, information to health professionals and patient associations, advertising), not to forget **supply** (continued supply, as well as anticipated management of shortages for medicines of major therapeutic interest, on top of wholesale and storage).

- In a nutshell, this scheme brings four benefits to authorities:
- **Simplicity:** a single point of contact for any quality and safety matter,
- **The big picture:** a watchman informed at every step of the product life cycle,
- **Reliability:** a health professional taking personal responsibility,
- **Efficiency:** a manager with authority on all pharmaceutical operations.

The pandemic crisis indeed showed how this responsive scheme helps authorities to act. For example, when ICU units were hit hard by medicines shortages, authorities were able to direct notifications by hospital pharmacists of ICU needs directly to these key managers. French CPOs were also responsible for the iSPOCs for the European Medicines Agency. Moreover, they were empowered to identify the critical/essential medicines, as well as their security stocks and contingency plans.

Securing medicines quality, safety and supply at EU level: a European SPOC network of physical persons with a comprehensive view

Directive 2001/83/EC currently does not foresee a continuous SPOC network of responsible persons in the industry. For example, it requires manufacturers and importers to have one or several qualified person(s) with some responsibility, but marketing authorisation holders have a qualified person only for pharmacovigilance and (by default) at EU level. No specific person is responsible for the all-important obligation of continued and appropriate supply. Companies do not have a single point of contact for key compliance matters. In contrast, Regulation (EU) 2017/745 recently introduced a single Person responsible for regulatory compliance in the field of medical devices.

The upcoming revision of directive 2001/83/EC is an opportunity to create a SPOC network throughout the chain, at EU and national level. Making these SPOCs physical, responsible persons, orchestrating the key quality, safety and supply activities in their companies could foster efficiency and much-needed anticipation. It would actually contribute to several of the goals set by the Pharmaceutical Strategy for Europe: ensuring supply, improving efficiency, enhancing safety and patient-centered care.

For example, having such compliance SPOCs for the market life of the product, including European public service obligations and early notification of market withdrawal, would improve the detection and mitigation of shortages, while giving both authorities and patient associations a responsive interlocutor. Another advantage experienced in France is that such responsible persons would be able to connect the dots between pharmacovigilance signals, variations and complaints so as to make quicker decisions about the market withdrawal of a medicinal product.

That is why it could be worth exploring the introduction of a person responsible for end-to-end regulatory compliance in all pharmaceutical companies. **Having a continuum of responsibilities for quality and safety within the chain has the potential both to improve processes for the industry and health authorities, and to close in on the primary goal of such processes: bringing the best possible service to patients.**

Building Adult Immunisation Back Better in the Wake of the Pandemic

THOMAS BREUER

MD, MSc. Senior Vice President and Chief Medical Officer, GSK Vaccines

SUE MIDDLETON

MBE. Vice President, Communications and Government Affairs, GSK Vaccines

Introduction

The impact of the Covid-19 pandemic has been devastating for all regions of the world including Europe. At the time of this writing, more than a million deaths in Europe had been attributed to the pandemic disproportionately impacting older adults and vulnerable people.[1] The economic toll is also severe, with sharp decreases on GDP and other indicators.[2] Health systems across Europe have been heavily disrupted and these effects are expected to persist well beyond the pandemic period. Exiting this pandemic and reopening the economy requires the swift roll-out of vaccines and therapeutics across the world, both in the short-term and to possibly deal with what is to become an endemic virus. A successful recovery in Europe must also include a focus on prevention and healthcare delivery, including to specific target groups. This includes rebuilding and expanding routine immunisation, especially for older adults. The mobilisation of national health systems in response to COVID-19 offers an opportunity to make policy choices that more accurately reflect the value of adult immunisation, to educate European citizens about the importance of vaccines for all ages, and to build a stronger life-course immunisation system.

People of all ages are vulnerable to infectious disease, including many infections that can be prevented by vaccines, but the youngest and the oldest are at greatest risk.[3] In 2020, persons ≥65 years old accounted for approximately 20% of the European population, and this is expected to increase to approximately 30% by 2050.[4] Common vaccine-preventable diseases (VPDs) affecting older adults in Europe include pertussis, influenza, pneumonia, respiratory syncytial virus (RSV) and shingles, among others. Adult immunisation programmes are important to reduce morbidity and mortality of VPDs and co-morbidities typically associated with ageing to compensate for age-related decline in immunity in older adults.[5] For decades, European countries have implemented robust vaccination programmes for children, but significant gaps for adult immunisation programmes remain.[6]

Without concerted action, Covid-19 may widen these gaps. Around the world, this pandemic has caused patients and providers to delay most routine vaccinations, including for older adults for whom immunisation programmes were already absent or underperforming.[7] For example, in the US vaccine billing claims for teen and adult vaccines plummeted between 66-86% during the early months of the pandemic compared to the same timeframe in the year prior to the pandemic.[8] In Italy, vaccination coverage declined for various reasons including redeployment of staff normally employed in vaccination and public fear of accessing health services including for vaccination.[9] Continued disruption of routine adult vaccination risks significantly setting back Europe's progress in building stronger life-course immunisation systems. Moreover, the continued focus on Covid-19 vaccine roll out, whilst critical to exiting this pandemic, might further complicate or delay adult vaccination for other diseases.

Importance of immunisation for older adults

Classic vaccines like those for influenza and pertussis ("whooping cough") remain highly valuable for reducing morbidity and mortality for older adults. Although the severity of influenza epidemics varies, in the years immediately prior to Covid-19, influenza was associated with as many as 152,000 deaths

1 Coher J.F. et al. COVID-19-related mortality by age groups in Europe: A meta-analysis. Frontiers in Medicine, 2020.

2 Eurostat, 2021. GDP down by 0.6% in the euro area and by 0.4% in the EU. 53/2021.

3 Simon A.K. et al. Evolution of the immune system in humans from infancy to old age. Proceedings of the Royal Society B: Biological Sciences. 2015; 282:1821.

4 Eurostat. Population Structure by Major Age Groups, EU-28, 2018–2100.

5 Cassimos, DC et al. Vaccination Programmes for Adults in Europe, 2019. Vaccines 2020, 8, 34; doi:10.3390/vaccines8010034. (Accessed 18th May 21)

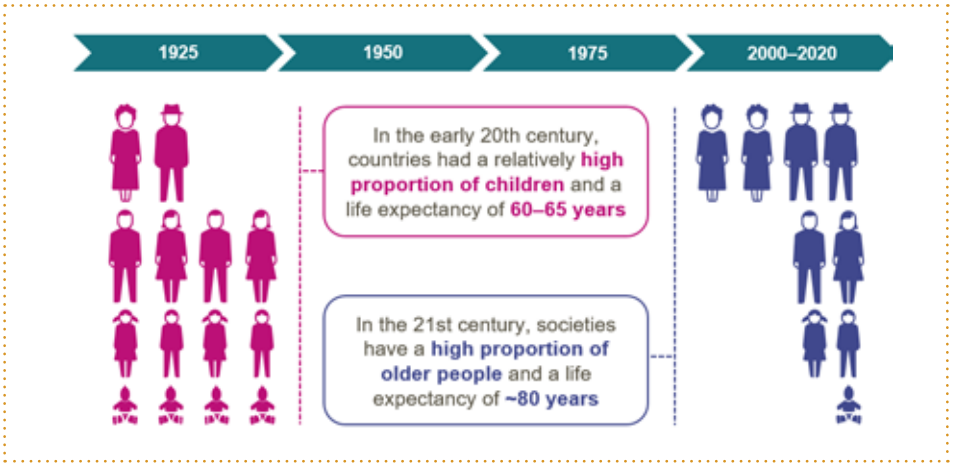


Figure: Increased life expectancy has shifted global demographics toward older populations.

6 Sheik et al. A report on the status of vaccination in Europe. Vaccine, Volume 36, Issue 33, 9 August 2018, Pages 4979-4992.

7 Stefanati et al. Value of Immunisations during the COVID-19 Emergency. International journal of environmental research and public health, 18(2), 778, 2021.

8 Avalere, 2021. Immunization Rates for Adolescents and Adults Have Decreased During the COVID-19 Pandemic. Available https://www.izsummitpartners.org/content/uploads/immunization-rates-infographic.pdf. [Accessed 18th May 21]

9 Bonanni et al., 2021 Maintain and increase vaccination coverage in children, adolescents, adults and elderly people, Vaccine, Volume 39, Issue 8.

in a single year across Europe, approximately 80% of which were among older adults.[10] Fortunately, influenza remained at bay during the 2020-2021 season due to lockdowns related to the pandemic,[11] however, it is important to strive for achieving a 75% target vaccination rate among older people set by WHO, which few countries have achieved.[12] Pertussis is a highly contagious respiratory infection, and despite widespread infant vaccination programmes, it remains one of the most poorly controlled VPDs, with resurgences continuing to occur every few years.[13] Pertussis leads to a high burden on healthcare utilisation and costs[14] and although booster vaccines have been available for adults for decades, they are still largely underutilised[15]. Timely booster vaccination of older adults against pertussis could help reduce the disease burden in this vulnerable population and will likely to reduce the demand and cost on healthcare systems.

The need to "build back better" for adult immunisation systems is made all the more urgent by recent advances in vaccine innovation that offer increasing value for adults, including expanded protection and increased efficacy.[16] For example, the use of adjuvants (substances designed to enhance the immune response to vaccines) have opened doors to better efficacy in populations with sub-optimal immune responses, including older adults at risk of developing diseases like herpes zoster (shingles) and potentially RSV. Nearly everyone ≥50 years of age is at risk for shingles, a blistering rash that can be excruciatingly painful.[17] Fortunately there is an effective adjuvanted shingles vaccine, which was approved for use in European countries in 2018.[18]

RSV is a respiratory disease that can lead to serious conditions like pneumonia and congestive heart failure, causing hospitalisation and sometimes death.[19] The good news is that there are multiple RSV vaccines under development, with at least 2 vaccines already in late-stage clinical trials, that—if successful—may help address this unmet medical need. Finally, new vaccine technology platforms such as mRNA vaccines for Covid-19 are producing encouraging real-world effectiveness data, including for adults ≥65 years old.[20] These advances will enable us to create new vaccines for an expanded range of diseases, with significant public health impact across the life course.

Policy recommendations for the EU

Despite the headwinds mentioned above, Covid-19 also creates opportunities for expanding adult immunisation capacities and capabilities in Europe. We briefly outline five policy priorities for governments in Europe to consider:

1. *Minimise further disruption of existing adult immunisation programmes.*

The roll-out of Covid-19 vaccines across Europe has the potential to further disrupt and delay routine immunisation programmes, including for older adults. For example, Covid-19 vaccine policies that require "blackout" periods for administering other vaccines may result in delayed or missed vaccination opportunities. When designing and implementing Covid-19 vaccination campaigns, governments should ensure routine immunisations can be maintained in parallel or get back on track, for both children and adults, as quickly as possible. For example, the US Centers for Disease Control and Prevention recently updated its guidance that Covid-19 vaccines may now be co-administered with other vaccines on the same day.[21]

2. *Build vaccine literacy and vaccine confidence among adults.*

The response to this pandemic has dramatically increased general awareness of the impact of vaccines amongst the public, especially adults who are not otherwise exposed to immunisation messaging (e.g. adults without children, older adults, etc.). Therefore, for European policy makers there is an opportunity to make meaningful progress to combat misinformation and increase vaccine literacy and confidence among the general public by investing in education and awareness for life-course vaccination.

3. *Prioritise adult immunisation in national health services planning and financing.*

As governments implement learnings from the pandemic in real-time, there is an opportunity to set in motion a paradigm shift towards more regular inclusion of adults in immunisation programmes. It is imperative to ensure there is funding to make this happen – at present on average European countries spend less than 0.5% of their health budgets on immunisation. Beyond funding, governments should set ambitious targets for adult vaccination coverage including lowering the eligibility age. The Covid-19 vaccination campaign in the US demonstrates the impact of setting vaccine coverage targets and monitoring them.

4. *Expand access points*

The pandemic response has required many European countries to expand vaccine administration services beyond the typical settings of care like physicians' offices. Governments should make plans to ensure that additional convenient points of access to vaccination (e.g. pharmacies, employment settings; with firm governance framework and appropriate education) become regular fixtures in the national immunisation system. Several European countries have demonstrated the benefit of improving access to vaccination through pharmacies, including France, Portugal, and Ireland.[22] Expanding this practice throughout the continent will help increase vaccine coverage rates for adults, both during the pandemic and beyond.

5. *Deploy and coordinate digital tools*

Finally, some European countries are leveraging digital tools to improve vaccine uptake and coverage, leading to better protection. This has become a clear imperative during the Covid-19 response, both to track overall coverage rates and to ensure course completion for 2-dose vaccines.[23] Europe should leverage this new digital infrastructure to make lasting improvements to national immunisation systems and to enhance connectivity between member states, especially as intra-continental mobility picks up again.

Conclusion

Vaccines and therapeutics are paving the way to an exit from the Covid-19 pandemic. Governments in Europe have an opportunity to build health systems back better – and this must include strengthening adult immunisation systems and practices. Many countries in Europe are already demonstrating best practices to get this done. Let's all learn from this experience and build toward a healthier Europe.

10 Nielsen et al., 2019. European all-cause excess and influenza-attributable mortality in the 2017/18 season: should the burden of influenza B be reconsidered? Clinical Microbiology and Infection, Volume 25, Issue 10.

11 Adlhoch C. et al. Very little influenza in the WHO European Region during the 2020/21 season, weeks 40 2020 to 8 2021. Eurosurveillance - Volume 26, Issue 11, 18 March 2021

12 OECD, Influenza vaccination rates, 2019. Available https://data.oecd.org/healthcare/influenza-vaccination-rates.htm. [Accessed 18 May 21]

13 Kandeil, W. et al, 2019. The burden of pertussis in older adults: what is the role of vaccination? A systematic literature review. Expert review of vaccines, 18(5), pp.439-455.

14 McGirr et al. The health and economic burden of pertussis in Canada: A microsimulation study. Vaccine. 2019 Nov 20;37(49):7240-7.

15 Williams, W. W. et al., 2017. Surveillance of Vaccination Coverage among Adult Populations - United States, 2015. Morbidity and mortality weekly report. Surveillance summaries (Washington, D.C. : 2002), 66(11)

16 Hanon E. et al. Is Europe Prepared for the Future of Vaccines Innovation? The European Files 2019.

17 CDC. Prevention of herpes zoster: Recommendations of the ACIP. *MMWR*. 2008;57(RR-5):1-30.

18 EMA, Shingrix, Available https://www.ema.europa.eu/en/medicines/human/EPAR/shingrix

19 CDC, 2017. RSV in Older Adults and Adults with Chronic Medical Conditions.

20 CDC, 2021. Fully Vaccinated Adults 65 and Older Are 94% Less Likely to Be Hospitalized with COVID-19. Available https://www.cdc.gov/media/releases/2021/p0428-vaccinated-adults-less-hospitalized.html. [Accessed 18 May 21]

21 CDC, 2021. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.

22 Kirkdale, C.L et al. Implementation of flu vaccination in community pharmacies: Understanding the barriers and enablers. Annales Pharmaceutiques Françaises, 2016

23 The Lancet Digital team. Can technology increase Covid-19 vaccination rates? Elsevier, May 2021

Innovating for Sustainable Health Systems in the European Union

BRANDON MITCHENER

Interim Executive Director, Health First Europe

In December 2019, just before the coronavirus crisis, European Commission President Ursula von der Leyen wrote a "mission letter" to Stella Kyriakides, the newly confirmed European Commissioner for Health and Food Safety. The Commission's health agenda at the time consisted of ensuring a supply of affordable medicines, implementing a new regulatory framework for medical devices, creating a new European "eHealth" data space for the exchange of anonymized health information for preventive analysis, fighting growing resistance of many microbes to common antibiotics and a new Europe's Beating Cancer Plan. Vaccinations were mentioned—but in the context of fighting the sadly widespread myth that they are ineffective or even dangerous. Pandemic preparedness wasn't mentioned.

How times have changed! Just three months later the Commission and in fact most of the world were in full crisis management mode, struggling to contain the COVID-19 pandemic which the World Health Organisation declared—far too late, it turns out—on the 11th of March.

The good news is that the crisis rudely exposed many of the weaknesses of the European Union's reliance on a public health system largely managed by its 27 Member States. In the light of the pandemic, EU Member States reluctantly assigned the Commission the task of coordinating contact-tracing apps that would work across borders; procuring COVID-19 vaccines on behalf of the bloc; coordinating travel restrictions and permissions within the bloc; and shoring up economies that went into freefall after coronavirus-related lockdowns closed borders, shops, stadiums, theatres and offices. This is good news because the EU was born in crisis and historically has made its biggest lasting gains in terms of integration, innovation and effectiveness as a direct result of crises.

The €5.1 billion EU4Health initiative, agreed by the European Parliament and European Council in March 2020, will finance a further transformation in the EU's role in coordinating and improving resilience to public health threats across the bloc going forward. Among other provisions, it will create a reserve of medical supplies for crises, train a reserve of healthcare staff and experts to be mobilised in future crises and lead a digital transformation of health services including mining anonymised health data from across Europe to prevent, spot and better manage future health crises, including chronic crises such as anti-microbial resistance, which many healthcare practitioners believe to be the next pandemic.

Health First Europe applauds EU Member States' rapid adoption of digital health tools during the course of the pandemic and hopes that temporary permissions for non-traditional healthcare services including telemedicine will be made permanent now that doctors, nurses and the public have embraced them.

At the same time, healthcare professionals across Europe have highlighted the need for the introduction of new technology to be accompanied by relevant training and upskilling for doctors and nurses. The EU could help drive this by creating EU curricula for healthcare professionals and common definitions of professions and specialisms across Europe (Why are intensive care doctors and nurses a recognised specialism in some EU countries, but not in others, limiting their mobility in times of crisis?); including digital literacy and skills among the core competences needed for the healthcare workforce of the future; and promoting cross-border e-learning opportunities.

At a recent meeting of the European Parliament's Interest Group on Innovation in Health and Social Care, organised by Health First Europe, MEP István Ujhelyi (S&D, Hungary) cited the experience of the COVID-19 pandemic response in Europe to conclude that Europe needs to "step up efforts to establish effective prevention systems within our existing healthcare systems." Dr. Loukianos Gatzoulis, a policy analyst in DG SANTÉ in the Commission, agreed that the EU's current health system lacks capacity, facilities, staff, supplies and digital technologies and said Europe needs to "reform, transform and invest" in order to improve resilience, resource efficiency and the overall level of care in health crises. The Commission, he said, can help with knowledge brokering, better exchange of best practices and providing access to EU funding. Maria Teresa Parisotto, representing the European Specialist Nurses Organisation, called on EU Member States to facilitate access to predictive health care data.

Ultimately, transforming Europe's healthcare systems to better face the next major public health threats, including anti-microbial resistance and the next pandemic, depends on the willingness of EU Member States to delegate authority to the European Commission to do things that are better done centrally as opposed to country-by-country. Health First Europe, along with most healthcare professionals, patients organisations and people working with the EU institutions in Brussels, are convinced of the logic of doing so. The question is whether the EU Member States will listen.

As I wrote this article, the World Health Organisation published the highly critical results of an independent study of its own and of national governments' handling of the coronavirus crisis. The study's co-chairs, former New Zealand Prime Minister Helen Clark and former Liberian President Ellen Johnson Sirleaf, said the whole world needs the same thing. The EU has an opportunity to lead the way.

The **digital healthcare transformation** as a catalyst for **resilient healthcare system**

CRISTIAN BUȘOI

MEP (EPP, Romania), Chair of the ITRE Committee, European Parliament

Nowadays, in the 21st Century, when access to health services should be fundamental, according to the last surveys conducted by the European Commission, OECD and WHO, there is still an unequal access to health services throughout EU and MS still have an inadequate primary care structure. Patients go with paper dossiers from one clinician to other. 80% of the healthcare costs are linked with non-communicable diseases and re-admissions, services are fragmented, prevention accounts only, on average, 3% of the total spending of health budgets.

Public health and the development of healthcare services should be a top priority for the policy-makers and funding should be an important component both of the EU budget and of national budgets. Unfortunately, funding was minimal compared to the societal and economical challenges of health.

The Union has limited intervention over the national health systems, but still the Union should support the efforts and actions on the MS in the field of health, and should provide guidelines and coordination, should promote the best practices between MS. Thus, the Union needs to put a robust funding mechanism for actions in the field of public health and to support the reform of healthcare systems, hence also digitalize healthcare.

We seem to forget the challenges we are facing and that we need to transform our healthcare systems to be resilient and future-proof, meaning patient-centred and outcome-based. This healthcare switch to more preventive medicine indicates a transformation that guarantees patients access to health services, as well as the optimization of health services. Digitalisation and a large innovative intake, which envisages a high part of AI in healthcare and more new technologies, is needed.

Even though digital health and digitalizing healthcare has proven to contribute at addressing the challenges in the health sector and has a great potential in making our systems more resilient, we are far from reaching its full potential. The success of the digital transformation in health, and its enormous beneficial impact on patients will depend on how much we plan for the next 5-7 years from today.

One of the priorities I have as the Chair of the ITRE Committee and Rapporteur for the EU4Health is to bring innovation in the health sector and digitalise healthcare, in particular through the creation and application of the European eHealth Record and the support for the creation and use of the Health Data Space future platform.

Innovation and research in the medical field, progress towards digitalization of the healthcare sector, improving health infrastructure by turning digital, it is of paramount importance and will facilitate better healthcare and access to healthcare for our citizens foremost, and of course will make our healthcare more resilient.

It is proven that innovation can improve health care, bring efficiency and bring in some cases the cost-savings. It changes the ways we buy and use health care. But also innovation uses new technologies to develop new products and treatments or to improve care.

When talking about innovation, Horizon Europe is the most ambitious Programme we have at our disposal for the next 7 years. Being at the forefront of innovation and research is the best way to ensure quality jobs and the future competitiveness and robustness of the EU's economy. Moreover Horizon Europe is a key instrument to address the many pressing issues, such as antimicrobial resistance, telemedicine, robotics, digitalization, innovative treatments and vaccines, and curing cancer.

Digital Europe Programme, and the RRF will support more substantial reforms, including in the infrastructure of the national healthcare systems, with the aim to reach the key value of the digital transformation in the health sector.

Moreover, introducing digitalisation in the healthcare systems and at level of regulatory authorities would tremendously make the difference in improving efficiency of the healthcare systems, enabling patience to have access to healthcare and to innovation in health, enabling authorities, European and national to fast react in critical situations, but also empowering patients in managing their diseases.

Electronic health records, e-prescriptions, electronic leaflet and telemedicine systems represent only a part of digitalizing healthcare. But a robust digital infrastructure, would interconnect EU and the national authorities, enabling them to better manage of critical situations such as shortages of medicines and to dramatically increase regulatory efficiency, enabling medicine agencies to focus their resources on patient and critical tasks rather than public administration.

One last example of brining innovation and new technologies into healthcare is AI. Artificial intelligence is not one technology, but rather a collection of them and complementary with digitalization. Most of these technologies have immediate relevance to the healthcare field, but the specific processes and tasks they support vary widely. We are talking about robotics, machine learning, telemedicine, and precision medicine, algorithms for better screening and diagnosis, or even the electronic health record.

Artificial intelligence (AI) and related technologies have been playing a robust and growing role in the world the past few decades, and are increasingly prevalent and applied to healthcare. These technologies have the

We need to see the digitalization and artificial intelligence as what it rightly is, a potential to transform many aspects of healthcare, in particular, in patient screening, care, as well as improving the administrative pathways in the healthcare in general, and healthcare systems in particular, making them more resilient.

Building strategic independence for the European pharmaceutical industry

KERSTIN JORNA

Director-General of DG Internal Market, Industry, Entrepreneurship and SMEs, European Commission

The COVID-19 pandemic has – more than ever – made us realise how vitally important it is to ensure everyone can access safe and secure medicines and vaccines. For Europe, the lessons learned from this crisis have led us to rethink our preparedness strategy, in order to better respond to future health threats.

A strong pharmaceutical industry is a prerequisite for preparedness. The sector is a keystone in Europe's economy and represents the second largest market globally. However, the pharmaceutical landscape has changed rapidly over the last years. Established businesses have increasingly outsourced functions, focusing investment on a limited number of therapeutic areas while disinvesting from others. In addition, the crisis has exacerbated Europe's dependence on third countries for critical medicines and active pharmaceutical ingredients (APIs). We have seen how the coronavirus has affected China and India, two of the world's largest pharmaceutical exporters. This has led to serious disruptions in medicine global supply chains, restrictions in manufacturing, distribution and trade, causing shortages for certain products.

It is therefore essential for Europe to diversify its supply chains, including by strengthening its strategic production capacities, to prevent new health security risks in the future.

The European Commission already started working on a Pharmaceutical strategy several months before the outbreak of the pandemic. The aim of the strategy is two-fold: to ensure security of supply across the value chains, while strengthening the competitiveness and the innovativeness of our pharmaceutical industry to uphold its global leadership.

As part of the Strategy, the Commission initiated a structured dialogue on the security of medicines supply with the relevant stakeholders, including the pharmaceutical industry, representatives of central purchasing bodies, health professions and institutions, patients, Member States and academia. This dialogue aims at better identifying and understanding the dependencies and potential vulnerabilities in the supply chains, in order to build a more resilient medicines' supply. It will also address the obstacles preventing European manufacturers from being competitive, and the innovation needs for maintaining pharmaceutical manufacturing capacities on European soil. The Commission will draw on the recommendations of the structured dialogue- expected to be presented by mid-2021 - to propose targeted solutions.

The current crisis has also raised the importance of critical manufacturing capacity, at speed and scale, for vaccines and therapeutics. This is why earlier this year, the President of the European Commission, Ursula von der Leyen, asked the Commissioner for Industry, Thierry Breton, to set up and lead a Task Force for Industrial Scale-up of COVID-19 vaccines. Over the past weeks, the Task Force has relentlessly worked to address the main bottlenecks, both in terms of capacity and supply chain issues.

The Task Force also hosted the first pan-European online matchmaking event, with over 300 participating companies, to accelerate additional vaccine production capacities across Europe. Our strategy, alongside the efforts of the Member States and of the industry, is bearing fruit: by mid-July, we will be able to deliver enough doses for at least 70% of Europe's adult population.

Moreover, the Commission has launched the "HERA incubator", an emergency programme to boost preparedness and increase the capacity to develop vaccines adapted to COVID-19 variants. It will serve as a pilot for the European Health Emergency Preparedness and Response Authority (HERA).

In parallel, the Commission announced "EU FAB", to set up a network of ever-warm facilities with multi-technology vaccine and medicine production capacities for emergency response. It will become over time an asset for the future HERA.

Finally yet importantly, the Commission has also addressed the overall resilience of the health ecosystem. The recent update of the EU's Industrial Strategy provides a thorough analysis of the health ecosystem's dependencies and capacities.

The EU's response to the COVID pandemic has highlighted that we can succeed in speeding up innovation and production dramatically when it is urgently needed. It has been the case for vaccines, and the Commission is now taking further steps for the development and manufacturing of safe and effective COVID-19 therapeutics at EU level.

These are areas where the EU pharmaceutical industry can fully develop its potential and strengthen its strategic autonomy. At the same time, it is essential for Europe to strike the right balance between autonomy and openness. We have already proved that we were capable of doing so, as we are providing critical vaccines and other medical supplies not only to Europe, but also to the rest of the world.

JOSÉ MANUEL FERNANDES

MEP (EPP Group) rapporteur of Invest EU

InvestEU: accelerate the **EU's strategic investment** in the production of **medical equipment** and **drugs**

The InvestEU Programme is the inheritor of the European Fund for Strategic Investments, also known as the 'Juncker Plan', which has mobilized more than 500 billion euros since 2015 and created more than 1.4 million jobs. It promotes flexibility, simplification and synergies by bringing together the 14 European financial instruments.

During the period of 2021/2027, the InvestEU intends to mobilize more than 400 billion euros in public and private investment, structured in four policy windows: sustainable infrastructures, research and innovation, SMEs and social. This mobilization has to be done in line with the EU policy objectives. Therefore, at least 30% of InvestEU must be used for climate objectives, with 60% being the target in the window of sustainable infrastructures.

In the aftermath of the COVID-19 pandemic, with a revamped MFF and an innovative Recovery Plan, InvestEU is thus a challenge, yet also an opportunity for the EU and its Member States, particularly in the field of health. The health sector represents more than 10% of the EU GDP. This sector is of the utmost importance to the Union, not only for the lives of all the European citizens, but also for its economic and innovative added value.

Whereas Europe is already facing a "perfect demographic storm", with increasing costs of healthcare and an ageing population, the resilience of the EU national health systems must be achieved through private and public investments. In the field of health, these investments can contribute to medical and pharmaceutical research, new pharmaceutical products, such as vaccines, the digitalization of health care services, as well as health infrastructures.

The modernization of infrastructures – whether public or private – is clearly encouraged by the respective InvestEU policy window. Moreover, the InvestEU Regulation explicitly foresees the support to "*research, development, innovation and manufacturing of pharmaceuticals*". The Programme can be used to create, for instance, a national instrument to support investments in the provision of medical equipment and health care services. It can also be used to capitalize SMEs: an imperative need amid the COVID-19 pandemic.

Furthermore, the InvestEU allows Member States to be programmers, rather than mere users of funds. The European compartment of the InvestEU provides a guarantee of around 26 billion euros, 75% of which will be for the European Investment Bank and the remaining 25% for national promotional banks or other similar institutions. However, the Programme also has a national compartment in which Member States may voluntarily put the amounts from their respective national budgets, so as to create national financial instruments dedicated to the investments that they wish to implement. In this context, the European countries can use a maximum amount of 4% of the national envelope of the Recovery and Resilience Facility (RRF), and 5% of the Cohesion Policy funds, for the constitution of this guarantee. Member States that have promotional banks are better positioned to access InvestEU and to "manufacture" and mediate the financial instruments they deem most appropriate.

Yet, this opportunity comes along with an urgency: the possibility of using the national compartment of the InvestEU must be foreseen in the national Recovery and Resilience Plans (nRRPs) and in the partnership agreements between the European Commission and the Member States in the framework of the EU Structural and Investment Funds (ESIF) for 2021/2027. To benefit from the leverage effect of the transfers between the national compartment of the InvestEU and the RRF/ESIF funds, Member States must absolutely design their nRRPs and partnership agreements accordingly, in full complementarity and from an early stage.

It makes perfect sense for the InvestEU to be additional. On the one hand, economically viable projects which aim to fill market failures and investment gaps in the EU and which would have no other form of financing are eligible. On the other hand, the EU encourages 'blending', that is, the merging of InvestEU loans with the grants provided by other European funding.

The Program includes an investor advisory platform (Advisory Hub), which is free of charge for public entities, and which will provide advice, for example, for the structuring of projects or the creation of national and regional investment platforms. Member States should also have an advisory structure that cooperates with the Advisory Hub, which would result in more and better investment. The InvestEU also has an Investment Portal where promoters can place their investment intentions, in order to raise financing from private investors.

Despite the European Parliament's efforts, the InvestEU does not foresee a specific policy window for strategic investments, following a regrettable veto by the Member States. Yet, the Programme can boost public and private investments in the health sector, strengthening competitiveness, increasing productivity, promoting to territorial, economic and social cohesion, while, at the same time, funding the health sector as an EU-wide strategic investment.

Through the InvestEU, the Union intends not only to keep the jobs of the European citizens, but also to create quality jobs, in a society in which health is more important than ever. The Europeans deserve it, and Member States must be up to the task.

'European Health Union': When political imperatives risk getting in the way of good policy

ANDREA CHIARELLO

Head of EU Government Affairs - Pfizer

"*A Union that strives for more*". This is how Ursula von der Leyen, then candidate for the Presidency of the European Commission, summarized her agenda for Europe back in 2019.[1] With issues such as migration, climate change and the digital transition making the headlines, few in the Brussels circles had imagined that 'striving for more' would expand to healthcare policy less than a year later.

The 'European Health Union' agenda launched in November 2020 is an ambitious, albeit politically inevitable, response to the wounds left by the COVID-19 pandemic. After a fragmented response of EU Member States in the first wave, increasing EU powers on health policy, once close to unthinkable, became a self-evident necessity and political urgency. German Chancellor Merkel has stated that she would even support changing the Treaties if necessary to make this happen.[2]

A more 'interventionalist' EU approach is also articulated in the *Pharmaceutical Strategy for Europe*. Under pressure from Member States to improve access, affordability and availability of medicines across Europe, the Commission is acutely aware that its current policy toolbox is limited in this area. 'Striving for more' has translated into ambitious plans to revise the incentives framework for pharmaceuticals (e.g. orphan and paediatric medicines) and the general pharmaceutical legislation.[3]

Although these reforms were in the EU's pipeline before COVID-19, one can argue that the pandemic strengthened EU policymakers' perception that public sector intervention be more and more needed, notably in areas where the private sector is perceived as not able or willing to deliver.

Almost paradoxically, the Commission is now facing the challenge of political imperatives getting in the way of good policy.

One telling example is the export transparency and authorisation mechanism for

1 https://ec.europa.eu/info/sites/default/files/political-guidelines-next-commission_en_0.pdf

2 https://euobserver.com/democracy/151627

3 See here and here for more information

Illustrations from Pfizer EU Policy #LivingInnovation campaign. More info on www.pfizereupolicy.eu

COVID-19 vaccines rushed through in late January.[4] Movement of goods and supply across borders is critical to the pharmaceutical industry, including Pfizer, and the patients we serve. Since the Regulation's inception, it has caused a significant administrative burden and uncertainty on our tightly calibrated global supply chains. There is no one single fix for complex issues such as vaccines development and distribution. The Commission's Task Force on Vaccines Scale Up, via a solid dialogue with the private sector, should enable a better understanding of key needs and enablers across the supply chain.

Another example relates to access and availability of medicines across Europe. In an attempt to address the increasing inequalities across Europe in this area, the Commission is exploring legal obligations for companies to make their products available in all 27 Member States within a certain timeframe after marketing authorisation. However, the root causes of access delays and unavailability, are multifaceted and lie mainly outside EU legislation.[5] Such a policy would not improve access for patients and could instead undermine the EU's stated ambition to be a world leader in pharmaceutical innovation. The establishment of a High-Level Forum for Better Access to Innovation would be a much-needed first step to facilitate multi-stakeholder discussions to identify the sources of the problem and tackle them together, at the most appropriate level.[6]

One area where we believe the EU has the potential to be a world leader is the fight against antimicrobial resistance (AMR). Differently from COVID-19, this 'silent pandemic' has been on the political agenda of the EU for years already, driven by the major public health need for a more substantial antimicrobial R&D pipeline.[7] To complement ongoing public-private partnerships like the Innovative Medicines Initiative (IMI) and other 'push' initiatives aimed at de-risking basic research, industry and experts have been calling for 'pull' incentives to significantly increase R&D investment.[8] In July 2020, the pharmaceutical industry launched the AMR Action Fund, an unprecedented 1 billion USD commitment to bring 2-4 new antibiotics to patients by 2030.[9] This initiative, however, is only a temporary fix and will not drive the required ecosystem change unless public authorities including the EU create the conditions that enable sustainable investment in antimicrobial R&D.

The proposals in the EU Pharmaceutical Strategy on AMR pull incentives are therefore encouraging. However, it will be crucial for the EU to open a frank, trust-based dialogue with the pharmaceutical industry to identify what incentives would be most impactful. Notably, in alignment with the principles highlighted in the IP PACT,[10] we would be keen to discuss with EU policy-makers how novel intellectual property mechanisms such as transferable exclusivity extensions could help create the conditions for sustained private investment against AMR to take place.

In conclusion, the COVID-19 crisis and the ensuing 'European Health Union' agenda have triggered a lively discussion on what the role of the EU could and should be in health and pharmaceutical policy. While there is no easy answer to this complex question, good policy does need to be based on constructive engagement with all stakeholders, including the pharmaceutical industry, to identify barriers and solutions. We at Pfizer, building on our leadership in the context of the COVID-19 pandemic, stand ready to continue partnering with the EU institutions in pursuit of these common objectives.

4 https://ec.europa.eu/commission/presscorner/detail/en/ip_21_307

5 https://www.efpia.eu/media/554527/root-causes-unavailability-delay-cra-final-300620.pdf

6 https://www.euhealthcoalition.eu/news/the-eu-health-coalition-calls-on-the-portuguese-presidency-of-the-council-of-the-european-union-to-work-towards-the-establishment-of-a-forum-for-better-access-to-health-innovation/

7 https://www.oecd.org/g20/summits/hamburg/Tackling-Antimicrobial-Resistance-Ensuring-Sustainable-RD.pdf

8 https://www.efpia.eu/media/219769/joint-ebe-efpia-and-ve-statement-on-amr-1.pdf

9 https://amractionfund.com/about-us/

10 http://www.interpat.org/wp-content/uploads/IP-PACT.pdf

Illustrations from Pfizer EU Policy #LivingInnovation campaign. More info on www.pfizereupolicy.eu

Addressing medicine shortages: the symbol of the creation of a Europe of Health

NATHALIE COLIN-OESTERLÉ

MEP (EPP Group - France),
Vice-President BECA Commission &
Member of the ENVI Committee

The shortages of medicines and medical equipment are not a new concern. However, the COVID-19 health crisis, with the sudden and rising global demand for these products, has shed light on a phenomenon that healthcare workers and some patients know all too well.

Stock-outs and supply tensions have increased twenty-fold between 2000 and 2018, posing considerable risks to patient safety and undermining the health systems of the Member States.

The COVID-19 health crisis also brought to light the EU's increasing dependency on third countries, chief among which are China and India.

We have discovered, albeit a little late, that public health has become a geostrategic weapon that can bring a continent to its knees.

While health is the responsibility of each Member State, it befalls on the European Union, in accordance with Article 168 of the Treaty on the Functioning of the EU, to coordinate and complement national measures, to take action to ensure a high quality health policy for European citizens, to protect citizens against health hazards, to improve surveillance and preparedness against epidemics and bioterrorism, and to strengthen the capacity to address new health challenges, including those arising from climate change.

Closer cooperation and improved consultation are therefore essential to strengthen European efficiency and responsiveness. This cooperation has finally begun to take shape and must absolutely be made permanent, the fight against medicine shortages being one of the catalysts.

This fight must be based on three pillars: regaining health sovereignty by securing supplies; strengthening European action to better coordinate and complement health policies in Member States; and developing cooperation between Member States. This was in fact the sole purpose of my work as the author of the own-initiative report on medicine shortages adopted by an overwhelming majority in the European Parliament on 17 September 2020. I am delighted that these ideas have been placed at the core of the European Commission's proposals for the implementation of its pharmaceutical strategy and the recast of the legal framework on serious cross-border health threats, as well as the revision of the European Medicines Agency and the European Centre for Disease Prevention and Control regulations.

First of all, it is crucial that the RescUE system be made permanent in order to turn it into a European emergency pharmacy for medicines of health and strategic interest, i.e., those for which a stock shortage would bring about a vital and immediate risk for patients suffering from a serious pathology, if there is no therapeutic alternative recommended by the authorities. The goal is to develop a few health strategies with a common basket of priority medicines and vaccines.

At the same time, it is essential to rethink tendering procedures by granting security of supply as much importance as price, by having suppliers set up multiple production sites to limit uncertainties or by awarding tenders to several winners.

We must also strengthen and ensure greater transparency in the distribution chain and better information for all the players concerned, through centralised information. It is crucial to counter the effects of "overstocking", particularly at Member State level.

One point that is particularly dear to my heart, and which the crisis has highlighted, is the issue of European production and the relocation of certain industries. I am therefore pleased that this key point in my report has been widely taken up at European level, particularly in the strategy put in place by the European Commission to encourage manufacturers to produce within the European Union, including by allowing national public aid, to guarantee our security and independence.

The last couple of months have shown us that the issue of development, access and distribution of treatments is fundamental to guaranteeing appropriate medical care to all European citizens. The COVID-19 crisis has laid bare our shortcomings and, above all, our naivety when negotiating contracts with companies and our international partners. This must not be repeated, and we must not wait for the next crisis before taking the appropriate steps. We are aware of some of our needs, and as developing production chains cannot be done overnight, we must lay the foundations today to secure our independence. To this end, knowing our current capacities is essential, as well as strengthening them if necessary and helping develop new ones. We also need to identify the weaknesses in our health systems so that we can address them. And finally, we need to promote, especially in times of crisis, the development of partnerships between companies to boost production, as it is currently the case with the production of COVID-19 vaccines.

The European continent must become the continent of the future through the promotion of research and innovation. Increasing the budget of Horizon Europe, Europe's research and innovation framework programme, is excellent news, as was the development of a new European agency, the European Health Emergency Preparedness and Response Authority. This agency will strive to improve the EU's preparedness and response to serious cross-border health threats by promoting the prompt availability and dissemination of, and access to the necessary countermeasures. However, if we really want to create our European "BARDA", we must bestow upon it the means to do so.

Finally, in my report I also suggested creating one or more non-profit European pharmaceutical establishments capable of producing medicines of health and strategic interest in critical situations, or no longer profitable for pharmaceutical companies. The aim is not to compete with laboratories and industrial players but to compensate for the lack of production. It is regrettable that at present this proposal, despite benefitting from the support of Parliament, has not been taken up, even though I believe it could guarantee access to medicines for every citizen.

Together, we must devise solutions to ensure the establishment of a real European health policy, one that would meet the needs of the patients.

How to **build** a **European Health Union**

NATHALIE MOLL
Director General, EFPIA

Cast your mind back just over a year ago to the early weeks of the COVID-19 outbreak. It was a time of deep uncertainty when industry, policymakers and citizens had more questions than answers.

Faced with a new virus that spread swiftly without regard for borders, European and national agencies scrambled to understand the threat and draw up solutions at speed. Patients worried about the impact of travel restrictions and border closures on the supply of their medicines. Researchers in companies, hospitals and universities worked around the clock to test treatments, diagnostics and vaccines that would be key to any exit plan.

The resilience of systems, agencies and institutions designed to respond to emergencies was on the line. *This was not a drill.* Today, while the pandemic is far from over, we are in a position to reflect on how Europe responded to the most severe cross-border health threat of our time. This stress test highlighted some of our strengths while revealing a range of weaknesses.

Ad hoc solutions were eventually found to most of the acute challenges posed by the first phase of the pandemic. Our task now is to build on what worked and address systemic shortcomings: we must keep the best and fix the rest. This evaluation should be based on facts and evidence rather than on short term or self-serving political statements.

Fighting future crises

None of us can know when the next public health crisis will arise or what form it will take. However, we can be sure that it will come. To be better prepared, we must permanently strengthen the capacity of the EU and its agencies to ensure a more agile and robust response.

It is vital that we have learned the importance of keeping borders between Member States open, avoiding unilateral export restrictions, and discouraging stockpiling of medicines. To do this permanently, we must improve data on demand for medicines so that patients get the treatments they need. Europe also needs more effective tools for accelerating research and deployment of medical countermeasures. And we should agree ways to safeguard the continuity of clinical trials during any future crisis.

This cannot be achieved without partnership between all the key players. The pharmaceutical industry welcomes the European Commission's commitment to build the foundations of a stronger European Health Union in which 27 countries work together to "detect, prepare and respond collectively", as Ursula von der Leyen, European Commission President, has put it.

Central to this will be reinforcing the role of two existing agencies – the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) – and the creation of a new one: the Health Emergency Response Authority (HERA).

Strengthening the ECDC

Prior to the pandemic, the limited capacity of the ECDC was a common grumble among European policymakers and industry leaders alike. Now we must take practical steps to strengthen its mandate. This will help the agency perform its core tasks more efficiently, address some of the shortcomings in the EU response to COVID-19 and raise the profile of the institution. When citizens look to Europe for a trusted source of information on infectious disease and vaccination, they should find a strong, scientific body capable of moving swiftly at a moment of crisis while playing a valuable role in preventative health in normal times.

It is critically important that the ECDC can get full and immediate access to all relevant data from Member States. The agency needs the internal ability to provide robust monitoring, surveillance, risk assessment and forecasting on epidemiological trends, health system capacities, and demand for treatment in relation to serious cross-border health threats. Surveillance networks and capabilities need to be strengthened to better assess the burden of infectious disease, evolving infectious disease epidemiology, vaccine safety, vaccine effectiveness, and vaccination coverage rates.

During the first wave of the pandemic, industry was deprived of up-to-date ECDC information on the likely progression of the pandemic in each country, as well as patient need and hospital capacity data. This information was crucial for manufacturers to adequately forecast demand and plan manufacturing and distribution arrangements, to supply those medicines to the right regions at the right time.

I sincerely hope that in renewing the ECDC we can create formal opportunities for regular interaction between the agency and pharmaceutical industry. We believe that the ECDC could draw on industry's knowledge and state-of-the-art expertise in many key areas. Such structured stakeholder engagement is compatible with responsible governance, as the WHO and the US CDC have shown.

A modern European Medicines Agency

By holding press conferences and public engagement events, the EMA has seen its profile raised during the pandemic. Its rolling reviews of new vaccines, and publication of expert risk assessments, show how the agency can support Member State authorities while guiding the public.

We are convinced that the EMA can do even more. The executive steering group on shortages should embrace ongoing collaboration between the EMA, the European Commission and stakeholders. A consistent and workable definition of shortages based on countries' actual patient needs should be agreed and used across Europe. It is what we were all in dire need of during the first wave of this pandemic to ensure treatments reached the patients who needed them, and it is something that we must resolve as soon as possible. The information contained in the national data repositories set up following the Falsified Medicines Directive could be used to monitor net stocks levels at aggregate level.

The work of the EMA in faster regulatory assessment of treatments and vaccines has been in the spotlight throughout the pandemic. The role of the Emergency Task Force should include the implementation of learnings from previous crises, regulatory support to HERA, and engagement with external stakeholders with the ambition of working on global preparedness plans.

Looking more broadly, I hope that the review of the EMA's mandate is a first step to future-proofing the agency. We must think beyond today's crisis to consider the role the agency can play in delivering on the objectives of the EU pharmaceutical strategy and in making Europe more competitive at a global level. We believe that a modernised EMA should have an executive steering group working on innovative products that blur the traditional lines between drugs, devices, diagnostics and digital. It is important to fight the next battle rather than refighting that last one.

Data-driven future

Whatever form the next crisis takes, having access to high-quality data can only help to inform the response. That is why integrating the EMA into the future European Health Data Space should be a priority. Enabling the Agency to access or query real world data (RWD) to support decision-making throughout the product lifecycle will also address some of the longer-term aspirations to improve the use of RWD.

I was heartened to see the Commission's proposal for a structure that would allow the EMA and ECDC to coordinate safety and effectiveness studies after vaccines are authorised and I would like to congratulate both agencies on the recent announcement that the EMA and ECDC are joining forces to strengthen post-marketing monitoring of the safety, effectiveness, and impact of COVID-19 vaccines in the EU. Vaccine developers would welcome the possibility to collaborate with EMA and ECDC on this new initiative.

A new HERA

Along with strengthening the institutions we had at the beginning of the pandemic, it has become clear that a new agency is needed. I welcome the ambition to create a HERA and look forward to seeing more detail on its scope and funding. HERA should have the flexibility, agility and collaborative instinct required to respond rapidly to emerging threats and to stimulate innovation. It should be embedded within the existing EU R&D ecosystem and establish strong ties with other agencies.

Emergency procedures launched by HERA should include appropriate liability protection for the parties involved in the development, manufacture, and deployment of therapeutics and vaccines, and compensation for people who suffer adverse events due to these products, in an effective and timely manner, via no-fault compensation systems, without needing to resort to litigation.

Crises tend to accelerate history. As we dare to look beyond the COVID-19 pandemic, we do so in the knowledge that changes are on the horizon if we are serious about improving our preparedness for the next emergency. This will mean rethinking our institutions and systems, and the overall EU mandate in the context of the coming Conference on the Future of Europe.

While the task is not to be underestimated, I know I am not alone in sensing an appetite for change. In building a European Health Union together, we must seize the opportunity to create a more resilient Europe.

The **urge** of **medicine accessibility**

SARA CERDAS

MEP (S&D, Portugal), Member of the ENVI Committee, European Parliament

As we are building an European Health Union we need to understand what the real needs are and how, as a Union, we can tackle them. As the pandemic struck the Members States in unprecedented waves and unveiled the gaps on preparedness and response to a health crisis, the European Commission has acted to mitigate the effect of the pandemic on all health determinants such as health care, vaccines, medicines, but also economic and social support to the ones who need it most.

European Health Union, a mechanism demanded by the socialists and democrats in the European Parliament, is taking its first steps and we will be more prepared, more coordinated and more resilient to future health crises, starting acting now at a local, national and EU level. It is essential that the health systems be as sustainable as possible and all resources should be allocated in the best way possible, to ensure that the citizens' and patients' needs are met. The long-time medicines shortages problem was exacerbated and clearly unveiled in the EU and highlighted the need to manage the EU pharmaceutical system.

One of the lessons we learnt from the pandemic is that we must ensure timely access to safe, high quality and affordable medicines at all times to all citizens.

The Pharmaceutical Strategy for Europe, alongside the revision of EMA mandate and other health actions and programs, as EU4Health and the EU Beating Cancer, are an opportunity for the EU to position itself as a champion and to revise the pharmaceutical legislation and work together to achieve true accessibility across the Union.

The momentum is now and it is necessary to increase the health of citizens and for that we must ensure secure, affordable and available medicinal products and medical devices, without deteriorating the other actions that will increase the health status and wellbeing of populations. In other words, we need to fight the battle fronts: promote health and prevention of disease on one hand and invest in better treatments and better quality of life for patients on the other.

For both we must have medicinal products to treat or cure diseases or to use them through their prophylactic effect. This is only possible by investing in research and development of new drugs, vaccines and devices.

The EU had a robust research and innovation investment programme, the Horizon 2020, that today gives place to Horizon Europe, that has supported a multitude of different research projects, with results widely known by the general population. One example is the mRNA vaccines, currently well-known by the population as the COVID-19 vaccines, in which the EU had a substantial role in supporting research projects that use this technique for years to achieve the knowledge level we have nowadays and allow the development of efficient vaccines in record time.

But it is impossible to dissociate the discussion of accessibility of medicinal products and medical devices from the discussion of transparency of net pricing and reimbursement of different treatments.

It urges a balance between investments in pharmaceutical research, to promote the fixation of companies within the EU in global competitiveness, to reduce the environmental footprint and to contribute to reduce the unmet needs of the population. One of the most prominent problems nowadays is the investment made to discover and produce new medicinal products (as medicines or vaccines) and its reflection in the cost of these products. Towards this end, the future European Health Emergency Preparedness and Response Authority (HERA) will play a key-role in enabling rapid availability, access and distribution of needed countermeasures in times of crisis.

As these costs are unaffordable to many of the European countries, the EU joint procurement should be promoted to increase the accessibility and affordability of new medicinal products to all Member States, reduce the competitiveness between countries and improve the negotiation leverage of the EU when purchasing certain medical products.

But we already had other agreements between Member States that are successful case-studies. The Valleta Declaration and the Benelux initiative are two good examples that allow Member States to have the accessibility to innovative medicines at the same time it contributes to the sustainability of the healthcare systems.

The success of these examples occurs due to strategic cooperation between Member States, with sharing of information, identification of good practices, extended evaluation of innovative medicines and treatments, and negotiation of price through joint procurements.

As we saw during this pandemic, the joint procurement agreement for medical countermeasures in case of cross-border health threats resulted in a united effort of member-states that allowed the EU to benefit from competitive advanced purchase agreements, allowing all citizens to have equality in the access to COVID-19 vaccines. But this mechanism can go beyond a pandemic crisis and should be developed to be a reality at all times, to allow countries to have rapid, fair, equal and affordable access to future vaccines and treatments once they are available.

It is time for the Commission to push forward the discussion of transparency of net pricing and reimbursement of different treatments, increasing the equality between the Member States when in negotiation with pharmaceutical companies.

As an European, I believe that the EU project is a way of achieving an equal, fair and sustainable society, but also a healthier one. Today we are building the future, we are building up a European Health Union and we need to act together to ensure safe and quality healthcare to all, including the access to (innovative) treatments, prophylaxis and medical devices. We can and we won't leave no one behind.

Research and Innovation brings Europe together

IRENE NORSTEDT

Director - People Directorate, DG Research & Innovation, European Commission

The COVID-19 pandemic has shown the importance of the countries working together to share experiences, data and resources. In the area of research, the ERAvs-Corona Action plan[1] was rapidly agreed between the European Commission and the EU Member States when the pandemic hit Europe in spring 2020. This plan has guided research and innovation actions and investments to speed up the work necessary to deal with the devastating situation the world was facing.

An important aspect for co-operation in response to the COVID-19 pandemic was the rapid set up and mobilisation of pan-European clinical trials networks. These networks facilitate the rapid assessment of treatment strategies in intensive care settings and evaluates the usefulness of repurposed or new therapies against Covid-19 through the RECOVER[2] and EU-RESPONSE[3] projects. These networks were rapidly followed by the set-up of the VAC-CELERATE[4] project that coordinates and conduct COVID-19 vaccine clinical trials. The networks brings together clinical trials sites across Europe and they work closely with the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) to make sure the clinical research are conducted in the most effective and best possible way, and that the most promising or important questions or aspects can be addressed rapidly.

Such networks are, and will be, at the core of the continued work to build up a better preparedness for future pandemics. This is also on the table for the discussion that have been launched in view of setting up a closer cooperation between the EU Member States though a Pandemic Preparedness Research Partnership to be set up under Horizon Europe, the new programme for EU funded research and innovation, and as also set out in the ERAvsCorona action plan.

However, collaboration between the EU Member States is nothing new in the area of research and innovation. The collaboration between national research funding organisations and the management of co-funded research programmes has been ongoing since 2003. In Horizon 2020 an increased interest of policy makers from both research and health authorities at national and regional has however been recognised.

This can be exemplified by the International Consortium for Personalised Medicine, IC PerMed[5], that brings together close to 50 partners and where several EU Member States are represented by both research and health policy makers with Germany, Austria and Italy as examples. Several regional health authorities are also members including the Spanish Basque and Navarra regions, the Italian Lombardy region, as well as South Eastern Norway. They all work together to support a strong science base and to investigate the benefits of personalised medicine approaches to citizens and health care systems.

A closer integration of research and health care is also ongoing with rare diseases as paving the way for this type of co-operation. To better support the estimated 30 million EU citizens that suffers from a rare disease, the European Joint Programme on Rare Diseases, EJP RD[6], has brought 130 institutions from 35 countries (including 26 EU Member States) together. This co-operation have created an efficient innovation eco-system making sure that research results rapidly can be taken up in clinical practice through one of the European Reference networks (ERNs[7]) The EJP RD will decrease the fragmentation of expertise and aims to improve the health care systems capacity to take up research results. All to make sure that diagnosis, adequate care and therapies faster are brought faster to those living with a rare disease.

The COVID-19 pandemic has also meant that the European Health systems has been facing exceptional challenges. This on top of the already pressing situation with an ageing population, increased costs, shortages of health professionals, and inequalities in access to health care. It is therefore good that preparations for stepping up health systems research is already underway through a new co-funded partnership foreseen under Horizon Europe.

The aims of this partnership are ambitious – but necessary - as it must bring together the whole value chain of stakeholders, and thereby taking the complexity of Europe's health and care systems into consideration by working across countries and regions, across health and care delivery and in close collaboration with researchers.

This partnership does not start from scratch has it will build on strong initiatives such as the To-Reach project[8] where policy makers, research funders and research organisations from 20 countries has over the last years has worked on a strategic research agenda. It will further build on the experiences of initiatives such as the Active and Assisted Living Programme[9], , the Joint Programming Initiative "More Years, Better Lives"[10] and the European Innovation Partnership on Active and Healthy Aging[11].

These are but a few examples of how research and health authorities increasingly work close together across EU Member States and European regions to address key challenges in the area of health and care and where research can provide new innovative solutions for the benefit of the European Citizens.

1 ec_rtd_era-vs-corona.pdf (europa.eu)

2 Recover Europe – Recovering from Covid19 (recover-europe.eu)

3 Home - EU-Response

4 Vaccelerate.EU

5 www.icpermed.eu

6 www.ejprarediseases.org

7 Work of the ERNs | Public Health (europa.eu)

8 TO-REACH - Towards a joint EU research programme on Health Systems

9 AAL Home 2020 - AAL Programme (aal-europe.eu)

10 Home - JP-Demographic

11 EUROPEAN INNOVATION PARTNERSHIP | on Active and Healthy Ageing (europa.eu)

The **EU** needs more people-centric **technological progress**

NILS TORVALDS

MEP (RENEW EUROPE / Finland), Member of the ENVI Committee.

Health is not an exclusive EU competency. It is the Member States and eventually regions and cities who have the responsibility to finance and deliver healthcare. So, should the EU just keep its hands off health-related issues, as you may hear from some voices, also within the European Parliament?

As with most challenging issues, the answer is rarely black and white. While I am not in favour of stringent one-size-fits-all EU health care regulation, I would argue that it would be irresponsible not to coordinate things on a Union level in cases where there are clear positive effects for all Member States. Recently, the Covid-19 pandemic has of course been the obvious case, which has opened many eyes for the need of such cooperation. The unfortunate fact is that if we would have been better coordinated from the beginning, countless of European lives could have been saved. Although no one can say that we were not warned, it is of no use to dwell in the mistakes that have been made in the past. However, what we can strive to do, is to act responsibly in the future.

EU coordination on combating global pandemics is one thing, but I would also like to raise two other things connected closely to the current pandemic and to future health care challenges in general, where EU involvement will be needed.

First, I am talking about the increased digitisation of society. Already before the pandemic, it was of course very clear that the future is ever more digital. However, in the last year the development has been more rapid than anyone could have expected before the pandemic and we have suddenly all become used to being more online than offline. The health care sector is following suit.

Second, I believe we have yet to fully expose the effects on our mental health following a long time of social distancing. People will always react to issues in different ways and future studies might even suggest some Member State specificities in this matter. However, no

Member State will go untouched. Previous initiatives, such as the European Framework for Action on Mental Health and Wellbeing, have unfortunately not received adequate follow-up and it is high time to take action.

In short, we are talking about the rising importance of eHealth and mHealth. Two very different topics but so very intertwined.

In an ageing continent, there is a constant push for improved and more efficient solutions in the health care sector. The eHealth solutions can bring a lot of savings in countries and regions with a shrinking pool of taxpayers, while at the same time providing more accessible and individualized help to people also living in remote areas, who might otherwise have difficulties reaching specialists.

When looking at the health sector from a European point of view, eHealth solutions not only provide opportunities to better healthcare access. By going digital, the barrier for international cooperation becomes lower, bringing further efficacy to the sector. An early example of this can be seen in Estonia and Finland, where the two countries share a common system for e-prescriptions.

Finland and Estonia can of course be seen as frontrunners in digitising their societies and the healthcare sector as a part of it. This can undoubtedly be attributed to the level of the digital literacy of the population (i.e. the ability of the population to find, read and process information online). Digital literacy and awareness of digitalized services is a key element in any potential success of an eHealth revolution.

We need to make sure that information about e.g., medication is shared and assimilated properly across platforms. This means that personnel need to be comfortable enough using the platforms to minimize mistakes. Patients on the other hand need to be comfortable enough using the platforms, so that they can be assured to have received and understood the often-vital information communicated through the platforms.

However, digital literacy alone does not guarantee comfort in using eHealth solutions. We must also realize that any digital solution is strongly connected to and relying on the use of data. It goes therefore, without saying, that data protection and patients' willingness to share health data needs to be in the centre of the development of any eHealth platform. The sensitivity of data becomes even more exposed when talking about mental health, which might be connected to a stigma.

I am convinced that we will solve the above issues with eHealth and this way help our health care sector, which is running on a tight budget all over the Union. I am a true believer in people's ability to learn and adapt to new norms, which are beneficial for the society. However, there is still one thing we need to keep in mind before putting all our chips unconditionally on eHealth.

A Swedish study from this year on the importance of caring relations in eHealth, has concluded among other things that in-person interaction was central to people's perceptions of good caring relations. The importance of patient-nurse relations was particularly emphasized.[1] We can assume that digital information literacy in Sweden is internationally very competitive and eHealth, especially in a sparsely populated country, can bring many benefits. But even in the case of Sweden, it cannot be advisable to fully embrace digital care, without any sort of essential in-person relations. An approach where the two will be combined in the best possible way needs to be the way forward.

In a year that we have discovered how well things can work remotely but at the same time in many cases how much the lack of social connection has affected our mental health, we should embrace the people centred technological solutions of the future without forgetting who they are for.

1 Lindberg, Bhatt & Ferm; Older people and rural eHealth: perceptions of caring relations and their effects on engagement in digital primary health care, 2021

Fostering innovative technologies: drawing lessons from what works

ALEXANDER **NATZ**
EUCOPE Secretary-General

Amongst the societal and personal dimensions, one of the most important lesson to take away from the COVID-19 pandemic, is the value of supporting an ecosystem for pharmaceuticals and medical technologies where small and mid-size companies can dedicate time and resources to developing innovative therapies. This was facilitated by an unprecedented collaboration between stakeholders and the EU institutions, resulting in the affirmation of the strength of European innovation in health technology with the most successful vaccines being developed in Europe. COVID-19 showed that a healthy environment for biopharmaceutical innovation is a key element of crisis' preparedness and response.

In 2020, the European Commission presented its vision for a Pharmaceutical Strategy that aims to create a future proof regulatory framework and to support industry in promoting research and technologies that reach patients in order to fulfil their therapeutic need. It forms part of the new industrial strategy for Europe which aims to make EU industry more competitive globally and enhance Europe's strategic autonomy and lead the twin transitions to a 'digital' and 'green' economy by being an "...industrial innovation strategy at heart."

Europe is home to a rich innovation ecosystem with start-ups, world-class research institutions, some of the world's top universities for life sciences and many small to medium-sized pharmaceutical and biotech companies. However, we often see challenges in scaling up pre-clinical and clinical research into innovative medicines for Europeans.

Delivering for patients: fulfilling unmet medical needs

For EU industries to remain competitive and resilient it is key to have a solid incentives and intellectual property (IP) framework in place which encourages industry to continuously adapt and innovate, and which allows companies ultimately make them available to the patient.

The EU pharmaceutical regulatory framework must provide predictable pathways for innovative therapies that work in unison with the IP framework, Health Technology Assessment (HTA) and national market structures for access to medicines. Together with the evaluation of the Orphan Medicinal Product (OMP) and Paediatric Regulations there is an opportunity to significantly strengthen the EU incentive environment, drawing lessons from what works in the areas of rare disease and medicines for children as well as from the shortcomings or market failures such as antimicrobial resistance (AMR) or technologies which have not yet seen sufficient commercialisation.

EUCOPE represents 130 companies, many focused on rare diseases, largely small to medium-sized, playing a key role in the European pharmaceutical environment. Some of them have unique profiles due to their highly specialised product portfolio, no or limited revenues to date, significant risky R&D investments. For these companies, incentives are crucial to sustain (re)investments and planning cycles required to foster research in rare and paediatric diseases.

It is clear that the magnitude of the challenges and the ambitions we should have to future proof system cannot be tackled in silos and especially not only at the EU environment – Members states along with payers, HTA bodies, patients researchers healthcare professional and all relevant stakeholder they have to work together to foster the EU health innovation environment.

We are at an important crossroads. The Pharmaceutical Strategy represents a one-in-a-generation opportunity to discuss and agree on the ecosystem we want for the medicines and medical technologies of the future.

MONIKA BENOVA

MEP (S&D Group, Slovakia) Quaster, Member ENVI Committee, European Parliament

Harmonization of **EU** minimum standards for **quality health care**, can help to improve the preparation and coordination in case of **health crisis**

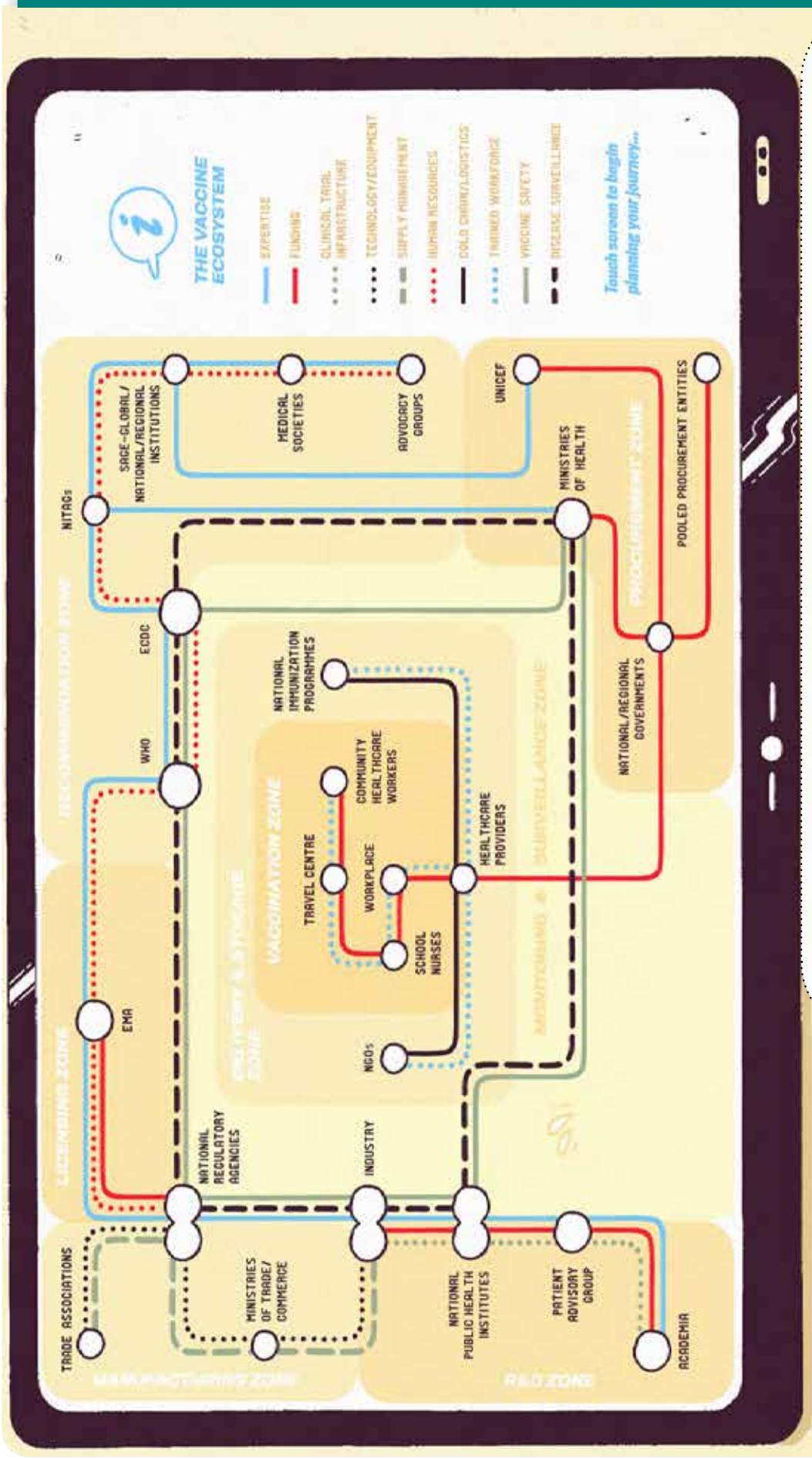
The European experience with COVID-19 pandemic has once again revealed an inconvenient truth. Despite screams and lies coming from various eurosceptic politicians from all around the Europe, it is clear that the European union (EU) can only be as powerful as its Member States allow it to be. At the beginning of COVID-19 pandemic, during the early spring last year, leaders of individual Member States feared from the new situation and have imposed restrictions which prohibited the export of medical devices to the most affected countries at that time, like for example Italy. Member States have adopted unilateral measures to counter the spread of the virus. Those have proved to be not only ineffective, but also disruptive to vital supply chains and the mobility of millions of citizens by ultimately preventing the flow of essential goods and people across the Union. These fragmented efforts in tackling cross-border health threats have made all Member States collectively more vulnerable. From the beginning, the EU couldn't act directly to save people's lives, even in an emergency situation, only Member States were entitled to do so. The COVID-19 pandemic has made it blatantly clear, that health can no longer be only a national issue. EU and its coordinated action has made a difference and helped to save people's lives. This shouldn't be only a case of COVID-19, similar cooperation is needed also in the fight with other diseases including cancer, cardiovascular diseases and many others. Based on this experience, the only way for EU and its member states to effectively protect public health, can be through the adoption of binding legislation and by relying on non-health-related competences, which are dispersed across the EU Treaties.

By no surprise, the vast majority of European citizens is now expecting the EU to play a more vital role in protecting their health, especially from the threats that threaten not only single states, but the whole Europe and the entire world. The common health policy is the third most common answer to the question of what would be most helpful for Europe's future. The excessive mortality caused by COVID-19 has shown the tragic consequences of the minimalist involvement of EU in the area of public health. The damage caused by pandemic in the society and its various sectors has shown that health is the main precondition for us to function normally and sustainably. Therefore, we have a unique opportunity to discuss and rethink the role that EU should play in the health sector, which should be the main topic concerning the creation of the European Health Union. Suitable forum for this discussion can be represented by the Conference of the Future of Europe which is starting already in May. If the outcome of the Conference will be that there is a need to go much further, the current proposals from the European Commission might need to be elaborated.

Despite the progress in vaccination, COVID-19 pandemic is unfortunately still ongoing and we don't know for how long. It is important for European institutions to tackle the root causes of what has prevented the EU from responding effectively from the early beginning of pandemic. Reasons for the lack of response can most likely be seen in the structural inequalities in health care capacity across the individual Member States. This includes differences in public investments to the health care systems, related inadequate availability of services, mainly in rural areas, or various difficulties in case of the most vulnerable groups.

From my understanding European Health Union will not aim to pass current competencies from national to the European level. The expectations are that it will help Member States to build more harmonized health care systems of more consistent quality. Setting minimum European standards for the quality of healthcare can definitely help. This would entail for example the introduction of a set of common criteria to be reported from Member States on the European level and on a regular basis. Those EU minimum standards for quality health care would guarantee European resilience in the face of pandemics and other possible public health crises, by increasing overall health care capacity across all Member States. Levelling up health care across the EU, would address many weaknesses of today's fragmented health care policy, including the absence of prescriptive EU supervision of the substance of preparedness plans and their enforcement. Requiring convergence among national health sectors would also help to build European health care infrastructure ahead of possible future health crises. From my point of view, this should be the right way how to strengthen the EU's resilience to various cross-border health threats.

THE VACCINATION ECOSYSTEM



The landscape of all stakeholders and players in the European ecosystem of vaccination is complex. Some stakeholders are linked to only one particular activity, such as licensing or making recommendations on vaccination. Others have a diversity of tasks. Some groups of stakeholders are connected through networks of experts only, or through the funding of activities. Some need to work closely together to establish a sustainable supply of vaccines or to share data for surveillance and monitoring. Still, they all need to work in concert, in order to ensure a healthy ecosystem that achieves common strategic goals in protecting the population.

Navigating in this landscape requires either many years of experience or a good map. Unfortunately, the diversity of systems in the EU means that such maps (if they exist at all) are very different between countries.

Analogy for illustrative purposes only and not based on scientific data

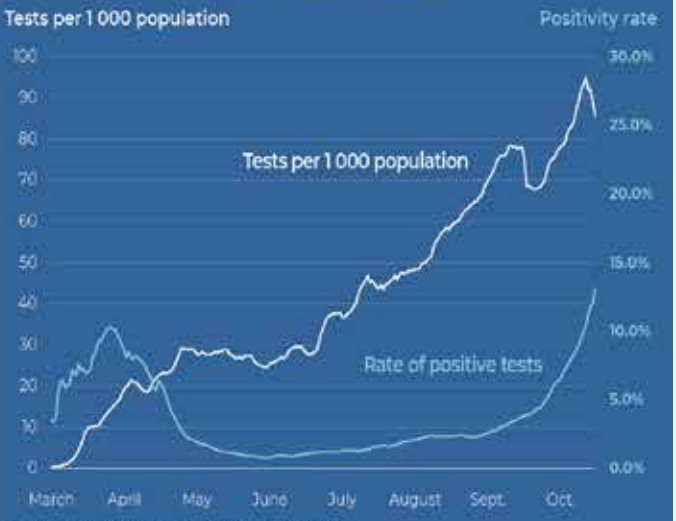
The two waves of COVID-19

First wave in Spring 2020 followed by second wave in Autumn 2020

Source: ECDC (data up to end October 2020)

More tests and more positive cases

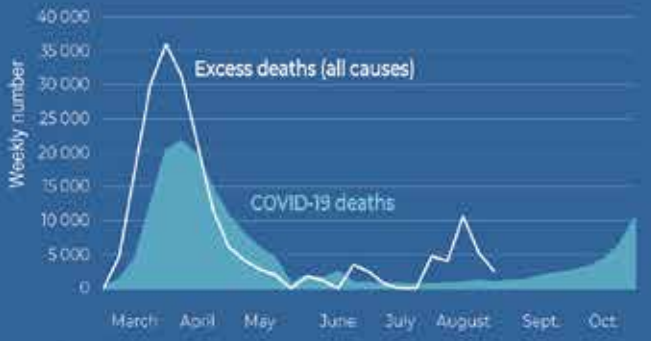
Tests per 1 000 population (left-hand axis) and rate of positive tests (right-hand axis), EU average



Source: ECDC (data up to end October 2020)

High and resurging fatalities from COVID-19

COVID-19 and excess deaths peaked in the spring and are on the rise again, (EU average)



Note: Data on excess deaths only available until end of August at time of writing.
Sources: ECDC (for COVID-19 deaths), OECD based on Eurostat data (for excess deaths)

COVID-19 has disproportionally impacted vulnerable groups

Across EU countries, around 90% of reported COVID-19 deaths have been among people over 60 years old. In many countries, approximately half of all deaths have been among people in nursing homes.

The poor, those living in deprived areas and ethnic minorities have also been disproportionally affected.

Source: ECDC

Too many people are still exposed to high levels of air pollution

Air pollution emissions (fine particles, $PM_{2.5}$) have reduced by 25% since 2005 in the EU.

Still, about 75% of people in European capitals were exposed to $PM_{2.5}$ levels above the WHO guideline between 2016-2018.

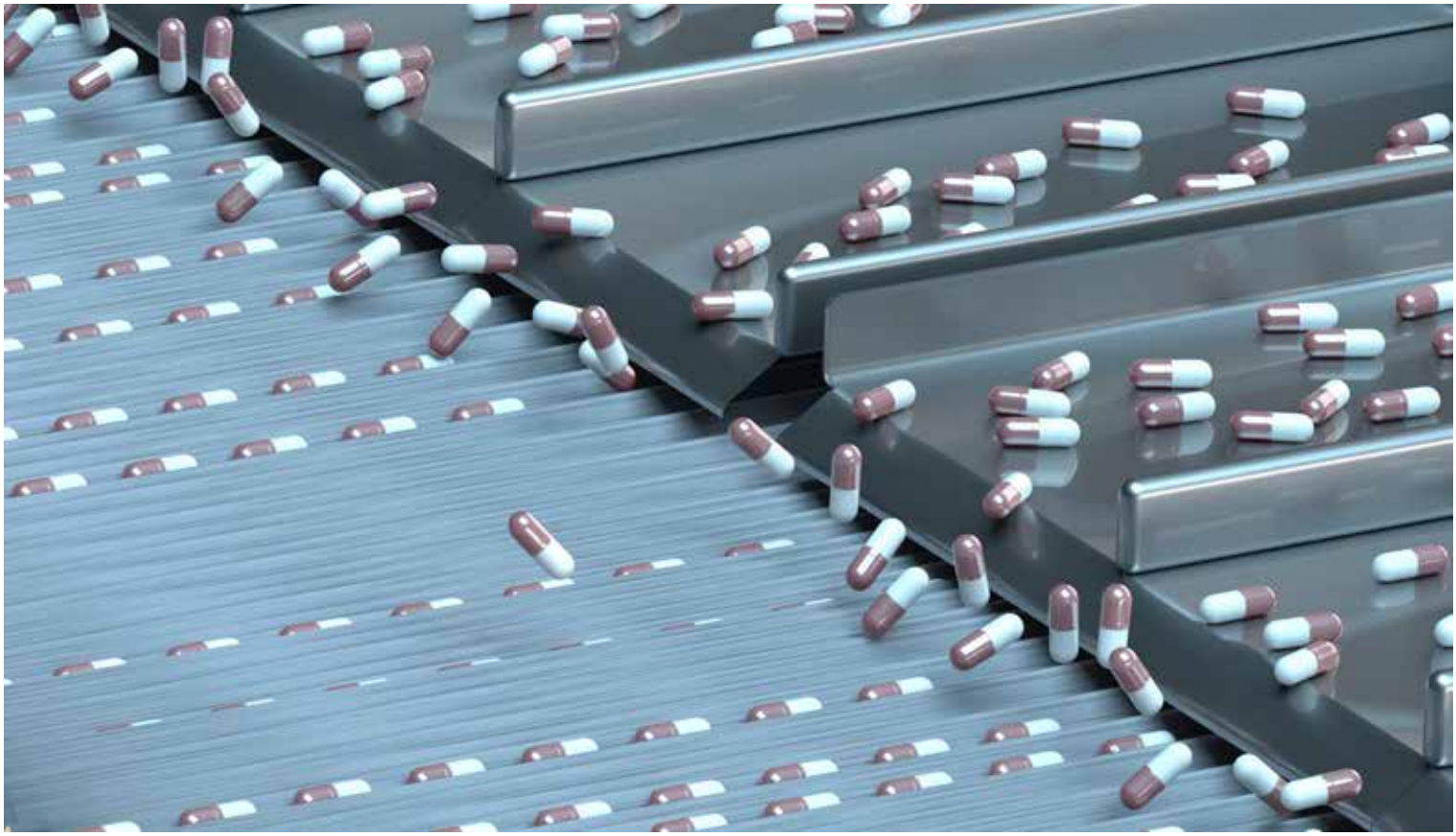
Across EU countries, between 168 000 and 346 000 deaths each year can be attributed to air pollution ($PM_{2.5}$).

Source: European Environment Agency, IHME

Massive welfare & economic losses from air pollution

In terms of premature death, loss of productivity & higher health spending

Source: OECD



Provider of Security and Trust to the Pharmaceutical Industry

The pharmaceutical industry has experienced in the past few years a breathless acceleration of innovations cycles, an increased globalization as well an unprecedented scrutiny from consumer and pressure from public authorities that require the industry to demonstrate increased transparency, to ensure the security of its products, and to provide traceability information to its audiences. It is also facing a dramatic surge in counterfeiting and other fraudulent practices from criminals that are determined to take their share of the growth experienced by the industry.

Piloting serialization, traceability and anti-counterfeiting operational applications for several years on a large scale and in all areas of the world, Advanced Track & Trace® brings in-depth market experience and the largest range of solutions to meet the strategies and different needs of laboratories.

Security:

- Fight against counterfeiting and derivatives such as refilling, re-use, etc.
- Control of overproduction from suppliers and subcontractors.

Traceability

- Identification strategies, serialization.
- Track & trace: detection of diversion, fraud and anomalies

Patient Relation Management

- Remote information, authentication, instruction for use, monitoring

---

About Advanced Track & Trace

Advanced Track & Trace® develops innovative authentication, identification and tracking technologies for a better protection of products, companies, citizens, and trade. For over 15 years, Advanced Track & Trace® has had trust-based relationships with leading customers and partners : companies, governments, institutions, based on its ability to offer creative, valuable, reliable, and durable solutions. www.advancedtrackandtrace.com

Advanced Track&Trace
Security and Traceability