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STRENGTHENING HEALTH IN EUROPE AFTER THE COVID CRISIS AND THROUGH AN AMBITIOUS PHARMACEUTICAL STRATEGY

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EDITORIAL

STRENGTHENING HEALTH IN EUROPE AFTER THE COVID CRISIS AND THROUGH AN AMBITIOUS PHARMACEUTICAL STRATEGY

The global pandemic of COVID-19 highlighted the importance of public health and well-being. Greater attention is being paid to supply chain resilience and strategic autonomy in developing and producing medicines. This (rediscovered) strategic importance of life sciences occurs in a decade long debate over prices of pharmaceutical innovation and concerns over healthcare expenditures sustainability.

Supporting the leadership and autonomy of Europe in the field of medical innovation (investing in innovation that is) while controlling pharmaceutical expenditures (spending less on pharmaceuticals) seems an impossible conundrum. Can those conflicting goals be at all compatible? The US, which is leading the field in terms of biotech innovation, is also one of the countries with the highest pharmaceutical expenditures in OECD countries. Meanwhile, industry advocates already point out the decade-long decrease in R&D investment in Europe and increasing complexity of bringing new therapies into a fragmented Europe – representing only 20% of pharmaceutical markets (compared to 50% in the US). Yet, this is the problem all European policymakers face today in the context of the revision of EU pharmaceutical legislation with the ambitious goal to support research, innovation, and the sustainability of national healthcare systems. The Pharmaceutical Strategy for Europe aims to establish a regulatory framework to address market failures and meet patients' needs by supporting industry's research and technological advances. But there are many other political and legislative discussions which need to succeed to have a life science ecosystem which can combine research, strategic autonomy, innovation and health goals.

First, and across all policy debates, it is essential to take into account the legitimate expectations of patients. The key challenge is to place patients at the heart of all healthcare policies, increasing their involvement in decision-making and guaranteeing continued access to innovative treatments. The objective is to ensure faster and fairer access to medicines for all patients in Europe.

Second, it is necessary to secure the EU's strategic autonomy in healthcare, which implies coordinating national healthcare strategies and diversifying supply chains. It is also important to strengthen the resilience of medical supply chains in order to guarantee access to essential medicines and reduce dependence on third countries. Long-term investment, strategic planning and partnerships with industry are needed to maintain an adequate supply base.

Third, investment in medical infrastructure capacity and modernization is important to strengthen healthcare systems. Digital transition, artificial intelligence and the European Health Data Space for research and medical data management are major elements in this evolution. However, cybersecurity represents an urgent challenge due to the increasing number of cyberattacks targeting healthcare systems. Measures such as the creation of a European Health Data Space and the adoption of a new regulation on serious cross-border health threats are required to facilitate digital transformation and strengthen data security.

Finally, when looking at access to innovation – policymakers will need to look at it holistically. Access to innovation is not only what determines pharmaceutical revenues or pharmaceutical budget. Access to innovation is ultimately what determines the success of previous research efforts – how good is European research if its fruits are not available to European patients? It is what determines continuous private investment in Europe – why invest in the development and commercialisation of drugs, if those medicines may not be approved and reimbursed? Could we also run the risk that European private companies or research(ers) decide to continue to focus their efforts outside Europe?

Most importantly – should we not have as a vision that all European patients have the best access to healthcare the world has to offer? That would require leadership in our infrastructure (medical, digital, supply chain), in our science, and in the therapeutic and non-therapeutic options available to EU citizens.

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New **EU pharmaceuticals rules** in a strong **European Health Union**

STELLA KYRIAKIDES

Commissioner for Health and Food Safety – European Commission

Since 2020, the COVID pandemic altered every part of our lives, our societies, and our economies.

It caught the world unprepared and exposed the weaknesses of our health systems.

However, the pandemic also highlighted that we are stronger when we work closely with our Member States for the benefit of our citizens. It transcended institutional taboos of the past and allowed us to invest instead in collaboration and global solidarity.

The strength of this solidarity could not have been better illustrated than through the EU Vaccines Strategy, in which the EU ensured deliveries of lifesaving COVID vaccines to all 27 Member States at the same time and under the same conditions.

That was the Rubicon moment for our European Health Union. A Health Union in which where the health of our citizens takes centre stage in EU policy, and we do more together with Member States to bring added value for public health and for every EU citizen.

This could not be truer than in the area of medicines.

Our current pharmaceutical legislation has been in place for more than 20 years. In that time, these rules have enabled the delivery of safe and effective medicines to all those in need, including hundreds of medicines for children and people suffering from rare diseases.

However, new scientific and technological advancements have revolutionised the health and pharmaceutical landscape in the meantime. Today our citizens' ability to find the medicines they need very much depends on where they live.

The numbers speak for themselves. When innovative medicines enter the EU market, 90% of them can be found in Western and bigger Member States. In Eastern and smaller Member States, that number is only 10%. The waiting time before they arrive on the shelves also differs a lot, with patients having to wait more than two years in some Member States and only a few months in others.

It is time for this to change. There can be no first and second class patients in the EU. Everyone deserves to have timely and equal access to medicines whenever needed.

That is why we need a true single market for medicines in the EU. To achieve it, we want to create an ecosystem for medicines that is both industry-friendly and puts patients at the centre; one in which availability, access, and affordability of medicines, as well as industrial competitiveness go hand in hand.

To ensure better access to medicines, companies will be given stronger incentives to launch in all Member States instead of just a selected few – new medicines should be available to patients everywhere in the EU. This should be our joint responsibility.

We have proposed a robust system of industry incentives to reward innovation and ensure that companies are rewarded for taking their medicines to all European countries. We will streamline authorisation procedures and shorten timelines for assessment to around 180 days so that medicines reach patients faster, and without compromising our high safety standards.

Affordability of medicines is a critical issue for patients and healthcare systems, and another key priority of the reform.

Generics and biosimilars, which are cheaper to produce, will be able to enter the market much quicker, which will help with availability and affordability. We will also help Member States to be in a stronger negotiating position when discussing market entry with companies, to negotiate prices and make decisions on pricing and reimbursement easier.

Over the last decade, reports of medicines shortages have increased significantly. When it comes to availability of medicines, we will put in place an EU alert system for potential shortages and require companies to have shortages prevention plans for their medicines. We will also establish for the first time an EU list of critical medicines to monitor the availability of essential medicines and address supply chain vulnerabilities.

Last but not least, tackling the increasingly pressing threat of antimicrobial resistance is crucial before it becomes the next global health crisis. Today, 35,000 people in the EU alone lose their life every year to drug-resistant bacteria.

We need urgent and ambitious action, which is why Member States have adopted in record time a new toolkit to address the AMR market failure.

This includes transferrable exclusivity vouchers as a powerful market incentive to promote investment and innovation in new antimicrobials, prudent-use measures and measurable targets for Member States to address overuse and reduce their consumption.

Taken together, all of these measures mean that access to innovative medicines will increase by 15% compared to today. This is an additional 70 million patients more in the EU who can potentially benefit from a new medicine and improved quality of life. This is what our European Health Union is all about.

Our reform of the EU's pharmaceutical legislation is a once in a generation opportunity to do more for citizens and for industry.

So that we ensure that no patient is left behind, while reinforcing the position of the EU as a global leader in for pharmaceutical innovation.

A **Critical Medicines Act** for **Europe**

FRANK VANDENBROUCKE

Deputy Prime Minister and Minister of Socials Affairs and Public Health Belgium

Introduction

Over the past few decades, Europe's manufacturing base for off-patent medicines, APIs, and starting materials has gradually decreased. This decline is clearly visible on the ground: each year, member states experience market disruptions and shortages as a result of manufacturers ceasing production within the EU. This year's thrombolytic shortage was caused in part by a German manufacturer permanently ceasing production as a result of a poor quality report. In the Netherlands, a producer of epileptics and other scarce products also announced closure of business. In Austria, the government bailed out the last European end-to-end manufacturer of antibiotics.

The problems we face today are part of a larger trend. While Europe still accounted for 53% of global production in *Active Pharmaceutical Ingredients* (APIs) in 2000, this figure dropped to 25% by 2020, with the vast majority of production shifting towards Asia, and particularly China. Trade data show that China accounted for 40% of global trade in APIs in 2019. This is also true for other ingredients necessary for API and medicines production, for which Europe relies for 74% on Asian imports, 70 percent of which coming from China. This Asian shift goes hand in hand with increased monopolisation across the value chain: in many cases, one or two producers control the global market, and several different APIs or components are manufactured at the same facility.

Time for a Critical Medicines Act

The consequences of the decline in European production are becoming increasingly problematic for our patients. The medicines market is not a flexible one: when a producer withdraws from the market it is often difficult, if not impossible, to find a replacement. We also see that there is a strong link between access to medicines and having domestic production: it is much easier for our medicines agencies to negotiate with a European producer than with a Chinese, Indian or American one. This was demonstrated not only during the COVID-19 crisis, but also during recent thrombolytics and antibiotics shortages. Moreover, the increased dependencies and market monopolisations pose security risks that must be addressed: a new pandemic, natural disaster, (trade) war or even a manufacturing glitch could have disastrous consequences for the world's medicines supply.

That is why Belgium, together with 21 other member states, proposed to launch a Critical Medicines Act (CMA). While the modalities for the Act are still under discussion in Council and within the Commission, we believe it should serve a three-fold goal: (1) to reverse the general negative trend of declining production of off-patent medicines in Europe, (2) to diversify our pharmaceutical supply chains, and (3) to secure some degree of "strategic autonomy" for certain critical medicines.

A toolbox with different instruments

There is not one silver bullet for solving Europe's supply problems. The Critical Medicines Act should therefore be viewed as a toolbox with different instruments, which can be roughly divided between "broad instruments" and "targeted instruments". While the former should help reverse the general decline in European manufacturing and diversify supply chains, the latter should ensure that Europe has in-house capacity to produce the most vital classes of medicines at scale to reduce security risks.

For instance, broad instruments could include specialised rules on public procurement which oblige procurers at national, regional and even hospital level to integrate security of supply, environmental and social criteria in their tenders. Today, the vast majority of tenders uses price as the sole criterium. This means that EU companies, who must comply with stricter environmental and social obligations, frequently lose out to Asian competitors, even when price differences remain as small as a few cents per product. On top of this, many procurers also use winner-takes-all approaches, meaning that only one big player is selected to supply the market, thereby eliminating competition and creating de facto monopolies. A coordinated European effort on public procurement could help increase the resilience of our medicines ecosystem, with several different companies supplying the market and security, social

and environmental efforts being properly rewarded.

Measures like these would benefit our overall resilience. However, in view of the rising geopolitical tensions, there are a few product classes for which we should not leave it to mere chance whether they are produced in Europe. These would for example include vaccines, antibiotics, and some oncology and ICU medicines. For such products, the Critical Medicines Act should contain targeted instruments

One such instrument, could be a specialised *Important Project of Common European Interest* (IPCEI) to reshore or expand production for some types of medicines, APIs and starting materials. This IPCEI should break away with some of the rigid EU criteria which traditionally inhibit the off-patent sector from participating in IPCEIs (such as strict innovation criteria), create faster, more predictable and less administratively burdensome procedures for companies and governments and pay attention to the whole supply chain. Instead of the traditional bottom-up coordination by member states, the Commission should take up a coordinating role to ensure that Europe meets its objectives. The special IPCEI should also be backed by EU-funding.

Europe's Added Value

We can expect that the debate on medicines shortages and EU strategic autonomy will remain high on the political agenda over the next few years. In absence of EU concerted efforts, Germany, France, Italy and Spain - the four biggest member states - have each announced their own action plans to promote or reshore European medicines production. A European coordinated approach would be less costly and much more efficient than a scenario where member states go their own way. Moreover, a fragmented, national approach would negatively affect smaller or poorer member states who are not able to hand out large sums to expand their domestic industry. The Commission should use the current momentum and propose a Critical Medicines Act for Europe. We have no time to lose.

SANDRA **GALLINA**

Director General - DG SANTE, European Commission

Building a **Strong European Health Union**: Blazing a trail in the European pharmaceutical sector

The start of the decade has crystallised the importance of healthcare policy, particularly due to the COVID-19 pandemic. This global crisis has revealed to us all the need for collective action to protect and enhance the well-being of our Union's citizens.

While the pandemic was not the initial catalyst, it served as a focal point that strengthened our determination to continue the ongoing efforts to improve our Union's health and pharmaceutical industry.

The journey to reform and rejuvenate the regulatory framework of the European Union's pharmaceutical sector was urged by both the European Parliament and the EU Council at the beginning of the Commission's mandate.

In 2020, as a response to the darkest days of the pandemic, the Commission's response took a new dimension with the proposal to establish the European Health Union (EHU).

Since then, new mandate for the European Medicines Agency has entered into force, the European Centre for Disease Prevention and Control has been given a stronger role in supporting the EU and its Member States in the prevention and control of communicable disease threats, and the European co-legislators have agreed on the "software" Regulation on serious cross-border threats to health providing a stronger health security framework for the EU.

The EHU also provided us with the Pharmaceutical Strategy for Europe, aiming to establish a regulatory framework for the 21st century. This strategy addresses market failures and puts patient needs at its core by supporting research and technologies in the industry.

As the flagship action under the EHU, the Commission has proposed the revision of the EU's pharmaceutical legislation, the first in over two decades. This proposal centres around the patient, providing greater access to affordable medicines while boosting the competitiveness of the European pharma industry and considering the environmental dimension too. It is fair to say that this reform would not have been the same if Europe and the world had not gone through the COVID-19 pandemic. We have seen, for instance, the power of solidarity through Europe's vaccine strategy. As Member States joined forces, all EU citizens benefitted from access to vaccines at the same time, under the same conditions.

A focus point in the strategy and the reform is to ensure access to affordable medicines for patients and to address unmet medical needs, including for rare diseases. Despite their name, rare diseases affect a significant number of Europeans, with up to 36 million people in the EU suffering from such conditions. The EU supports research efforts related to rare diseases through programs like Horizon 2020, which has allocated close to €900 million to over 160 collaborative projects.

Access to medicines is a crucial aspect of an efficient healthcare system. Our vision for a strong European Health Union includes a modern pharmaceutical system that is resilient in times of crisis and meets the daily needs of citizens. Whether it is treating allergies, vaccinating children, or providing innovative medicines to cancer patients, citizens should have access to the medicines they need regardless of where they live.

To maintain Europe's position as a trailblazer, the domestic pharmaceutical industry must retain its competitive advantage. Our strategy leverages innovation to offer quality, state-of-the-art, effective medicines domestically, while addressing medicine shortages. Additionally, the strategy enhances crisis preparedness and response mechanisms, diversifies, and secures supply chains, while maintaining the highest standard in quality, efficacy, and safety.

A key focus of our efforts is minimising the carbon footprint in line with the goals of the

European Green Deal. While we address the challenges such as medicine shortages, weak supply chains, and unequal access to medications among Member States, the European Union is committed to resolving these issues alongside concerted efforts to protect the environment.

To incentivise innovation in our pharmaceutical sector, we must adopt a new way of thinking. This involves implementing rules that leverage the power of research while streamlining official processes and reducing administrative costs by €300 million. Establishing a clear and uninterrupted path from research laboratories to manufacturers and ultimately to patients is crucial for a robust healthcare system.

To build a strong European Health Union, we need to prioritise access to medicines, improve transparency, reduce costs, and encourage innovation. Empowering citizens, enhancing collaboration, and establishing a streamlined pharmaceutical system that works for all: industry and patients, and will form the foundation of this strong European Health Union we are building together.

The Pharmaceutical Strategy for Europe also aims to increase the affordability of medicines more generally by promoting voluntary cooperation among Member States on pricing, reimbursement, and payment policies, while respecting their national competences in this area. We are supporting this cooperation through the group of National Competent Authorities on Pricing & Reimbursement (NCAPR), where Member States can share best practices to ensure affordable medicines.

We will need to have our house in order when countering existing and future health threats. The threat of antimicrobial resistance (AMR) comes to mind. Though it may lurk beneath the surface of our consciousness, this growing threat already claims around 35,000 lives in Europe every year.

The revision of our pharmaceutical legislation, together with the new Council Recommendation on AMR will drive EU action in this area, along with the help of incentives to reward the successful development of antimicrobials.

To face such threats, only an approach that considers the health of humans, animals, and plants, as well as the environment, can ever be effective. This One health approach will be the inspiration needed to bring about a strong European Health Union. A project that will undoubtedly be looked back upon as a pivotal moment in the history of the EU, and one of its greatest achievements. After all, there is no greater investment than in our health.

DOLORS MONTSERRAT

MEP (EPP Group – Spain) - EP COVI Report

The lessons **EU learned** from the **pandemic** towards a **better prepared** and **resilient pharmaceutical system**

The COVID-19 crisis has pushed health higher on the agenda of the European Union, but also on the list of top concerns of our citizens. In response to the consequences of the pandemic, the European Parliament on April 2022 set up a Special Committee on Covid-19, in a bid to assess the European Union's response to the pandemic, drawing conclusions and put in place recommendations for improving the EU's Health crisis management and preparedness for future emergencies. At the beginning of June, the Special Committee approved its report, for which I was the Rapporteur.

The EU, as well as the rest of the world, was not ready to cope with this unprecedented health crisis and its shock waves, which affected societies and economies worldwide. After a slow start, the European Union reacted with all the instruments at its disposal, and it is clear that its leadership, especially in trying to advance the search for and development of COVID-19 vaccines and treatments, while at the same time coordinating health, economic and social measures, has been crucial in saving millions of lives in the EU and beyond.

The development and deployment of COVID-19 vaccines and the EU Vaccines Strategy constituted a game-changer in the pandemic. The strong European Health Union we are building will be essential to strengthen our health systems and cope with future health crises, improving its resilience and quality, and ensure equal, universal, affordable medical care, while strengthening transparency of public funding for health research and governance.

Research and innovation have never been more important than today. A thriving and technically advanced European healthcare industry and a competitive research community is vital. The EU needs to maintain a strong European intellectual property system to encourage R&D and manufacturing in the EU Health sector and to ensure that Europe remains innovative and a world leader, while supporting third countries to improve their technical expertise and manufacturing capacities.

The medical emergency affected the security and stability of social and economic conditions, influencing, in particular, the life of vulnerable people, including people with disabilities and chronically ill patients, with consequences linked to delays and disruption to diagnostics and treatments. This cannot happen again.

It is of absolute importance to create more quality jobs along the entire healthcare sector, and invest in continuous education and training for the health workforce in the European Union, while facilitating mobility at EU level, with the support of NextGenerationEU.

The multiple challenges currently facing the EU show the need for ensuring the EU open strategic autonomy in Health. In the context of the pandemic, the EU needs to find permanent solutions to avoid dependency on third countries for medicines, in particular active ingredients and medical devices. The role of HERA will be crucial. The EU needs to increase its production capacity by encouraging its industry, but also by diversifying its supply chain and ensuring better coordination of national health strategies.

The Commission and Member States need to promote more joint European public procurement as has been done for Covid-19 vaccines and innovative procurement procedures incorporating criteria such as: 'Made in Europe', timely delivery, eco-sustainable production, security and continuity of supply, talent retention.

We have entered the EU decade of Health and together with the Green Transition, the Health sector need to endorse and implement the Digital Transition, benefitting our Healthcare Systems and Services with the most advanced digital solutions, the Artificial Intelligence and the EU Health Data Space, for

the most modern, high quality and effective research, treatments and data management, while protecting the patients' privacy.

Digitalization in Health comes with an urgent need for cybersecurity. Cyber-attacks on hospitals and health systems have become almost a weekly occurrence in several parts of Europe. We call on the Commission and Member States to form a unified strategic approach and to set up instruments and funding programmes to fight cyber threats.

Finally, we call for the swift implementation of a holistic approach to pandemic prevention and response. The EU should adopt the G20 Rome Declaration and establish innovative cross-sectoral primary prevention programmes to reduce risk factors and promote healthy lifestyles, integrating a One Health and Health-in-all-policies approach, throughout agriculture and food production, transport, the energy sector, industrial development, education and social services.

In conclusion, I consider the report a key document in the event of future health emergency crises and not only, providing solid guidance based on the lessons learned from a real pandemic. We recommend capitalising on it by taking forward actions from the report, which will contribute building a European Health Union, and a much more resilient European economy and society, able to face any threat not only to health, but also to security, while protecting the welfare and lifestyle model of European citizens.

A strong European Health Union needs a clear, ambitious, up-to-date EU pharmaceutical regulatory framework, able to stimulate and support research and innovation, cooperate with a globally competitive secured European industry, and veil for the sustainability of our National Healthcare Systems while putting the patients' need at the centre. After twenty years, with the EU Pharmaceutical Legislation review now in the European Parliament, we have a tremendous opportunity to achieve it.

The findings of the COVI Committee report point to the need for a stronger political will among national governments when communicating and working together on Health under the coordination of the European Commission and the Parliament. If the EU wants to withstand the onslaught of the next pandemic, it has to be prepared with financial investments, new legal instruments, and a more cohesive and harmonized cooperation among the Member States, European institutions, and the international organizations.

PIERRE DELSAUX

Director General of the European Commission's Health Emergency Preparedness and Response Authority (HERA)

Enhancing the **resilience** and the **competitiveness** of the **pharma supply** chains to secure access to **critical medicines** and other medical countermeasures

When the COVID-19 pandemic hit, countries around the globe were caught off guard. In Europe, each country initially responded on its own before realizing the need for a coordinated approach. Thankfully, with the lead of the European Commission, and thanks to the solidarity of EU Member States, vaccines were quickly made available to everyone in the Union at the same time. Early investments through a number of "Vaccines Advanced Purchase Agreements" supported the development and production of COVID-19 vaccine, at scale, in record time. This did accelerate the availability of a large portfolio of effective and safe vaccines that benefited not only European people but the world population. Around two-thirds of COVID vaccine doses produced in the EU have been exported to the rest of the world. Europe was the world's pharmacy when others closed their doors.

COVID-19 will not be the world's last public health emergency. Europe needs to be better prepared for future crises, whether they are pandemics or other threats like bioterrorism. We have learned some important lessons from the current pandemic. Acting quickly and working together is crucial.

At the occasion of the publication of the EU Economic Security Strategy on 21 June 2023[1], President von der Leyen recalled that global integration and open economies were a force for good, for Europe. Recognising that the world has become more contested, she also called for reducing Europe's excessive dependencies in certain essential sectors. Europe's heavy reliance on external sources for essential medical supplies has been particularly clear during the COVID-19 pandemic as well as due to the ongoing increase in geopolitical tensions, leading to alarming shortages of essential medicines.

Creation of HERA

In September 2021, to improve Europe's ability to respond to health emergencies, the European Commission established HERA, the European Health Emergency Preparedness and Response Authority. HERA's job is to strengthen Europe's readiness to prevent, detect, and respond rapidly to health emergencies. It focuses on making sure we have the necessary medical supplies and countermeasures, coordinating efforts between EU Member States, industry, and other stakeholders. HERA is also tasked to address vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of medical countermeasures.

A strong international dimension

To ensure the availability of medical countermeasures, HERA works closely with partners outside the EU, to benefit from relevant efforts of other entities, and create synergies with scientific and industrial powers. But to strengthen preparedness and response at the global level, HERA also contributes to the international efforts for the development of regional or local capabilities for the production of vaccines, medicines and medical supplies whenever the need arises. HERA is not only working closely with the World Health Organization, funding clinical trials for emergency medicines in Africa, but also looking for synergies in epidemic intelligence with the WHO Berlin Hub[2]. Closed partnerships are being established already with similar entities across the world: BARDA[3], the US Biomedical Advanced Research and Development Authority, as well as with new or in-the-making entities in South-Korea[4], Singapore and Japan.

Joint efforts are essential to ensure the development of innovative medicines. Building on existing structures, HERA is for example funding CEPI[5], a global partnership working to accelerate the development of vaccines against epidemic and pandemic threats. In Africa, HERA is liaising closely with the Africa Centres for Disease Control and Prevention while coordinating with other EU initiatives to support the development of local capabilities for detecting threats, monitoring epidemics, and producing medical supplies.

Industrial dimension

Promoting research on pathogens as well as incentivising research, innovation and development of relevant technologies and countermeasures is important during preparedness phase. For this, HERA relies mainly on Horizon Europe, the EU's research and innovation programme. In June 2023, as part of the mid-term assessment of the European budget, the Commission put forward a proposal to mobilise additional money on the resilience and the competitiveness of our

1 https://ec.europa.eu/commission/presscorner/detail/en/ip_23_3358

2 https://health.ec.europa.eu/latest-updates/global-health-hera-and-who-hub-strengthen-cooperation-pandemic-and-epidemic-countermeasures-2022-12-06_en

3 https://ec.europa.eu/commission/presscorner/detail/en/IP_23_2771

4 https://health.ec.europa.eu/latest-updates/global-health-hera-and-republic-korea-strengthen-cooperation-preparedness-and-response-cross-border-2023-05-23_en

5 https://health.ec.europa.eu/latest-updates/health-hera-and-cepi-agree-stronger-cooperation-development-medical-countermeasures-2022-10-24_en

economy, including for the biotech sector, together with deep tech and clean tech[6].

HERA works also closely with the European Medicines Agency (EMA) to create an EU clinical trials network to facilitate the authorisation process of new medicines. Special procedures and financing are being prepared for crisis times.

As shown by the COVID-19 pandemic, a lack of industrial reserve manufacturing and supply capacities, complex global value chains for production and distribution of pharmaceuticals, and lack of diversification of sources of dependencies from third countries can quickly result in shortages of essential medical countermeasures. This must be addressed through enhancing the EU's industrial resilience. Longer-term investments, strategic planning and strategic alliances with industry are required to make the Union more resilient to external shocks and maintain an adequate supply base in the EU. HERA aims at coordinating EU and Member State efforts to reduce supply risks, secure resilient supply chains, and shrink excessive external dependency. Initiatives like HERA's EU FAB concur at increasing, or securing existing production capacity.

Finally, the high-risk nature of investments into the development and production of innovative medical countermeasures against cross-border health threats which are hard to predict, leads to a lack, or at the very least insufficient private investment. Teaming up with the European Investment Bank, HERA is launching in 2023 a pilot investment scheme called HERA Invest to de-risk private investments in this field.

Shortages of medicines

Shortages of medicines are an ongoing concern in the EU and affect all EU Member States. Their root causes are diverse, including manufacturing issues, supply chain disruptions, unexpected increases in demand and commercial decisions by companies. In their meeting of 29-30 June, EU Leaders in the European Council invited the 'Commission to propose an initiative for urgent measures to ensure sufficient production and availability of the most critical medicines and components in Europe and to diversify international supply chains'. During an informal meeting in Stockholm organised by the rotating Presidency, a large number of Ministers for Health supported the idea of a Critical Medicines Act.

HERA is working closely with the European Medicines Agency, EMA, in the Executive Steering Group on Shortages of Medicines. Together, EMA and HERA are liaising with key suppliers to better understand their manufacturing capacity and demand forecasting for the next winter.

Antimicrobial resistance has been identified by HERA to be one of its three priority health threats. HERA's actions against antimicrobial resistance focus on promoting innovation and access to medical countermeasures: antibiotics but as well alternatives (e.g. phages and microbiome-modulating agents) and diagnostics, to rapidly identify or exclude bacterial infection. Shortages of antibiotics have been a recurrent issue. They can harm patients either directly or indirectly, due to the unavailability of effective therapeutic options for bacterial infections, or through the potential increase of antimicrobial resistance linked to an increased use of reserve antibiotics when first-line antibiotics are in shortage.

In this pilot phase, HERA and EMA are focusing their efforts on a number of antibiotics regularly used in national health systems for respiratory diseases and known to be at risk of shortages.

To ensure swift access to essential medical supplies, diversify supply chains, and stimulate the market, public procurement plays a vital role. The EU Vaccines Strategy for COVID-19 is an example of how it can be effective. HERA is working on building stockpiles of critical products to prepare for future emergencies. Joint procurement allows us to pool resources, reduce bureaucracy, and support each other among EU Member States.

By learning from the challenges of the COVID-19 pandemic, we are taking steps to ensure that Europe is better prepared for future health emergencies. Through cooperation, research, and strategic measures like HERA, we can strengthen our ability to respond swiftly and protect the health of our citizens.

6 https://ec.europa.eu/commission/presscorner/detail/en/ip_23_3345

NATHALIE MOLL
Director General of EFPIA

Rethinking the EU general pharmaceutical legislation for a competitive, more resilient and healthier Europe

As discussions surrounding the revision of the EU pharmaceutical legislation take place, two fundamental questions come to the forefront: how to ensure equitable access to medicines for all Europeans and how to foster a highly competitive and innovative pharmaceutical industry. I am concerned that the current draft legislation does not adequately address either of these objectives.

Tackling barriers to access

Achieving faster and more equitable access to medicines is as fundamental as it is challenging. One contribution to this that can be achieved at EU level is by streamlining regulatory decision-making processes which will lead to expedited approvals of new medicines for European patients. For the rest, from analyses published over time, we note that delays predominantly occur during the pricing and reimbursement phase within Member States, necessitating collective action from various stakeholders. Competencies influencing access therefore reside firmly at country level, rather than within EU legislation. The attempt made in this reform to retrofit national access frameworks into EU legislation primarily designed to determine product approval and support innovation will not work.

Acknowledging the urgent need to improve access, EFPIA has taken concrete measures. These actions include a commitment to file for pricing and reimbursement in all Member States within two years of EU approval linked to a dedicated portal and regular reporting of that commitment to track progress. Additionally, EFPIA proposes that the adoption of novel pricing mechanisms and the introduction of tiered pricing based on ability to pay, can empower Member States to effectively introduce and finance new medicines. Implementing these measures as a comprehensive package can result in timely improvements in patient access to medicines, without compromising competitiveness or Member States' health competence. Our modelling predicts an improvement of up to 64% in medicines access and reduction of delays for European patients up to five months.

Establishing a multistakeholder group involving industry, patients, payers, and providers to address access barriers in the present, rather than waiting for the revised legislation to be agreed upon, should be prioritised by the Commission and Member States.

Safeguarding Europe's competitive edge

At a critical time for Europe, a resilient and globally competitive pharmaceutical sector is essential to ensure the long-term health of Europeans as well as the region's strategic autonomy and a thriving economy. However, over the past 20 years, Europe has witnessed a continuous decline in its global competitiveness, particularly in terms of research and development (R&D) investment. This decline has resulted in a significant loss of ground to regions such as the United States and China in medical innovation, a trend that is deeply concerning and requires immediate attention. It is crucial to address this ever-increasing gap and ensure that Europe's 20-year-old regulatory framework becomes more agile, streamlined, and responsive to the rapidly evolving pharmaceutical landscape.

In order to close the gap and stimulate further investment in the region, it is key to provide more attractive conditions than existing ones. The revision of the legislation gives us the opportunity to do just that and yet, instead of improving the conditions we propose to worsen them. I am particularly concerned about Europe's intention to go in the opposite direction to its competitor regions when it comes to incentives for innovation. The draft proposals suggest reducing regulatory data protection and orphan market exclusivity. These proposed reductions, coupled with the introduction of conditions that hinder innovators' ability to recover incentives, cannot be considered ingredients to improve the investment environment for life sciences in Europe. They will contribute to worsening existing negative trends, such as the 25% decline in European R&D investment and the reduction in Europe's global share of clinical trials from 25% to 19%. The recently released EFPIA annual figures, show that China's R&D spending growth between 2018 and 2022 exceeded Europe's by more than three times, underscoring the urgent need to for action to close the gap.

To tackle antimicrobial resistance, the draft legislation proposes to improve the investment environment by introducing better conditions. Here provisions aimed at reinvigorating antimicrobial R&D include a transferable exclusivity voucher scheme. While this demonstrates a commendable effort to support research in a critical area, the system as it is drafted today will not reach its aims due to the excessively stringent conditions attached to the incentive. To effectively promote antimicrobial R&D, it is necessary to strike a balance between encouraging innovation and providing realistic conditions for companies to engage in R&D activities.

In addition to the detrimental effects that the revision of the pharmaceutical legislation in its current form could have, and in a context where Europe and Member States are focused on how to strengthen the region's strategic autonomy, we see other policies being developed that could further negatively impact our competitiveness and increase dependency on other regions. A ban on PFAS materials - widely used in pharmaceuticals,

manufacturing facilities and packaging - could be in place by 2027. This could reduce manufacturing capability in Europe, leading to shortages in the EU and globally and could see manufacturing move to other parts of the world.

Enhancing the pharmaceutical legislation for patient-centric innovation in Europe

To effectively serve patient needs and fulfill the core purpose of Europe's pharmaceutical legislation, I believe that a series of actions must be undertaken now.

- As proposed in the draft legislation, it is imperative to further enhance the regulatory framework to ensure a robust and efficient system. This involves maximising the use of expedited pathways, such as accelerated approval and priority review, to improve the availability of innovative treatments that cater to patient needs effectively. By optimising regulatory decision-making processes and reducing unnecessary administrative burdens, Europe can significantly improve access to life-saving therapies.

- In line with June 2023 European Council Conclusions, a critical step will be to strengthen, rather than reduce, the region's incentives for innovation such as regulatory data protection and orphan drug market exclusivity. Adequate levels of incentives are essential to attract more investment in R&D activities in Europe, start to stop the declining trend and hopefully even reverse it, to close the gap. Creating separate conditions that specifically target unique challenges in healthcare can further drive innovation and ensure that the evolving needs of European patients are effectively addressed.

- Addressing barriers and reducing delays in accessing new treatments necessitates a collaborative approach based on a shared understanding of evidence. The recently published Industry European Access Hurdles Portal offers valuable insights into the various access challenges faced by patients, healthcare providers, and payers. By actively engaging all stakeholders, Europe can collectively overcome these barriers and develop targeted solutions to ensure timely access to life-changing treatments.

- To incentivise research efforts focused on meeting the needs of European patients, it is crucial to develop a patient-centered, broad definition of unmet medical need. By acknowledging the value of incremental innovation and encouraging advancements in treatments and care, Europe can ensure that no patient is left behind.

- Europe must establish supply chain and environmental requirements that are proportionate and aligned with the shared objectives of addressing medicines shortages while reducing the sector's environmental impact.

- Finally, considering the industry's significant contribution to the EU trade balance and its role in driving economic growth, it is also necessary to conduct a comprehensive competitiveness check on the Commission's legislative proposals, in line with President von der Leyen agenda. This evaluation would ensure that the measures being considered foster a thriving pharmaceutical sector that can close the gap with the other regions in the world and can firmly contribute to a healthier and more resilient Europe.

Charting a path to success

Europe finds itself at a critical point, requiring immediate and decisive action to secure timely access to medicines and increase competitiveness within the pharmaceutical sector to close the gap with other regions that have been outpacing us for 20 years. Looking ahead, the challenge lies not in whether medical innovation will occur, but rather in determining where it will happen and how European patients can benefit from it.

Patients in urgent need of life-saving treatments cannot endure the prolonged process of finalising revised legislation. Europe must proactively streamline regulatory decision-making, collectively address access barriers, and strengthen intellectual property rights to establish an environment that promotes innovation and ensures equitable access. The time for action is now, as the repercussions of inaction or ill-action will be detrimental to both patients and Europe's position in the global pharmaceutical landscape. It is imperative for all stakeholders to unite and chart a path that maximises access, strengthens innovation, and secures Europe's competitive edge.

As an industry, we are fully committed to meeting the challenges that lie ahead. Europe cannot afford to miss out on groundbreaking innovations that have the potential to revolutionise patient health and well-being.

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The **patient** at the center of all **health policies**

SARA CERDAS

MEP (S&D Group – Portugal), ENVI, SANT and COVI Committee Member

In the wake of the global COVID-19 crisis, Europe stands at a critical juncture in shaping its health policies and strategies for the future. The European Health Union has awakened and the European Union (EU) is becoming more and more active in health legislation considering our role in the treaties on protecting public health. Health systems are being rebuilded, strengthened and new approaches are now in practice to achieve these ambitious objectives. The major challenge from now onwards is making sure the patient is at the center of all health policies when transforming healthcare in Europe.

When considering a patient-centric approach one can fear that we are just applying a jargon of policy making; however, we can actually be consequent. Many political groups will try to take over this concept and use it as political priority when, not surprisingly, they will just feed their populist narratives. Others will definitely address individual needs, preferences, and experiences to guide policy formulation as only responsive, socially inclusive, and effective delivery of high-quality universal health coverage care can really be at the heart of this very important principle.

The European Health Union is composed of many important legislative and non legislative files from digital transformation with an European Health Data Space, a Global Health Strategy, a new Regulation on Serious Cross-border Health Threats, better prepared and equipped European Medicines Agency and European Centre for Disease Prevention and Control, an European Beating Cancer Plan, a Pharmaceutical Strategy and a Mental Health Strategy, just to name a few.

Patients have to move together with digital transformations with joint steps based on a trustworthy system, with clear lines on transparency, accessibility, capacitation, and direct benefits from their valuable contribution. Healthcare delivery can be absolutely revolutionized and patient engagement needs to be enhanced. Electronic health records will finally be in their control and we must acknowledge the value that telemedicine and data sharing can bring, whilst respecting privacy and security.

A patient-centered approach in global health is making the EU concede the technological and legal means for third countries to properly manage and solve global crises such as in vaccine, medicines and medical devices manufacturing. Population growth worldwide highlights the importance of universal health coverage where the EU can play a pivotal role.

To achieve a patient-centered healthcare system, collaboration and cooperation among all stakeholders are essential. During the COVID-19 pandemic, an EU coordinated approach underlined the importance of better prevention, preparedness, response and control of cross-border health threats.

Although innovation, medicinal product development might play a significant role, primordial, primary and secondary prevention are at the core of a patient-centered approach and the same applies to non communicable diseases. This is why the European Beating Cancer Plan stresses so much on prevention and early detection and that the EU4Health Program 2021-2027 is such a powerful tool in modern health policy at EU level.

And we stand at a cross point where two jewels of this crown are left in the heart of a storm. The Pharmaceutical Regulation and Directive are presented in such a way where political consensus will only be possible in the mid future, very likely in the next mandate where populist groups will try to take over the patient-centered approach and turn it into a industry/private interest-centered approach. Moreover, Mental Health could have had the proper attention if 2023 was chosen to represent it and EU institutions could have had the space to develop more initiatives about it. Otherwise, it might be forgotten or even twisted in such a way where no social group representativity will exist.

The attention should now be turned into these two pieces in the chess table. Ensuring equitable access to affordable, safe, and effective medicines for all European citizens is paramount and mental health services accessibility, early detection, targeted campaigns and solutions to vulnerable groups must be the axis to where we should be going.

Let's value involving patients in decision-making processes, promote health and digital health literacy and give health professionals the most crucial tools for delivering quality care.

As Europe navigates the post-COVID era, it must seize the opportunity to place the patient at the center of all health policies. Things might change after the next elections but our struggles will be similar. Is anyone ready to give up on a patient-centered approach?

Share the goal of faster and more equitable **access** to **medicines** for **patients across Europe**

NICU STEFĂNUȚĂ

MEP, (Group of the Greens/European Free Alliance – Romania), Member of Subcommittee on Public Health

Access to affordable medicines represents a universal human right and a significant target included in the Sustainable Development Goals of the UN. Unfortunately, in Europe we are faced with a growing gap between Member States in terms of equitability in accessing medicine.

Although innovative medicines receive market approval for the entire EU, the facile and timely access to these medicines for patients varies differently from country to country, with some severe cases like that of Romania, reporting an average delay of almost 883 days.

While new developments in healthcare hold the promise of greatly improved health outcomes, these also lead to the risks of deepening inequalities and the development of new forms of discrimination and marginalization.

From my point of view, it is imperative that innovative treatments and new healthcare technologies are made available in an equitable and timely manner. Access to such novel treatments and technologies must ensure that everyone, without discrimination, is offered a fair opportunity to receive them in a safe and effective manner. We as a Union need to take better care in addressing the issue of growing inequality when it comes to ensuring that our citizens benefit from the same standard of care across all Member States.

Nonetheless, equitable access to medicine does not concern only innovative drugs, which are highly expensive, but also less expensive treatments like generic medicine which are plagued by a recurring medicines shortages phenomenon, driving patients and medical personal to find bio-similar treatments or to change the treatment altogether in some instances or even to pause the treatment with some severe consequences for the outcome of treatment.

The EU needs to find a common ground in fighting the growing health inequality gap, and the COVID-19 pandemic was useful in putting in the spotlight the misalignments between health systems across Europe and the need to have a holistic approach spearheaded by EU institutions in order to combat global health crises.

Solving the inequity gap requires a common and integrated approach to key issues like pricing, supply and distribution, market accessibility and regulatory frameworks. EU wide health technology assessment will allow medicine producers to apply for evaluation reducing waiting times and enabling innovative medicine to get to the patient's bedside faster.

Other initiatives like joint procurement of medicine can lower prices and ensure an equal access to treatment for all patients, as well as combat the side effects of parallel trade of pharmaceuticals products due to price differences from one country to another.

Intellectual property (IP) needs to be upheld and the EU must become a world leader in medical innovation, but we must also make sure that IP is not used to prolong market exclusivity rights longer than allowed by law. Reaserch and development of novel medicine using public money should have this public subsidy reflected in the final price of the medicine.

Nonetheless, having equitable reimbursement for medicine is quite useless if there are still regions in the EU without proper access to proper medical infrastructure with trained personnel, so there is also a need to invest in capacity building and infrastructure modernization.

Close collaboration between Member States and the EU institutions is necessary in overcoming the growing gape in inequality, ensuring that financial instruments and legislative frameworks are design as such that there is a synergy in addressing key issues like accessibility, pricing and reimbursement, cross-border healthcare and innovation.

Health security strategy: strengthening Europe's pharma industry base

OLIVIER CHARMEIL

Executive Vice President, General Medicines, Sanofi

A resilient and dynamic ecosystem for healthcare innovation is key to strengthening the European Union.

A comprehensive strategy brings patient well-being, economic value, and social cohesion.

The COVID-19 pandemic, now officially over, accentuated the European Union's dependence on third countries, particularly China, for pharmaceutical products. It also highlighted the fragility of supply chains in the face of massive disruption that has led to medicine shortages.

Europe's industrial response to COVID-19 is of vital concern to all Europeans. We only have to look westwards and eastwards to see countries and regions who are out of the starting blocks and well down the track: The US has forged ahead with its 'Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States'[1], China has unveiled its 'Dual Circulation Strategy'[2] with its stress on state-led growth and self-reliance while India has homed in on its 'Self-reliant India'[3] initiative.

But, what about Europe? While Europe's long-delayed revision of its pharmaceutical legislation[4] is finally out, its approach towards pharmaceutical supply chains fails to address the critical situation in which the EU finds itself: losing ground in the biopharmaceutical sector.

EU leaders call for a Critical Medicines Act

EU leaders are acutely aware of this as shown by their recent invitation to "continue and accelerate work on the proposed reform of the pharmaceutical legislation, including as regards access to medicines and an innovative and competitive pharmaceutical sector"[5]. The same goes for the 21 Member States who have supported the Belgian initiative on "Improving the security of medicines supply in Europe"[6].

This comes in the footsteps of the European Chips Act and the Critical Raw Materials Act. Like these, this initiative would support European production of essential medicines, vaccines, active pharmaceutical ingredients, and intermediate ingredients for which the EU is entirely dependent on one country or a handful of manufacturers. To dovetail with existing initiatives, it should be complementary to the ongoing review of the pharmaceutical legislation, albeit proceeding at a quicker pace.

This call, in favour of greater European sovereignty in health, is a welcome step. But we believe that a full-bodied European mission must go beyond cutting-edge – green and digital – production of critical medicines towards a real strategy to strengthen Europe's health security and open strategic autonomy[7].

A European Act to strengthen Europe's health security

Europe will undoubtedly face other pandemics, but it will also have to deal with an increasingly uncertain geopolitical order threatening the stability of its supply chains and perhaps on a grander scale than we've seen before

Addressing this will require innovative research, new technologies, and best-in-class manufacturing to walk hand-in-hand, providing the EU with a competitive advantage at global level.

How to achieve such a synergy? By building on Europe's approach to a clean-energy circular economy, a holistic industrial, innovation and investment strategy encompassing a broad portfolio of policies from digitization and decarbonization to health and trade as well as global health partnerships.

Only by adopting this all-encompassing approach will Europe be able to improve the efficiency of its research and development processes while strengthening its supply chains and reinforcing its position as a leader on key technological platforms and in spearheading innovations.

This would be the embodiment of Sanofi's philosophy. We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability

1 Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs

2 如何理解"国内大循环""国内国际双循环"

3 Atmanirbhar Bharat Abhiyaan

4 EU pharmaceutical legislation

5 European Council meeting (29 and 30 June 2023)

6 Improving the security of medicines supply in Europe

7 The future of EU's Open Strategic Autonomy: Ensuring citizens' well-being

and social responsibility at the centre of our ambitions.

Advancing the (re)industrialization of Europe

The first step towards health security and sovereignty will be to restore the European Union's competitiveness at global level by:

1. Facilitating public private collaboration in R&D and advanced manufacturing capacity.
2. Fostering capacity building through HERA (Health Emergency Preparedness and Response Authority) and the recently announced Strategic Technologies for Europe Platform[8].
3. Speeding up the regulatory process to ease the uptake of innovative technologies in manufacturing and R&D.

It is reassuring to see that this ambition is also in the mind of Ursula von der Leyen, President of the European Commission, who just re-confirmed her wish to "improve the EU's capacity to manufacture innovation at scale"[9] while driving investments into Europe. This support for innovative industry should also apply to vaccines: as demonstrated by COVID-19, innovative vaccines will be at the forefront of public health responses to future pandemics.

Decarbonising the health ecosystem

At a time when climate change is rightly on everyone's mind, industrial policy needs to support the greening of the manufacturing process. Responsible for 5% of global emissions, the health ecosystem should figure strongly within Europe's climate goals and circular economy, with the Net Zero Industry Act[10] serving as a blueprint for action.

Starting at product level, measures should range from the first stages of development to advance low-carbon value chains in health by *inter alia* supporting the generalisation of digital clinical trials, regulatory flexibility and solutions: at Sanofi, our objective is to save 330 tons of plastic per year and achieve carbon neutrality by 2030 for all our products including vaccines.

Combined with the development, and implementation, of EU-wide targets for cutting emissions along the entire patient care pathway, this will pave the way for increased investment in mitigating the environmental impact of healthcare systems.

Building today's resilience to safeguard tomorrow's European open strategic autonomy

Beyond the industrial and green components, EU strategy will require a global perspective under the European Global Health Strategy around three main areas:

4. The resilience of supply chains.
5. Crisis response and pandemic preparedness as in the WHO Pandemic Accord negotiations.
6. Global partnerships and trade policy.

As a trusted global actor, the European Union should make full use of international fora (such as the WHO, WTO, United Nations, G7, and G20) to defend such a strategy and reassure its partners that it eschews protectionism and will foster open strategic autonomy by diversifying European supply chains.

In addition, the HERA should be strengthened to prepare for future health emergencies in cooperation with other national and international agencies. This would allow the EU to take the lead in managing priority areas for drawing up medical countermeasures at global level (via target pathogens and technologies).

This renewed focus on health security as a global issue could then translate into bilateral partnerships built on stronger ties when it comes to the manufacturing and supply of pharmaceuticals and vaccines.

Conclusion

The current global context has given the European Union a new impetus to support its strategic industries, first and foremost the pharmaceutical industry.

By proposing a European Act to strengthen Europe's health security, it would be positioning itself in favour of competitiveness and innovation, while sending out a clear message to foreign investors keen to invest in attractive, stable, and progressive territories.

Crucial for the industry, the European act will ultimately benefit European patients: at a time when shortages are increasing and making life more difficult for patients, we must propose solutions to guarantee them rapid access to vital treatments.

The appeal of the Member States must be heard by the new European Commission which will take office at the end of 2024. At the same time, it will be vital to put into practice the European Council's ambition to make health a strategic priority for the next five years[11].

The time has finally come to close the gap between Europe and its Chinese and American counterparts or lose out definitively in the competitiveness stakes.

8 Strategic Technologies for Europe Platform

9 Statement by President von der Leyen

10 Net Zero Industry Act

11 Letter from President Michel on the next Strategic Agenda

FRANCESCA **COLOMBO**
Head, OECD Health Division

Policy priorities to prepare for the next **health crisis** - including building more **resilient medical supply chains**

With 7million reported COVID-19 deaths and over 19 million excess deaths estimated worldwide by January 2023, COVID-19 brought to the fore the weakness of health systems as well as interconnected sectors and systems, ranging from elderly care to the innovation ecosystem, to medical supply chains.

Put it simply, health systems were not resilient enough as we thought they ought to be. They lacked ability to prepare for, absorb, recover from and adapt to major shocks. Such vulnerabilities need to be urgently addressed to be ready for the next crisis – no matter whether this will be a novel pathogen, a natural disaster, a cybersecurity attack, or an armed conflict. Otherwise, the costs will be larger and the impact on people greater.

The recent OECD report, Ready for the Next Crisis? Investing in Health System Resilience sheds light on major pre-existing vulnerabilities of health systems exacerbated by the COVID-19 pandemic: health systems were **underprepared**, **understaffed**, and **faced underinvestment**. Annual investments to improve health system resilience would represent around 1.4% of GDP, on average across OECD countries, relative to 2019 expenditure. **Targeted priority investments** are needed where health systems proved insufficiently resourced to withstand shocks: in the health workforce, alongside increased spending on prevention and health information systems and infrastructure to improve the use of data for better decision making, surveillance and research.

Ensuring that health systems are better prepared and that the next shock does not leave such a challenging legacy also requires **preparedness, adaptation, and improvement of the interconnected systems to healthcare and global co-operation**. For example, promoting global co-operation will be key to finding better ways to pay for global public goods like vaccines. Public support will be essential for financing, regulation, manufacturing, and provision of health technologies needed for resilience in the future. These changes must be accompanied by credible obligations if such technologies are to be equitably distributed, especially in times of crisis.

Another critical area concerns reinforcing **medical supply chains resilience**. The effective functioning of health systems relies on the availability of adequate and reliable supplies of equipment and therapeutics, such as essential medicines and medical devices, including consumables. Medicines and medical devices are sophisticated products, subject to complex regulatory frameworks and manufactured through long international supply chains.

Already before the COVID-19 pandemic, issues of quality, concentration of markets and profitability of some products contributed to supply disruptions and shortages. In the initial stages of the pandemic, supply chains showed considerable elasticity in the face of extreme stress. Nonetheless, disruptions and shortages of key medical supplies were experienced due to spikes in demand and bottlenecks in supply. Widespread shortages of essential medicines and medical devices were experienced especially at the beginning of the pandemic. Almost all OECD countries saw problems securing personal protective equipment and testing material.

Three key policy options can be considered to improve the responsiveness and reliability of medical supply chains for future health crises.

First, improved market intelligence to monitor flows and state of supply chains. Difficulties in identifying the suppliers and countries involved in medical device supply chains can undermine assessment and mitigation of risks by governments. Greater transparency and improved reporting are therefore needed to ensure resilient and secure supply. Real-time information and co-operation between countries and manufacturers may be required to anticipate and address issues. In the context of the food

price crisis of 2007-2008, the experience with the establishment of mechanisms such as the Agriculture Market Information System (AMIS) created by the G20 in 2011 could offer some lessons for health systems. AMIS allows governments to share information on markets, policies and stocks of four key food commodities, supporting transparency and helping to identify bottlenecks and emerging risks thanks to consistent reporting and monitoring on market indicators and policy decisions.

Second, smart procurement and diversification in suppliers. Quality issues may be at the origin of shortages of some medicines and medical devices. Rules and standards exist to avert quality issues, but implementation and enforcement can be challenging. Having sufficient manufacturing capacity drawing on diversified sources of supply helps to prevent quality issues from driving shortages. Market dynamics and regulatory requirements may discourage investment in production capacity and limit diversification in supply. Greater supplier diversity and increased capacity require a reassessment of current procurement and pricing practices for some products. Caution should be exercised to ensure that policy instruments do not disrupt the smooth functioning of international supply chains. Trade and transnational production are important to enhance diversification of supply and create additional capacity at the global level. In particular, trade is important for access to technology and equipment.

A third resilience strategy to mitigate spikes in medical products demand is strategic stockpiling. To be efficient and effective, stockpiling strategies of emergency supplies should be planned and co-ordinated with the private sector and across countries. Securing supply chains for essential medicines and medical devices will improve outcomes during crises, strengthening overall health system resilience. It will also encourage predictability and reliability between disruptions.

Overall, promoting the long-term resilience of medical supply chains will benefit from stronger collaborative approaches that balance measures best undertaken by the private sector with those more appropriately managed by governments, as well as internationally harmonised and co-ordinated approaches to regulation and stockpiling.

The next crisis may not take the form of a pandemic, and the global community faces the prospect of a continuing "polycrisis". Against this backdrop, there are significant social and economic benefits of investing in health system resilience including in stronger and reliable medical supply chains. Doing so now is vital to facing tomorrow's challenges.

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Visit the OECD Health Systems Resilience webpage

An **EU Immunisation Strategy**: making **Europe** more **resilient**

SIBILIA QUILICI

Vaccines Europe Executive Director

Vaccination is critical to our health security infrastructure, laying the foundation for a more innovative, healthier, prosperous Europe, writes Sibilia Quilici, Vaccines Europe Executive Director.

The world has witnessed the critical importance of immunisation, playing a pivotal role in eradicating and significantly reducing diseases in improving health in Europe and around the globe, and in helping to fight pandemics. Nonetheless, the current geopolitical situation is a stark reminder that immunisation constitutes a component of national security which deserves dedicated financing and accountability.

Over the course of the last couple of years, the COVID-19 pandemic has demonstrated the importance of robust public health systems. The world we operate in has changed, revealing the vaccine industry to be a critical feature of Europe's health security infrastructure.

However, given the major challenges the EU is facing today – including a rapidly ageing population, the climate emergency, conflict at its borders, economic pressures and inflation, declining science literacy and trust in institutions – it is easy to overlook how vital strong immunisation policies are. Yet, many of the challenges we face are interconnected with the spread and rise of existing and new infectious diseases.

We are now entering a momentous phase in the history of pharmaceutical policy in the EU with the legislative debates around the European Commission's General Pharmaceutical Legislation about to start in the coming months.

This revision represents a unique opportunity to strengthen our healthcare systems, by giving prevention policies, including immunisation policies, a more prominent place.

Immunisation must be at the heart of building more resilient and sustainable health systems, serving as a powerful tool that prevents sickness, saves lives, saves money and contributes to strong growth and strong communities.

In the words of Charles Michel, President of the European Council, speaking about the next strategic agenda, the European Union "*must be equipped with general political directions and priorities to ensure lasting prosperity for the benefit of its citizens, (...) starting by consolidating the EU's economic and social base with the green and digital transitions, competitiveness, innovation, health as priority areas*".

This is why Vaccines Europe, representing the innovative vaccine industry in Europe, calls on European lawmakers to put in place an EU Immunisation Strategy.

By backing new vaccines research and development and strengthening protection against vaccine-preventable diseases across all generations, this strategy can help build an innovative, healthy and prosperous Europe.

"*We know that immunisation can bring incredible benefits to our societies, but the fact is that we are currently not realising its full potential. In the next mandate, we must put our learnings into action for a more resilient Europe through stronger immunisation policies and targets*", stresses Sibilia Quilici, Executive Director, Vaccines Europe.

An EU Immunisation Strategy: One Strategy – Three Results

Immunisation is paramount for building more resilient and sustainable health systems. It is an investment that delivers innovation, health, and prosperity.

An innovative Europe

Vaccine innovation is the foundation that will enable both health and economic gains and help us to be one step ahead of public health threats. Discovering and developing safe and effective vaccines relies on an innovative research, development and manufacturing ecosystem with robust and predictable intellectual property protection frameworks. Regulatory agility is needed to support faster acceptance of changes in manufacturing processes and more unified packaging, including e-leaflets.

To boost its defences against infectious diseases, Europe needs robust surveillance and e-health systems with interoperable databases for collecting epidemiological data, monitoring vaccine coverage rates, collecting/tracking data on vaccine confidence, and generating high-quality real-world evidence to inform immunisation policy.

This is why the EU Immunisation Strategy focusses on promoting forward-thinking policies that foster **innovation**, including the **establishment of a framework for transparent, inclusive and regular exchange between all relevant stakeholders in decision-making**.

Immunisation shields us from diseases and disabilities from the moment we are

born until the late stages of life, through paediatric, adolescent and adult immunisation programmes. It safeguards public health by protecting everyone against vaccine-preventable diseases. It contributes to preventing antimicrobial resistance. It helps to keep both adults and elderly with weakening immune systems healthy and active, thus contributing to society and the economy whilst easing the growing pressure on health systems.

A Healthy Europe

However, vaccines alone do not protect against illness. Vaccination does.

To ensure vaccine uptake and protection, it is time to **put life-course immunisation targets in place**. Combined with robust monitoring, this will help guarantee that all people in the EU, regardless of their socio-economic situation or age, wherever they live or travel, get the same level of protection.

A Prosperous Europe

High vaccination rates contribute to economic and social prosperity. They help workforces stay healthy and productive and contribute to economic growth. However, many do not get the vaccines they need, and national immunisation programmes face delays in including new vaccines in their schedules. Because only a very small percentage of national healthcare budgets go to prevention; with a minute proportion – only 0.5% – going to immunisation. If we are to improve immunisation rates to cope with a growing and ageing population, **the EU must set appropriate financial targets to increase financing of national immunisation programmes.** Europe's Member States should invest in prevention via immunisation.

An innovative Europe is a healthier Europe. A healthier Europe is a more prosperous Europe. These are the pillars of a resilient European Union.

We call on the EU to put in place an EU Immunisation Strategy in the next mandate that strengthens protection against vaccine-preventable diseases across all generations.

The **role** of **pharmacists** in prevention and **vaccination policies**

PHD ILARIA PASSARANI

Secretary General PGEU (European Community Pharmacist)

The COVID-19 pandemic took a devastating impact for public health and people's wellbeing, with a high number of deaths and lifelong consequences on the citizens quality of life. Despite the fact that the pandemic is now over, lessons must be drawn from this period, learning from it, and using it as an opportunity to improve preparedness and response of the healthcare system to address current and future challenges. Furthermore, there is a strong and urgent need to reinforce and strengthen Europe's healthcare systems and act swiftly. European community pharmacists welcome a revision of the EU general pharmaceutical legislation as a tool to help ensuring Europe's supply of safe and affordable medicines to meet patients' needs and to support the financial sustainability and the resilience of health systems.

There is a need to move from a hospital centred care to a patient centred care, monitoring and treating patients as close to their home as possible. This means investing more in primary care. According to Eurostat, on average in the EU, only 2.8% of public and private health expenditure is invested in preventive care.[1] Academics, policy makers and international institutions have repeatedly stressed that investing in primary care pays off: with undeniable evidence clearly indicating that it reduces hospitalization rates, prevents unnecessary emergency rooms visits and ultimately saves lives and money.[2]

Before, during, and after the pandemic, the pharmacies network near people's homes has been playing a vital role in supporting local communities and ensuring their continued access to medicines and care. Expanding the scope of practice beyond the traditional supply of medicines, pharmacists provide pharmacy services to the population, with added value to the healthcare system. Pharmacies have been accessible nonstop, even during lockdowns, and in many regions, especially in rural areas, community pharmacies were the only healthcare service available to local communities. Pharmacies have been the first line of advice, treatment, and referral on common ailments, successfully preventing unnecessary visits to emergency rooms, whilst being structurally involved in influenza and COVID-19 vaccination and testing strategies.

Across Europe, community pharmacists contribute in meaningful ways to vaccination campaigns. During COVID-19, pharmacists were involved in the supply management tasks and vaccines preparation in e.g., mass vaccination centres, the distribution of vaccines to care structures and providing reliable and understandable information and advice to the general public, but also vaccinating. Currently pharmacists are able to vaccinate against flu, COVID-19 or other diseases in 14 countries. In particular, pharmacists have also often been the first trusted source for patients to address questions around the safety and effectiveness of vaccines.

With countries putting efforts to recover after the pandemic, Europe cannot afford to continuing putting on hold disease prevention and health promotion, especially when facing the challenge of rapidly ageing societies. European community pharmacists are committed to taking up the challenge and remain in the front-line against fighting infectious diseases, providing their communities with timely access to treatments, reliable information, performing rapid tests and vaccinating. Furthermore, pharmacists are also ready to use their knowledge and expertise to provide more efficient and more effective care to patients.

The wide array of community pharmacies interventions on COVID-19 demonstrates

1 https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20210118-1

2 https://www.oecd.org/coronavirus/policy-responses/investing-in-health-systems-to-protect-society-and-boost-the-economy-priority-investments-and-order-of-magnitude-cost-estimates-abridged-version-94ba313a/

the highly reactive and adaptive character of pharmacies in response to the pandemic. The 400.000 community pharmacists across Europe, through the network of 160,000 community pharmacies near people's homes, are eager to reinforce the delivery of core pharmacy services and to go even further, assuming new responsibilities through advanced pharmaceutical services, proven to improve people's quality of life and health systems' sustainability. This should be encouraged by national governments by adequately remunerating community pharmacists for the services they provide. We should use this opportunity to make health systems stronger, more resilient, and more responsive to patients' needs. New models of care delivery should be defined, which involve multi-professionals' teams working seamlessly, to ensure continuity of care, especially for patients with chronic conditions.

Interprofessional collaboration and increased investment on disease prevention and health promotion measures are also key to improve health outcomes. Community pharmacy has demonstrated its value for patients and healthcare systems and is ready to further expand this contribution as part of sustainable and resilient collaboration models with other healthcare professions in the community.

Community pharmacists believe that governments should work towards making health systems stronger, more resilient, and more responsive to patients' needs. This can happen through expanding the scope of community pharmacy practice to maximise their contribution to patients and health systems in ensuring continuity of care and treatments, increasing vaccination coverage and offering an accessible first line of advice, consultation, screening, treatment and referral on common ailments to patients. Recognising the value of pharmaceutical services that have proven to improve people's quality of life and health systems' sustainability can be done by adequately remunerating community pharmacists for the services they provide.

Finally, the reform of the Pharmaceutical Legislation is a key opportunity to develop the resilience of health systems – focusing on critical aspects such as medicine shortages and the security of the supply chain, fighting antimicrobial resistance and ensuring access to medicines across the European region.

The **future** of **European healthcare** depends on what **happens now**

ANA PAULA CARVALHO

Western Europe President at Pfizer, discusses the implications of the European Commission's 'Pharmaceutical Package' and shares her perspective on the future of healthcare in Europe

European healthcare stands at a pivotal moment. The pandemic may feel a lifetime ago, but we are yet to fully define the 'post-COVID' era – and what happens next will shape healthcare across the region for decades to come.

Many lessons were learned that we should hold onto. Healthcare collaboration within countries and across Europe was unprecedented. We went on the journey together to bring vaccines and treatments to patients – leading to a far greater appreciation of the effort this takes and why good health and timely access to innovation matters so much for society to thrive.

As European decision-makers and stakeholders, including industry, engage in talks following the publication of the European Commission's (EC) proposed 'Pharmaceutical Package', we must remember the quality and resilience of our future healthcare depends on this continued collaboration.

At the heart of this partnership is a unified objective – to put the needs of patients first, just as during the pandemic. Across pharma, health systems, patient groups and clinicians, we all want to see more timely and equitable access to affordable medicines. Our destination is the same, but we have different perspectives on the route that will take us there – and we must listen and learn from one another if we are to deliver for patients.

From our point of view at Pfizer, the proposals contain several welcome improvements. These include streamlining and future-proofing the European Union (EU) regulatory system, the introduction of electronic product information, an EU-level 'pull' incentive to stimulate Research and Development (R&D) investment against antimicrobial resistance (AMR), the proposal for a rolling review of data, and regulatory sandboxes to test innovative ideas and processes.

These proposals show we can learn from our shared experience during the COVID-19 pandemic. We are encouraged by the potential to improve collaboration between manufacturers and regulators, speed up regulatory processes to bring innovation to patients sooner, incentivise R&D in a key area of unmet medical need such as AMR, empower patients through greater access to treatment information and respond to patients' needs more directly.

However, the draft legislation also presents real, practical challenges to achieving the change we want to see for patients. We are all aware that the pandemic, the war in Ukraine and rising inflation have increased inequalities in access to innovative medicines across the EU, exacerbating Member States' budgetary issues and increasing the focus on healthcare resilience. These issues are all crucial but need to be addressed in a coherent, comprehensive way between the EU and at a Member State level.

Improving access to innovative medicines, for example, is at the very heart of our industry's purpose. The recently published 2022 Patient WAIT Indicator Survey shows that across Europe we can witness a tenfold variation in the time to access new medicines.[1] We can all agree that this is unacceptable and we need to work together to address it with urgency. We are fully supportive of policies that enable our medicines and vaccines to reach every last patient faster, no matter where they live. This is a shared responsibility between industry and governments and, exactly as with the COVID pandemic, it will take the power of collaboration to make it happen.

With these inequities in mind, in April 2022 Pfizer and other EFPIA (European Federation of Pharmaceutical Industries and Associations) member companies launched a commitment to file pricing and reimbursement applications in all 27 EU Member States as soon as possible and within two years from receiving a marketing authorisation, provided that local systems allow it.[2] We expect this commitment alone to contribute to improved medicines' availability and accelerated time to access for European patients.

Our industry is serious about taking responsibility to improve access in areas within our control. But to make the greatest difference for patients, we believe European governments can raise the bar too. As shown in a recent study highlighted by EFPIA, the root causes of access delays and unavailability of innovative medicines are found in national healthcare and reimbursement systems, not in EU legislation.[3] This is our deepest concern with the EC 'Pharmaceutical Package': the pursuit of legitimate, shared goals (access, affordability, availability) but with the wrong tools (EU regulatory and intellectual property incentives) will not be effective and may have undesired consequences.

1 https://www.efpia.eu/media/s4qf1eqo/efpia-patient-wait-indicator_final-report-2023.pdf

2 https://www.efpia.eu/news-events/the-efpia-view/efpia-news/new-proposals-from-the-research-based-industry-can-reduce-inequalities-in-patient-access-to-medicines/

3 https://www.efpia.eu/media/677292/cra-efpia-root-causes-unavailability-delay-080423-final.pdf

4 EU Competitiveness: Mind the gap between rhetoric and reality (efpia.eu)

5 Why Europe must future-proof its pharma legislation (efpia.eu)

As they stand, the reforms proposed run the risk of jeopardising, rather than enabling, the industry's efforts to deliver medical innovations across the region. In effect, the reforms could negatively influence companies' R&D decisions by proposing increased obligations and requirements on what, when and how we study, develop, launch and supply our products across a range of areas, together with a weaker, more complex and unpredictable incentives framework.

Notably, reducing the baseline duration of regulatory data protection (RDP) or orphan market exclusivity (OME) and linking its recovery to factors outside of a company's control – especially 'launching' in all EU markets, with all the uncertainty around how 'launch' will be interpreted and implemented – will not help address current access inequalities across EU countries. Beyond access variation, we also need a system which promotes a proportional and risk-based approach to supply resilience. Medicine shortages are complex issues which require better use of demand data and ongoing dialogue between manufacturers and authorities to address.

On innovation incentives, the narrow, centralised definition of Unmet Medical Need (UMN) in the legislation presents a further challenge. From an ethical standpoint, the primary driver of medical innovation should be the patient perspective: how to improve outcomes, reduce side effects, and/or the burden on their caregivers. To encourage more R&D where currently no treatment option is available, more innovation is needed, not less.

Let's also remember this is taking place while Europe's global competitiveness as an R&D investment destination is already declining vis-à-vis the USA and Asia. Over the last 25 years, treatments emanating from Europe have dropped by 30%.[4] During that same time, US over EU spend on R&D has increased by $23B. Europe's share of total incoming R&D investment among the US, China and Japan has dropped by from 41% to 31%. In the meantime, China shares of international R&D investment grew from 1% to 8%.[5] As for clinical trials, activity is steadily declining with a drop of 6.3% in 2020 versus the previous decade.[5]

At a time when investment is moving away from Europe, we must tackle the challenge head on and work to reverse the trend. Our shared goal should be to create a system that is fit for the future of Europe, and that meets the needs of European patients now and in preparation for the years ahead.

We must not let the post-Covid political weather overshadow the long-term goal of realistically advancing patient access to innovative medicines. Nor should it hinder our mutual goal to strengthen Europe's global competitiveness and attractiveness for R&D investment.

There is much work to be done – and EU policymakers can get this right if these concerns are heard. Given the European Parliament elections in May 2024, it is unclear whether the new legislation may be adopted before 2025, with a further 18-month period before it will apply. The opportunity to create a resilient, sustainable healthcare system is here, now. We must achieve equity of access and focus on a broader approach from prevention to treatment. Few of us feel comfortable imagining it – but we must also safeguard against future pandemics, the threat of antimicrobial resistance, and the predicted health impacts of climate change. We've seen with COVID how events can turn 'under control' patients to 'highly vulnerable' – many of whom represent historically underserved communities that society owes a debt to – and we must prepare realistically for what may be just around the corner.

In summary, we must work together today to create a European health system that is fit for tomorrow. The opportunity is ours to seize, now.

Putting **patients** at the **centre** of the **EU health** and **pharmaceutical agenda**

CLAUDIA LOUATI
EPF Head of Policy

The COVID-19 crisis exposed the vulnerabilities of national healthcare systems and highlighted the importance of health policies that truly address the needs of European citizens. The European Commission's proposal for an EU Health Union, put forward in November 2020, represented a welcome response to reinforce the EU's health security framework and crisis preparedness. With strengthened mandates for the European Centre for Disease Control and Prevention (ECDC) and European Medicines Agency (EMA) and a brand-new European Health Emergency Preparedness and Response Authority (HERA), Europeans should expect more coordinated monitoring and response to public health threats and better management of medical product shortages in the future. We are far from a fully integrated Health Union however, and there is no room for complacency. As millions face the worst cost-of-living crisis in nearly 40 years, public health once again risks falling victim to economic downturn. Budget cuts risk further deteriorating patients' access to healthcare and social services while poorer households struggle with food and housing insecurity at a scale not seen in many decades. A perfect recipe for failing the patients of today and the many more patients of tomorrow. That is, unless the pandemic's wake up call for people-centred health systems continues to resonate and European countries leverage every opportunity to coordinate their efforts.

It is against this backdrop that the EU is revising its pharmaceutical legislation for the first time since the early 2000s. For patients, this is a once-in-a-generation opportunity to enshrine patients' involvement across the lifecycle of medicines and improve – to the extent possible given limited EU competences – access to safe, effective, and high-quality medicines across the EU. The Commission proposed some positive developments in this sense. EPF welcomes the inclusion of patient representatives in the EMA's Committee for Medicinal Products for Human Use (CHMP) and strengthening of patients' representation at the Pharmacovigilance Risk Assessment Committee (PRAC). This is an important milestone in the years-long journey of recognising the value patients bring to the medicines' development and regulatory processes. Moving forward, their participation in the CHMP's scientific working groups and in the Coordination Group for Mutual Recognition and Decentralised Procedures also needs to be formalised. As patients are asked to contribute more, ensuring appropriate compensation and training of patient representatives becomes more pressing. A legal definition of "patient organisations" and specific measures to support their sustainability would make a considerable difference in this regard.

The proposal's focus on speeding up regulatory approval and incentivising the launch of new medicines in all 27 EU member states also represents a positive step towards a true single market for medicines. Unacceptable disparities persist. It can take years for

patients to access some medicines in some countries after the granting of the EU marketing authorisation, if they can access them at all. Of course, more accountability is needed at all levels, especially as regards member states' compliance with legal deadlines for pricing and reimbursement decisions[1]. Another important element is the adaptation of the regulatory framework to innovation, as well as the introduction of new regulatory procedures and pathways for promising new therapies. While regulatory flexibilities should not undermine patients' safety, they have the potential to speed up patients' access to life-saving products.

Other aspects of the Commission's proposal, however, can be further improved. The "elephant" in the proposed directive is of course the definition of "unmet medical needs". Whether a static definition of such a key concept should be set in law is questionable, as it may become outdated faster than the legislation is implemented. If the legislation is to include a framework for assessing unmet patient needs, it must be defined in full cooperation with patients. Only patients can ensure that research and development of new medicines targets the most needed medicines from their perspective. Unmet patient needs are not just about morbidity and mortality, they encompass considerations of quality of life, disease severity, available treatment options – including convenience, adequacy, availability, etc. Only patients can define what added therapeutic value means from their lived experience. Not everything "new" is innovative, and patients' involvement throughout the medicines' lifecycle is the key to prioritising those products that make a tangible, positive difference to them.

Access to high-quality, patient-centred, and timely healthcare, including medicines, is a fundamental right of patients. For many patients living with chronic diseases, medicines are an essential aspect of treatment and therefore, this new legislation is crucial. It should constitute another building block of a true EU Health Union, equipped with the right resources and instruments to address systemic challenges such as access to quality care, inequalities, healthcare digitalisation, and tackle non-communicable and communicable diseases alike. We will continue to advocate for patients' full involvement in the development and implementation of the EU health agenda and for healthcare systems that meet all patients' needs.

1 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems.

Getting the message across: A path to a **healthy future** for **Europe**

CHANTAL FRIEBERTSHAEUSER
SVP, General Manager, EMEAC, Moderna

NICOLAS CHORNET
SVP Manufacturing, Moderna

While Europe wrestles with pressing questions over its health strategy following the end of the COVID-19 public health emergency, practical answers – more than a billion of them - have been coming from a biotech that was born in the US only a decade ago. A COVID-19 vaccine that helped overcome one of the biggest health crises of modern times sprang from a pioneering approach to combating disease, coupled with the company's agility to rapidly scale up an international manufacturing footprint.

There is the promise of more. Around a major European hub in its newly-established global network, the company is ramping up its investments in pursuit of a revolutionary vision. Capitalising on its expertise in its own technology, it is developing products that could bring breakthroughs in the fight against infectious pathogens, cancers, rare diseases, cardiovascular disease, and much more.

This is the story so far of Moderna, the company that emerged from obscurity in the heat of the COVID-19 pandemic to become one of the world's leading providers of vaccines. In just a few months following the emergency of the SARS-CoV-2 virus in 2020, it developed its COVID-19 vaccine - its first commercialised product. It was able to do so because of its ten years of expertise with a technology that has since acquired fame: mRNA. But great products are not enough. Memories are still sharp of the anguish with which health authorities – and patients and their families – cried out for vaccines back in early 2021 when the first supplies were being counted in trickles of mere millions. Acute health needs meant demand was high for this mould-breaking defence, and Moderna expanded manufacturing of mRNA-1273 beyond the US, widening access in Europe and elsewhere.

Achieving large-scale production for Europe against the background of urgency demanded all the responsiveness that Moderna had already shown in its short history. It requires agility to drive to reality the design and production techniques that have dramatically shortened timelines without compromising quality or safety. Light-footed and nimble, Moderna worked closely with established contract manufacturers in Spain, France and Italy and national and European regulators on the challenges of introducing its still-novel technology. Moderna had no supply chain in Europe but moved in less than a year to delivering over 800 million doses of COVID-19 vaccine by the end of 2021 – instead of the years required with traditional processes. Central to the achievement was Spain, which had no specific vaccine manufacturing plants when Moderna struck a deal with ROVI for fill-and-finish operations, in addition to signing deals with Lonza in Switzerland and Thermo-Fisher Scientific in Italy for drug substance and fill-finish support, respectively. ROVI operations have since matured into Moderna's largest end-to-end production hub outside the US, producing a vaccine that has been helping to prevent severe COVID-19 disease, hospitalisation, and death in over 70 countries worldwide.

Spanish Prime Minister Pedro Sánchez visiting the ROVI facility in Granada, January 2022

Moderna has just created a European quality testing platform in Madrid, its International Centre of Excellence, with its laboratory designed to service future products derived from the same mRNA-based technology. The investment reflects Moderna's engagement as Europe's attention turns increasingly to future preparedness, in line with the European Commission's recognition that "longer-term solutions are needed for mitigating future detrimental health events or crises." Moderna is already using the agility of its technology to adapt its vaccines to new strains and is ensuring a capacity to respond at scale and pace to potential future disease outbreaks and pandemics. The broader risks

from respiratory diseases – underlined by EU health commissioner Stella Kyriakides in the European Parliament in January - are motivating its development of vaccines against other respiratory viruses. Investigational mono and combination vaccines against COVID-19, influenza, and respiratory syncytial virus (RSV) are in clinical development among the 47 programmes in its pipeline, 36 of which are already in clinical trials.

The same mRNA -technology is being used to develop potential vaccines against latent viruses and some of the pathogens that global warming may inflict on Europe, such as Lyme disease and malaria, and to develop treatments that offer new hope in cancer, autoimmune diseases and some of the rare conditions for which no therapies currently exist.

mRNA is the message!

Moderna was built on the guiding premise that if using mRNA as a medicine or vaccine works for one disease/pathogen, it should work for many others, potentially leading to treatments for diseases impacting millions to medicines individualised down to a single patient. Generally, the only thing that changes from one potential mRNA product to another is the instructions to produce specific proteins that solicit an immune response. This means we can use the same chemistry, formulation, and manufacturing processes across medicine portfolios, potentially increasing the probability of success from clinical trials to approval.

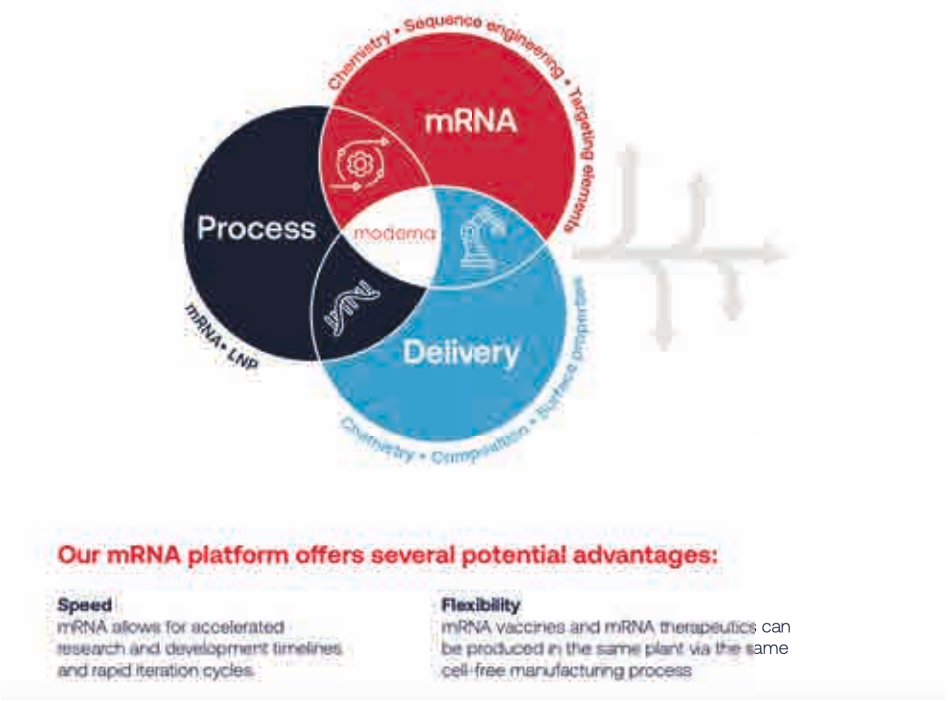
Moderna shares the European Commission's view that successful health policy will depend on new approaches, and the COVID-19 pandemic has demonstrated the importance of effective collaboration among Member States, the European Parliament, the Commission, EU health authorities and "stakeholders from science, research, industry and beyond". But new approaches can go much further, and collaboration can go much deeper.

The supportive approach of the Spanish government and its health authorities to creating the Moderna platform has been crucial to the company's development in Europe, as has the receptivity of the European Medicines Agency in discussions of a new category of medicines. However, the greater regulatory flexibility that the EU is now entertaining with its proposed pharmaceutical legislation reform may not be enough if the potential of technologies such as mRNA is to be realised in product innovation. Concepts that proved their worth during the pandemic in boosting speed to market and increasing flexibility in allocating product where needed most should be permanently embedded in the EU framework – rolling regulatory reviews in product authorisations, streamlined regulatory procedures, shared European packs, and electronic patient information, as well as close collaboration to facilitate distribution. This is the right moment to re-examine all the tools and mechanisms for promoting innovation: the traditional approaches may no longer be enough to ensure timely access to innovative vaccines and medicines in Europe.

The accent on prevention in the EU's Pharmaceutical Strategy should provide a clue. Demographics-induced shifts in the population's health status demand an adequate response by policymakers and suppliers to ensure healthy ageing. Moderna is ready to play its part - not just with new vaccines aimed particularly at adults, but in espousing a new approach to health care that could draw inspiration from the Covid experience of public-private collaboration and could generate new understanding of how best to tackle the healthcare challenges of the future.

Helpfully, the incoming Spanish presidency of the EU Council also plans to promote strategic thinking by setting as its top priority the reinforcement of Europe's strategic autonomy. Moderna is continually maximising its own capacities for end-to-end manufacturing in the EU and elsewhere. Still, the risks of over-reliance on remote raw materials and components suppliers have been painfully demonstrated with bottlenecks even on cardboard for packaging. At the height of the crisis, Moderna was occasionally obliged to fly individual components across the Atlantic or transport individual vaccine batches across Europe to meet emergencies. At the company level, stronger internal integration can ease access to some critical inputs, but Europe as a whole will benefit from a deliberate build-up of independence.

As the Pharmaceutical Strategy underlines, "Investment in research and development for innovative medicines and treatments is essential for making progress in preventing and treating diseases." Moderna agrees. Cooperation, determination and dedication among many players in the last three years provided millions with protection against the sudden emergence of a lethal infection, and Moderna is proud to have played its part. But we are only at the beginning of our story. Moderna is unique in its sole concentration on mRNA, and in its technology, its resources and its team provide the seeds to change medicines forever. Now, against the background of Europe's recovery planning, this is an opportune time to discuss health security and pandemic preparedness. Across the many dimensions of European policy, we are looking forward to continuing to build our involvement, to more fully deploy our skills and agility, and to develop new and enduring partnerships with EU governments, authorities and stakeholders for the benefit of patients and society.



The **European Health Data Space** to promote **innovation** and **health** in areas of high needs

TOMISLAV SOKOL

MEP (EPP Group – Croatia), ENVI Co-Rapporteur for European Health Data Space

The European Health Data Space (EHDS) represents one of the central building blocks of the European Health Union and a milestone in the EU's digital transformation. Also, it represents one of those few pieces of legislation where we create something new on the European level and can be considered a ground-breaking proposal.

Ensuring the availability and accessibility of relevant and high-quality data is crucial for EU's healthcare systems. However, currently there are variations in data collection methods, formats, and systems across different Member States and even within national healthcare systems. Timely access to up-to-date data is essential for effective decision-making, especially during public health emergencies or outbreaks. The COVID-19 pandemic has clearly demonstrated the importance of digital services in the health area. The uptake of digital tools increased significantly during this time. However, the complexity of rules, structures and processes across Member States makes it difficult to access and share health data, especially cross-border. With the EHDS, EU is changing this.

EHDS proposal envisages two types of data usage. Primary use of electronic health data enhances healthcare on a national and cross-border level. Normally, medical information is stored in electronic health records, which encompass segments of a patient's medical background, whether centralized or involving multiple healthcare providers. The EHDS aims to enable individuals to access their health data and share it with their preferred healthcare professional, even when they are in a different Member State and using a different language. Consequently, patients can receive more accurate diagnoses and treatment, minimizing medical errors and avoiding unnecessary tests. Clearly, a regulatory framework specifically focusing on individual rights, reducing fragmentation in the digital single market, and facilitating secure data utilization is undeniably required. On the other hand, secondary use of electronic health data takes place when health data is analysed to inform public health policies or to facilitate research. A more direct method of acquiring data access within a reliable and secure framework will be advantageous for R&D in Europe. This practice has the potential to improve patient safety, advance the creation of new medicinal products and medical devices, and contribute to the development of personalized medicine. It is crucial for researchers, innovators, and policymakers to have more effective access to high-quality data while ensuring its security. EU-wide action is necessary and appropriate therefore, to promote the free, cross-border flows of personal health data and to foster a genuine internal market for personal health data and digital health products and services. In short, it will help deal with problems that would otherwise persist.

Negotiations between political groups are currently in progress in the European Parliament, and I believe that the main points of contention will be about the secondary use of health data.

The main challenge is to strike the right balance between enabling the utilization of health data and safeguarding privacy and data protection. To achieve this balance, my approach is to uphold the basic principles of the Commission's proposal, which involves adopting a comprehensive approach that facilitates data use and fosters interoperability while ensuring the highest degree of data protection. Furthermore, it is imperative to strike a delicate balance between sharing data and protecting intellectual property (IP) rights, which are crucial for promoting research and innovation within the EU. Therefore, it is essential to find a solution that effectively safeguards these IP rights while facilitating the secondary use of data. Last but not least, the question of patients' decision making in the secondary use of health data will also be challenging, but I believe that a compromise will be reached among political groups. I would also like to add that the present Commission proposal lacks the provision for active stakeholders' engagement in governance bodies, including patients' organizations, healthcare professionals, and industry representatives. As a result, I have proposed in the Draft Report the participation of different stakeholders in the EHDS Board, Health Data Access Bodies, and Digital Health Authorities. Furthermore, funding remains a major challenge as the EHDS is proposed to be financed using existing financial instruments available to Member States, such as the Recovery and Resilience Facility. However, additional centralized funding from the EU is necessary to make EHDS operational, given that the current financial instruments were devised before the EHDS proposal and prioritize other health-related projects. To overcome this, we need a significant boost in EU-level funding for the EHDS, which I believe will gain strong support in the Parliament.

The EHDS should be a 'new era for the EU's digital health policy. By facilitating the secure and responsible sharing of health data across Member States, the EHDS can contribute to a deeper understanding of diseases, medicinal products and real-world outcomes. The EHDS can put Europe at the forefront of health data usage.

Towards an integrated European health approach for better and equal patient care

ISTVÁN UJHELYI

MEP (S&D Group – Hungary), Member of the ENVI Committee

Before the devastating COVID-19 pandemic, it was heresy to talk about a unified European health policy. The member states - despite the inherited differences and intolerable health inequalities - jealously took care to keep health care under national competence. At most, coordination and the issuing of recommendations could have been considered, while in a very few areas, such as blood safety, shared powers were approved.

It took a real public health crisis claiming many lives, as well as the initiative and advocacy of the Group of the Progressive Alliance of Socialists and Democrats, for the European Parliament to recognize the need for joint action. This is how the landmark public health resolution, with the concept of the European Health Union (EHU), was born in July 2020.

This resolution called for cooperation, which included the elaboration of quality standards for healthcare in all member states. This objective would be possible as a result of stress tests in the EU countries to assess the resilience of national health systems as a matter of urgency, to identify weaknesses, and to check whether health services could cope with possible further outbreaks of epidemics. An important aspect of the document was how to address health inequalities, for example through equal access to medicines and medical devices.

The last 3 years brought considerable progress in the implementation of the EHU. Among others ECDC's powers were broadened and important projects such as the European Health Data Space and the Europe's Beating Cancer Plan were launched. A promising development has been achieved with the EU budget 2021-2027, which has 13 times more funds than the previous envelope, with around €5.3 billion for health programmes (EU4Health).

Currently, the new European pharmaceutical strategy and the draft of the related regulations are in the crossfire of debates. The key pillars of the concept would enable patients to receive affordable and transparent medicines throughout the EU. There is a lot to be done, because while in France or Germany, for example, 80 percent of total drug budget are covered by the state or social insurance, in Hungary, Romania and the Baltic countries, patients pay more than 50 percent at the pharmacy (including prescribed and over-the-counter products). Many people do not get access to innovative drugs at all or late.

In the integrating Europe, it cannot be allowed that there should be a shortage of medicine in any member state or that low-income families should not have access to expensive antibiotics. The acceptance processes that determine the subsidies should be simplified and unified, and web-based patient registers should be built for accurate and common monitoring of the therapies. I truly believe that the Commission's idea which puts the patient in the middle of the proposal is a great idea and good direction, on the other hand I think we have to find the right balance in order to create something timeless.

In May 2023, welcoming the WHO's announcement that COVID-19 is no longer an emergency of international concern, Commission President Ursula von der Leyen said: "The pandemic...has taught us that the EU's strength lies in its unity, including when confronted with major health crises...changed the face of the EU, which has become a true European Health Union."

Although this optimistic vision of the future can be achieved in long run, progressives have a moral obligation to stand up for EHU's values and integrated approaches. One of the next steps in the series should be aimed at formulating and adopting the uniform minimum quality criteria for healthcare. The content of these demands must be discussed with a multitude of professional and civil society organizations; however, the criteria should include minimum requirements in terms of primary care, health workforce density, share of health expenditures in government budget and more.

Sooner or later, it is inevitable to amend the basic EU treaties, including the introduction of shared health competences in a couple of issues as it has been raised at the recently concluded large-scale civil consultation on the Future of Europe. A specialized council configuration for health should also be created to strengthen the voice of national health representation at EU level.

It is a legitimate suggestion that common EU-level decisions are needed in a public health emergency, e.g., when WHO declares a pandemic. All the more so, because the experiences of the COVID-19 have confirmed that isolation and separate solutions represent a dead end.

Finally, it is an encouraging sign that in January 2023 the European Parliament established its public health subcommittee (SANT) within the Committee on Environment, Public Health and Food Safety (ENVI). This is certainly a message that the issue of health is becoming higher on the agenda of the EP members and foreshadows the possibility that the area will receive an independent main committee in the next term.

Driving towards or away from innovation?

ALEXANDER **NATZ**

Secretary General, EUCOPE – European Confederation of Pharmaceutical Entrepreneurs

How the EU Pharmaceutical Package impacts smaller companies and orphan developers

The EU Pharmaceutical Package represents a unique opportunity to build on the success of the existing rules and create a competitive and innovative healthcare ecosystem over the next two decades and beyond. Impacting how every therapy approved in the EU, ranging from evidence generation to regulatory pathways, approval timelines and incentives, the revision introduces numerous provisions that will streamline and digitize regulatory process, and improve the functioning of the biopharmaceutical ecosystem.

The proposed Package will also revise the incentive framework for both innovative medicines and orphan medicinal products (OMPs). Providing adequate incentives to small and mid-sized companies, the key drivers of biopharmaceutical innovation, is a vital pre-condition to address underserved areas and ensure patients' access to groundbreaking therapies. Overall, the European Commission's proposal continues to be very concerning with several of these provisions creating significant negative implications for industry, especially smaller companies, and the predictability of the ecosystem.

Orphan Market Exclusivity (OME)

A key change to the orphan system is a reimagination of the orphan market exclusivity (OME) framework – the incentive awarded to a developer that markets a therapy for an orphan indication. Venturing away from a one-size-fits-all approach, where all orphan therapies receive 10 years of OME, the proposal will see reductions to their baseline period, and modulation upon certain conditions that are difficult to fulfil and will *de facto* create unpredictability in the ecosystem.

The new approach proposed by the Commission does not address the core challenges that would encourage the development of therapies for rare diseases with no treatment options. By reducing baseline incentives and increasing unpredictability, the proposed modulation of OME will hinder innovation, reduce investments and, therefore, make the EU less competitive and attractive to innovative companies. Instead, we would suggest another modulated approach, based on five principles, such as the investment case and chance of therapeutic success, developed by the multi-stakeholder OD Expert Group.

(High) Unmet Medical Need (HUMN)

One of the key focuses of the EU Pharmaceutical Package is addressing unmet medical needs within the EU market. Frequently, UMN is regarded as relating to a condition for which there exists no satisfactory method of diagnosis, prevention, or treatment. Aware of the fact that different needs exist in the rare disease space and to prioritize the development and availability of innovative medicines for rare diseases, the Commission has proposed to link orphan incentives to the concept of HUMN.

While this objective aims to improve development of new therapies where no effective options exist, it will present challenges for smaller companies and overlook other patients that would benefit from innovative therapies. In order for companies to demonstrate that a medicinal product addresses a HUMN, developers must generate supporting evidence at very early stage of development. By setting criteria and stringent requirements to identify medicinal products addressing HUMN, the European Commission fails to take a holistic perspective.

With its restrictive definition, this concept will have an adverse effect on innovation, while ignoring different patient populations, and restricting the longevity of the legislation. The latter refers to the fact that HUMN constantly evolve with science and society, thus a definition in legislation would not stand the test of time. A modulated approach that reflects the probability of therapeutic success and rewards it accordingly, would actually encourage developers to continue to invest in

underserved areas and launch within the EU. Beyond incentives, a HUMN definition creates an actual ranking of patients and 'stamps' therapies with a label at a very early stage of development. Those products without a (H)UMN stamp are likely to face significant downward pricing pressures or reduce their commercial viability, leading smaller developers to look away from Europe.

Orphan drug developers should be encouraged to maximise the impact of the research and knowledge they develop, and find additional uses for existing compounds, especially if this opens the door for those patients with no other options. Defining (H) UMN in legislation could have unintended consequences for developers and hamper R&D, leading to diminished therapeutic innovation and patient access, and lesser reward for smaller innovative companies.

Which way to innovation?

The EU Pharmaceutical Package brings both opportunities and challenges for biopharmaceutical companies operating in or considering expansion into the European Union. While the legislation aims to foster innovation, enhance patient access to medicines and promote public health, smaller companies will face various hurdles. These challenges include a reduction and conditional modulation of incentives, therefore making investments more unpredictable and riskier.

This increased effort to apply a downward pressure on pricing in the EU, will have major consequences on the ability and willingness of companies to bring products to the market and shape research priorities for decades to come. Small and mid-sized companies are the key drivers of life science innovation but without proper investment and incentives, sadly, they may be forced opt to venture elsewhere.

While the legislation will take several years before being adopted and start applying, it will have an impact on all health technology developers – small, medium and big - for at least two decades after its entry into application. Now is the time to strengthen our past successes and forge the right path towards a sustainable ecosystem that promotes investment and innovation while increasing patients' access to advanced therapies in Europe.

About EUCOPE

For 15 years, the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) has been the voice of small to mid-sized health technology companies in Europe. Representing 2600+ innovative biopharmaceutical companies directly or through national associations, EUCOPE advocates for sound public policy that supports innovation, while fostering a community built on a shared purpose: improving and saving the lives of European patients through innovative therapies and medical technology. Learn more at www.eucope.org

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

Regulatory **modernization** to support **innovation** and **growth**[1]

GENEVIEVE MICHAUX
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Innovation1[1] in the pharmaceutical industry requires the right incentives, and such incentives can be diverse. Sufficient regulatory protection and adequate pricing and reimbursement are essential in encouraging innovation; an efficient regulatory system is also key. Companies, especially non-European Union (EU) companies, will not seek EU approval for their innovative medicinal products if, in addition to insufficient protections and a patchwork of increasingly restrictive national pricing and reimbursement laws, the regulatory regime is slow and burdensome. This could be the last straw. The benefits for European patients of attracting innovative products and for the European economy of attracting international investment need no further explanations.

The EU regulatory system is often compared to the US system and considered – rightly or wrongly – slower, more complex, and less amenable to innovation, though of course similar criticisms flow in the other direction.

The European Commission's legislative proposals contain numerous provisions to improve our regulatory system, many of which are inspired by the "exceptional" regulatory measures adopted to approve COVID-19 vaccines. However, do they go far enough for the EU to remain attractive for foreign companies, their innovative medicinal products and their investment?

The EU regulatory system is slow since the average approval time is longer than in the U.S. This is speculated to be due to FDA's more intense use of accelerated pathways. Meanwhile, FDA's accelerated approval authorities are growing, with reforms enacted in December 2022.[2]

The EU pharmaceutical legislation already includes expedited approval mechanisms: accelerated assessment, conditional marketing authorization (MA), and MA under exceptional circumstances. While the US system does not have conditional marketing authorization, it does offer an array of expedited programs, including breakthrough therapy designation, fast track (including rolling review) and priority review, and accelerated approval.

The Future Regulation adds to the EU armory by codifying PRIME and instituting a rolling review.[3] Their scopes however is limited since PRIME is restricted to certain medicinal products such as those likely to address unmet medical need or expected to be of major public health interest, and the rolling review to products likely to offer an exceptional therapeutic advancement related to a life-threatening, seriously debilitating or serious and chronic condition. This arguably would be similar to the current US regulatory environment, where breakthrough designation is limited to drugs intended to treat serious conditions with supportive preliminary evidence and fast track is limited to drugs intended to treat serious conditions with potential to address unmet medical need.

While the Future Regulation is a step in the right direction, broader scopes for PRIME and the rolling review would be welcome. That said, the Future Regulation cannot secure more approvals on an expedited basis if the issue comes from EMA's reluctance to use expedited pathways or lack of resources to handle more expedited applications (which could only be resolved by increasing EMA's permanent staff and number of national experts working on centralized procedures, both of which seem unrealistic at present).

The EU regulatory system is complex and therefore burdensome. Complexity takes several forms, most of which flow from the nature of EMA which, unlike FDA, is not an integrated agency.

EMA does not have its own assessors but rather relies on a network of national regulators grouped in scientific committees (where all Member States are represented) and working parties. Nor does it have any decision-making power for approvals since they are decided by the European Commission in collaboration with the Member States (through the Standing Committee).

The Future Regulation reduces the number of EMA's scientific committees and transforms the abrogated committees into working parties. This may not be sufficient but, again, this is a step in the right direction of simplifying and improving EMA's structure and functioning. Reliance on working parties rather than formal scientific committees should ensure that scientific experts are appointed based on their scientific credentials rather than their nationality, which strengthens the scientific capabilities of the regulatory system and permits the creation of multidisciplinary working parties to tackle more complex issues.

1 The article focuses on the centralized MA procedure because innovative medicinal products are typically approved through that procedure, which involves the European Medicines Agency (EMA) and the European Commission.

2 FDORA (Consolidated Appropriations Act, 2023, Pub. L. 117-328, 117th Cong., §§ 3001–3631 (2022) ("Food and Drug Omnibus Reform Act of 2022")). See client alert (https://www.kslaw.com/news-and-insights/not-quite-the-titanic-the-food-and-drug-omnibus-reform-act-rescues-some-fda-policy-initiatives)

3 The Future Regulation also reduces the official approval time, formalizes an automatic withdrawal of MA applications, etc.

A step further could be to lower the number of CHMP members in charge of assessing and concluding on the quality, safety, and efficacy of Union medicinal products but to appoint those (fewer) CHMP members based on the characteristics of the product or disease concerned.

In any case, it is essential that Member States support allocating resources from national Medicines agencies to, and ensure that sufficient resources are available for, EU assessments.

Furthermore, all aspects of drug development are not in EMA's remit (clinical trials, for example, are still authorized at the national level) whose only material scope is medicinal products. EMA's limited role seriously impacts the efficiency of the EU regulatory system, especially as innovative products are now less frequently in the form of chemical tablets but are becoming increasingly complex—such as biological combination products integrating cutting-edge technologies. An integrated approach is essential for such products.

Since an integrated European agency is not an option for now, the Future Regulation expressly sets out more coordination and interaction with other EU bodies. This approach is useful, provided that cooperation and interaction are mandatory, start at an early stage in drug development, and do not unreasonably delay approvals.

Finally, *the EU regulatory system is not flexible and technology-oriented*, which prevents the quick approval of more complex, technological medicinal products. Of course, in some scenarios, FDA is still seen as too risk averse, too reluctant to permit novel technologies, and too intent on requiring large volume data sets. But in other scenarios, FDA seems to better deal with innovative, cutting-edge products than the EMA. So, FDA faster releases guidance addressing new, emerging issues (such as the FDA's recent discussion paper on the use of AI/ML in drug and biologic development) and that guidance often is broader and less prescriptive than EU guidelines (for example, FDA guidance on digital health generally focuses on process rather than product).

The legislative proposals seek to make the EU regulatory system future-proof as illustrated, among other modifications, by the new concepts of regulatory sandbox and platform technology. However, those new features will only reach their objective if the EU regulators interpret and apply them both with the spirit and objective of their adoption in mind and by adopting a risk-based approach. Like expedited approval pathways, flexibility to embrace novel products requires not only adequate rules but also regulators' adequate mindset.

Overall, the legislative proposals show the European Commission's willingness to modernize the regulatory system in many ways. Further steps however could be taken, which will hopefully be brought during the legislative process. Otherwise, international companies will move away from the EU and bring both their innovative medicinal products and investment to more hospitable, *i.e.,* more flexible and less risk-adverse, countries.

MARIANO **VOTTA**

Director Cittadinanzattiva-Active Citizenship Network

The value of investing in **Advanced Therapy Medicinal Products**: combining sustainability, innovation and **respect** for **patients' rights**

To move towards the European Health Union, we probably also need to go beyond the current narrative concerning the European pharmaceutical legislation review which – in synthesis - seems to be limited to the following statement: "the fate of the pharmaceutical sector is at stake as well as the future of national health systems". Talking about the future scenarios of the Advanced Therapy Medicinal Products (ATMPs) that the review might outline, what about the justified expectations of patients? What is holding us back from including and considering in the debate also the point of view of the so-called 'final users' of the health service, the ultimate recipients of the decisions whose effects will be experienced in practice? Travelling at different speeds, how can innovation and access be combined? To try to answer these questions, Cittadinanzattiva - through its EU branch Active Citizenship Network – has recently presented a proposal at the European Parliament, endorsed by 43 Patient Advocacy Groups (PAGs) from 12 Member States, to try to make up ground on patients' right to access advanced therapies, calling for a change in institutional mentality to classify spending on ATMPs as an investment and not as a cost.

All potential, eligible patients have the right to access Advanced Therapy Medicinal Products, and national health budget constraints cannot be an obstacle. Nowadays, traditional reimbursement and budgeting schemes are unable to amortise the value of ATMPs, whose costs and benefits are not aligned. These types of therapies need new and different payment and accounting methods, which consider the high initial costs and the large and lasting benefits over time, both for patients and for national health systems. It is time to change the institutional mindset to classify the expenditure on Advanced Therapy Medicinal Products as an investment and not as a cost, which is possible if a decision is made to review – from Eurostat downwards – the current economic and financial classifications of healthcare expenditure. The cost of these therapies could be amortised over the years in relation to the savings generated over time. In particular, they could be entered in the state budget over several years and not all in the year of expenditure. This would significantly increase the financial sustainability of these costs by the public sector over time and promote greater and more equitable use of ATMPs in the population, without putting public finances at risk.

This proposal - realised with the unconditional support of VITA (Value and Innovation for Advanced Therapies coalition) - also received an encouraging endorsement from Italy's new Health Minister during an official Hearing at the Senate of the Italian Republic in January 2023 while, at the European level, the European Health Commissioner Stella Kyriakides, on the occasion of the European Patients' Rights Day held in April 2023 emphasised that "ATMPs give hope to patients where therapeutic options are currently lacking or non-existent and they must be able to reach patients sooner. Our (European Commission's) priority is always to put patients' interest first".

Above all, we believe that the two aspects can only be better combined and find a point of connection with each other if, in the field of ATMPs, we also succeed in strengthening and guaranteeing spaces for the participation of citizens and PAGs in the decision-making process. This is also why, in Italy, we warmly welcomed the invitation of national institutions to join the National Ethics Committee for clinical trials on advanced therapies ('ATMPs'), set up in February 2022 at the Italian Medicines Agency, as the only actor to represent the civic and patient point of view on the issue. For the same reason, we urge to overcome the extreme polarisation of the public/private debate that is accompanying the pharma legislation review, which, despite its inevitable complexity, needs to be integrated from a civic and patient perspective.

The patients' rights to innovation and to access, both stated in the European Charter of Patients' Rights, should be inextricably interlinked in every area of healthcare. Unfortunately, in many contexts this does not happen, and even in the field of ATMPs, where innovation is advancing, there are cases of withdrawal or threatened withdrawal of existing and accessible therapies. So, in the presence of innovative therapeutic solutions, approved by the competent regulatory authorities, available on the market and already being used by eligible patient groups, having already proven their efficacy, we should have the courage to affirm the principle of irreversibility of access to treatment. Those who are already using them cannot be continually exposed to this situation of uncertainty. What is at stake is the credibility of the healthcare system as a whole and of all the actors involved, public and private. But above all, it concerns the medical history of so many patients who see in these innovative treatments a hope that was not even imaginable a few years ago, as well as the dreams of those who live alongside them, and the ultimate essence of ATMPs is that of being "dream savers".

Promote more joint **European procurement** of **medicines**

KATEŘINA KONECNÁ

MEP (GUE/NGL Group – Czechia), Member of SANT Committee and COVI special Committee

At the beginning, I would like to state that I am a big supporter of the idea of joint procurement of medicines at the EU level. Especially of orphans, drugs against cancer and advanced therapy medicinal products. I supported this idea years before the COVID-19 pandemic, when it was, just a fantasy of a party of weirdos dealing with public health policies in the European Parliament. Subsequently, during the pandemic, the Commission, which never wanted joint purchase of medicines, rediscovered them and introduced them as a tool to purchase vaccines and treatments against COVID-19 for all member states. What was a for decades figment of the imagination of a few dreamers has become a reality in matter of few weeks. We hoped that it would not stop there and that after the end of the pandemic this solution would also be applied to other groups of medicines under the Pharmaceutical Strategy Package. Unfortunately, that didn't happen.

We have to admit that the potential of the EU joint procurement agreement reaches beyond vaccines and treatments for communicable cross-border health threats. I personally have a number of fundamental doubts and complaints about how the joint procurements of vaccines were implemented during the pandemic. After all, much has already been written about the lack of even fundamental transparency in both the negotiation process and the signed contracts with pharmaceutical companies. The scandalous treatment of patents developed with the money of EU's taxpayers or the non-liability of pharmaceutical companies for the resulting product are only the tip of the entire disgusting iceberg of the desperation of the European Commission's policy in times of a pandemic.

Even the most ideologically hardened supporter of the big pharma must admit after the pandemic that the information and power asymmetry between the multinational pharmaceutical industry as the vendor and national governments as buyers contributes to unsustainable drug budgets and difficulties with thoroughly assessing the proven clinical benefit of new drugs. We have to create a sufficient counterbalance to big pharma and increase our negotiating power. The pharmaceutical industry on the other hand hopes that cross-border purchases of medicines remain a limited possibility because they apply divide and conquer tactics.

If we put aside the purchases of vaccines during the COVID-19 pandemic, then during the last 15 years, we have seen different types of very successful cross-country collaboration initiatives. Such as BeNeLuxA, the International Horizon Scanning Initiative, the FINOSE Collaboration or the most recently the Nordic Pharmaceutical Forum (NPF) initiative). These cross-country collaborations have shown that pooling resources can facilitate access to new medicines for patients at a fairer price. And yes, I do not support this tool for common medicines such as antibiotics or analgesics, which are often missing from the EU market today (EU medicines shortages crises), because from many reasons it is completely inappropriate for the purchase of these drugs.

So, why do I support joint procurement of orphans, drugs against cancer or advanced therapy medicinal products? Due to the indisputable fact that it will help with their availability, price and it will ease the burden on our public health insurance systems and increase their sustainability across the EU. As the EP stated already in 2017 in its resolution on the access to medicine on which I was the shadow rapporteur, high prices are a major barrier to accessing medicines for patients and a threat to health systems, even in some of the richest countries in the EU.

Joint procurements of the of orphans, drugs against cancer or advanced therapy medicinal products can strengthen bargaining power and aim for fairer prices through joint negotiations, Will ensure the sustainability of healthcare systems. Last but not least they should enhance the understanding and transparency behind the price of medicines and cross-border learning through more information, experience sharing, and horizon scanning. Finally, I also believe that the introduction of these purchases for some drug groups would be positive for pharmaceutical companies as well. They can find opportunities to increase sales revenue by accessing countries that were previously out of reach due to unfavorable market conditions. In addition, they may benefit from increased forecast availability, standardization of supply, and economies of scale.

Unfortunately, big pharma won in the first round, as the Commission presented a proposal for the Pharmaceutical Strategy Package without these joint procurements of medicines. It did not even propose a stable framework for the purchase of drugs against rare diseases. Which is absolute nonsense economically and socially. The small EU member states should realize during the negotiations that joint procurements of at least these drugs are to their advantage because they do not have market which would be lucrative for a big pharma. I hope that they will help us in the upcoming negotiations. Yes, the Germans and the French will always secure orphan drugs for their patients at a reasonable price. But what about states where there are only a few units of patients in need of a highly innovative and expensive drug? Me and my colleagues in the EP are determined to bring this back into the game. We'll see how successful we are. However, we must at least try. After all, we owe it to our patients.

Addressing Antimicrobial Resistance in Spain:

A call to boost prevention and control measures in Europe

Hacer frente a la resistencia a los Antimicrobianos en España:

Un llamamiento a impulsar las medidas de prevención y control en Europa

19 September 2023, 10:00 - 12:00 CEST

European Parliament, Office in Spain

Paseo de la Castellana, 46, 28046 Madrid, Spain

Hybrid Event

Interpretation in Spanish and English

AMR PATIENT GROUP

HEALTH FIRST EUROPE

FEP foro español de pacientes

POLICY DIALOGUE

Task Force on the European Health Union: EU Health in a post-pandemic era

Tuesday 12 September 2022

10.30-12.30

Venue : European Policy Centre, Rue du Trône 14-16, 1000 Brussels

Register here

This policy dialogue is the final event of the European Policy Centre's Task Force on the European Health Union. The Task Force identified challenges and shortcomings along with the action needed at the EU level to build Europe's resilience to prevent and protect against future pandemics, to address dependencies on other parts of the world as well as to promote healthy populations, reduce health inequalities and build Europe's R&D ecosystem. The reflections gathered during the meetings of the Task Force were used to formulate policy recommendations which are included in the final report of the Task Force. The key findings of the paper will be presented at this public event with further discussion on the future of the health and the European Health Union, particularly in the context of the upcoming European elections and the new mandate of the European Commission.

Participation is open to EPC members only, the media, and EU officials

This event is held under the auspices of the EPC Social Europe & Well-being programme with kind support from Sitra, Eithealth, Amgen, MSD and Johnson&Johnson

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