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Vaccines Europe
An industry for healthy lives

Lessons learned from COVID-19

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Summary

Since the onset of the COVID-19 pandemic, the research-based pharmaceutical industry has been committed to working collaboratively across the research and healthcare communities, relying on its world-leading science, people and resources to tackle the outbreak. The fruits of these collaborations can be seen today. Two years after COVID-19 was declared a pandemic by the World Health Organization (WHO), the results have been unprecedented:

1. **33 vaccines and 32 therapeutics have received regulatory approval**[1];
2. more research and development (R&D) is ongoing, with **521 additional vaccines and 1630 therapeutics currently being researched**[2].

This is a considerable achievement, as under normal circumstances, it takes on average 10 to 15 years to research and develop a vaccine. Additionally, therapeutics can play a key role in saving lives, freeing up capacity in intensive care units and treating patients living with long COVID. Such response would not have been possible without advanced understanding of messenger RNA (mRNA), resulting from decades of scientific research in this field, and without **close collaboration between the EU institutions, governments, healthcare systems, regulators and the research-based pharmaceutical industry**. In this respect, more than 370 collaborations, most of which include technology transfers, have been set up throughout the pandemic.

Ensuring equitable access to innovative COVID-19 vaccines across the world has been a key challenge, and our industry has worked around the clock to support its realisation. Today, however, **the primary challenge is not the shortage of vaccine supply**, but healthcare system absorption capacity and vaccine acceptance. As a result, unused stocks of COVID-19 vaccines around the world are rising fast. The number of doses produced (12.1 billion) is increasingly exceeding the number of doses administered (9.2 billion). Vaccine distribution has ramped up, as witnessed by COVAX surpassing one billion doses delivered, and deliveries for low- and middle-income countries exceeding four billion doses. At the same time, **vaccination rates of primary vaccination course, consisting of two doses, vary significantly across the world.** In the EU, they range from 95% in Portugal to 35% in Bulgaria, and they remain very low in Africa, with only 15% of the African adult population fully vaccinated.

The pandemic has also revealed the **vulnerability of immunisation systems worldwide**, with substantial disruption to routine vaccination, leaving millions of children and adults unvaccinated, and increasing the risk of potential outbreaks after lockdowns. While there has been an unprecedented effort by governments to resume childhood immunisation programmes, larger impacts were observed in adolescents (including *human papillomavirus* vaccination to prevent cancer) and adults, where vaccine coverage rates are not always known.

The experience of COVID-19 vaccination also demonstrated that digitalisation can allow for daily monitoring of vaccine coverage rates, setting a precedent for all routine vaccinations. This should be combined with catch up programmes and continuous efforts to increase uptake, to protect public health. Furthermore, in Europe, the main issue for every vaccine except COVID-19 vaccines, is the absence of pan-European data and timely monitoring of coverage rates across the life-course.

1. AirfinEuropeanity (2022)
2. Ibid.

The European Health Data Space should integrate the immunisation dimension, with the European Centre for Disease Prevention and Control (ECDC) playing a central role in data collection and sharing.

R&D has given the world safe and effective tools against COVID-19. Yet the current situation underlines the need to address a set of **short to medium term** priorities:

1. **Strengthening healthcare system capacities**, including through collaboration across professions in the roll out of COVID-19 vaccination campaigns, and through adequate monitoring systems across Europe and in lower middle- and low-income countries. Additionally, the infrastructures put in place in decentralised health systems to coordinate decisions, should be maintained, as they can help with catch up programmes for routine immunisation.
2. Equally important **is to address vaccine hesitancy** and ensure infodemic management, as well as public education, via a robust and transparent communication plan, leveraging the range of possibilities offered by digital technologies.
3. With a significant risk of new variants emerging, **continued R&D and testing of efficacy of current vaccines and treatments** against variants of concern remains vital.

In **the long term**, there are opportunities to be leveraged to be better prepared for future pandemics:

1. The research eco-system that has provided the major solutions to health threats such as COVID-19, is built on **intellectual property (IP) rights**. To enable medical innovation, **Europe needs a dynamic and well-funded research eco-system**. This means ensuring long-term investment in R&D, skills, networks and health data infrastructure, as well as regulatory flexibility and a supportive IP framework.
2. Medical countermeasures, and especially vaccines, are complex products using novel technologies and ingredients. It is therefore important that **policies introduced by the EU and national governments aim at strengthening global supply chains to support the production and free flow of such technologies**. In particular, the experience gained during the first wave of the pandemic underlined the importance of removing export restrictions, as strongly advocated by the European Commission, and of opening borders to ensure the safe supply of vaccines and medicines to patients across Europe.
3. A range of **regulatory flexibilities** (e.g., on rolling review) provided during the pandemic, can add value beyond emergency situations. The application of such flexibilities should not end with the COVID-19 pandemic.
4. The pandemic has generated renewed interest in joint procurement for healthcare products, and EU-level coordination of procurement has been able to help with challenges that are specific to a pandemic crisis. However, since joint procurement is complex, potentially leading to access delays, **joint procurement procedures should be limited to emergency situations**, when the purchase and supply of medical countermeasures cannot be ensured by other means.
5. The creation of a **European Health Emergency Preparedness and Response Authority (HERA) is a first step to putting Europe on the front foot in addressing global health threats**. To attract long-term investments in high-risk R&D pandemic projects and in sustainable surge capacity during health emergencies, it will be critical for HERA to provide funding at scale.

Detailed considerations

Since the onset of COVID-19, medical innovation has been key to address the devastating human and economic costs of the pandemic

IP protection played a central role in the development of vaccines and therapeutics against COVID-19. The existing IP framework enabled the fast development and manufacturing scale up of COVID-19 vaccines, thus proving it to be part of the solution, rather than a barrier. With an unprecedented number of collaborations launched (currently 377 for vaccines), the global scale up in production means that there is now no shortage of vaccine supply to address. Indeed, it is now widely accepted that **the issue is not producing doses, but the capacity to get those doses to citizens in lower middle- and low-income countries.**

- The COVAX facility recently indicated it has more available doses than have been requested by the countries it was designed to support.
- The Africa Centres for Disease Control and Prevention is suggesting that some donations of vaccine doses should be paused as countries are struggling to vaccinate the population fast enough.
- In November 2021, South Africa asked vaccine manufacturers to delay delivery of COVID-19 vaccines.
- In May 2022, the WHO and Gavi stated that they have no immediate plans to buy vaccines made by Aspen in South Africa, with Aspen's CEO stating it would be forced to re-purpose about half of its vaccine production capacity if orders did not pick up.

The **lack of investment and infrastructure to support adult immunisation, and widespread vaccine hesitancy, have also been identified as key barriers** to vaccine uptake during the pandemic. On the other hand, increasing vaccination sites and vaccinators, as well as better digital communication with the public, have shown to improve the convenience of, and compliance to vaccination.

Despite these developments, the ongoing debate at the World Trade Organization (WTO) is illogically focused on IP, with **inadequate attention on the trade issues that would make a difference to patient supply, such as eliminating export restrictions and introducing measures to support distribution of critical goods across borders**. This can be done, for example, through the Trade and Health Initiative (TAHI) at the WTO. Ultimately, proposals such as the so called "TRIPs waiver" or the "Quad text" only have the potential to reduce innovation and harm industry competitiveness when these are most needed, without bringing any benefit to the shared objective of equitable access to vaccines and treatments.

Companies run global supply chains, and are more likely to ensure continuous supply to all EU countries if the action is coordinated at supranational level

In pandemic situations, **national uncoordinated actions can have a detrimental effect on the supply of medicines in other countries**. These include unilateral trade restrictions, that have proven to be major bottlenecks to distribution, and national mandatory stockpiling requirements, that have prevented the reallocation of vaccines and medicines where they are most needed by patients. In addition, the opacity of the supply chain downstream prevents manufacturers from allocating supply where patient demand is. This constitutes a major weakness of the system, which the EU should address by building an **integrated system connecting upstream supply with patient demand**. This would require a **harmonised definition of shortage, and data on patient need in Member States by**

the European Centre for Disease Control (ECDC). The European Medicines Verification System (EMVS) data repositories should also be used to monitor how medicines are placed on different markets, as well as the rate of their consumption at the national level.

Many regulatory flexibilities introduced during the pandemic could help in tackling future pandemics, as well as beyond crisis times

The EU and national regulatory agencies responded to the pandemic by issuing guidance outlining regulatory flexibilities for COVID-19 vaccines and therapeutics. Many such **flexibilities could provide value for tackling future pandemics, and beyond emergency situations, particularly where the EU and Member States have aligned closely to provide a streamlined regulatory environment**. Some examples include flexibilities and guidelines that promoted the use of virtual and digital methods for executing routine tasks, flexibilities on language and labelling to be potentially used for addressing shortages and supply constraints beyond the pandemic, as well as flexibilities on GMO derogations and rolling review. In addition, the pandemic has proven that administrative processes need to be revised where existing regulatory requirements are too burdensome or redundant (flexibilities on quality variations, importation testing and protocol amendments).

Joint procurement helped with challenges that are specific to a pandemic, and highlighted significant issues that may be anticipated for joint procurement in other areas

EU-level coordination of procurement during the pandemic has helped with challenges that are very specific to a health crisis: coordination between Member States to equitably allocate initially limited supply quantities in a transparent manner, and the need to prevent issues related to national distribution channels, or the risk of inefficient stockpiling. **It also underlined significant challenges that may be anticipated for joint procurement initiatives beyond crisis**: varying degrees of Member States' ability to assess the situation, and their understanding of the local epidemiology, as well as the capacity and capabilities of national health systems to effectively use a medicine or implement vaccination programmes, and different perceptions of the value of a medicine and the need to act fast on behalf of patients. These factors can lead to significant delays in reaching a common agreement, resulting in delays in patient access.

Joint procurement should therefore be based on voluntary participation, and structured to streamline product allocation, and to prevent the negative consequences of unilateral national stockpiling initiatives during public health emergencies. For vaccines in particular, other measures, such as greater funding allocation for immunisation programmes, are better suited to address access issues beyond pandemics. Immunisation programmes, notably beyond pediatrics, have shown significant weaknesses in terms of implementation and performance. For example, the budget dedicated to primary prevention via vaccination against debilitating and life-threatening infectious diseases represent less than 0,5% of the healthcare budgets (less than 5€ per capita) and has remained constant in most EU countries over the past five years.

Fit-for-purpose funding and contracting terms will be key to the success of HERA

While during the pandemic the EU reacted to issues as they arose, the creation of HERA is a first step to putting Europe on the front foot in addressing global health threats. To ensure seamless coordination, information exchange and the pooling of knowledge, **partnering with developers will be instrumental to HERA's success**. It will be critical for HERA to provide **funding at scale with attractive**

funding rates, and maintain a robust and predictable IP framework that incentivises companies to develop and commercialise medical countermeasures in a manner that promotes public health objectives. Clarity on IP ownership and control supports addressing public health needs, as it helps gain industry's support and secure industry's participation, while advancing commercialisation and distribution goals. In addition, HERA should contribute to equitable access to medical countermeasures for priority populations globally. Collaboration with governments and other global partners will be key to achieve this objective.

European citizens should equitably benefit from no-fault compensation in case of serious adverse events from a medical countermeasure developed for emergencies

While safety and efficacy remain key priorities for any measure taken, or medical countermeasure developed for emergencies, the risk of serious adverse events will always exist, particularly when a new product or intervention is deployed rapidly, and when medical countermeasures are likely to be used by larger patient populations than usual. In those circumstances, **there is a need to ensure efficient access to adequate compensation for patients who have suffered serious adverse events**. No-fault compensation systems are based on the principle that injured parties can be compensated without having to prove that the opposing party is at fault for the injury, and without having to prove any defect to a product which caused the injury. HERA should ensure that patients who suffer injuries because of medical countermeasures developed and supplied via HERA, can be compensated. Individuals can thereby **secure prompt compensation without incurring the cost, delay, and uncertainty of the judicial process**. Setting up no-fault compensation systems in all EU Member States is also essential, complemented by an EU compensation fund, to support Member States in this effort. Such measures would play a key role in **securing public trust in the medical countermeasures deployed and would strengthen the EU's ability to effectively respond to health emergencies**.

The COVID-19 pandemic has demonstrated that global health security starts with pathogen surveillance and sharing

As demonstrated by COVID-19, open and timely sharing of pathogen samples and genetic sequence information is essential to enable a rapid response to a pandemic, as well as guarding against potential national epidemics. For COVID-19, a delay of just one month in accessing the SARS-CoV-2 virus samples could have led to an additional 400,000 lives lost. Delays are not just a hypothetical scenario: **pathogen access has increasingly deteriorated since 2014, when the Nagoya Protocol on Access and Benefit Sharing (ABS) came into force**. To date, 134 countries have become a party of the Nagoya Protocol, many of which have implemented national ABS legislation with potential impact on the sharing of pathogenic material and associated genetic information. Currently, bilateral negotiations of access and benefit sharing contracts are required, which are lengthy and block any possibility of quickly responding to public health emergencies. **Legal certainty regarding the status of pathogenic material under ABS legislation is necessary, and pathogens and associated information should be exempted from the bilateral obligations of the Nagoya Protocol and national implementing regulations.** In this respect, the EU can play a leading role in seeking an **effective and coherent international approach, to ensure quick and predictable sharing of pathogens and associated information**.

A well-functioning European Health Data Space (EHDS) can be a key enabler for an ecosystem that boosts EU's preparedness for future crises

One of the few positives to emerge from COVID-19 has been the accelerated adoption of digital healthcare delivery. It will be essential not to lose that momentum. Maintaining it will require

investments in the digital infrastructure and a focus on data governance to ensure maximum system interoperability, both within and between national health systems. Going forward, EU countries need to **strengthen infrastructural investments, and harmonise processes and standards to drive efficiency. Equally, a well-functioning EHDS will be instrumental to ensuring an innovation-friendly ecosystem** that enhances the EU's ability to deliver care and boost preparedness for future pandemics.

Furthermore, **financial incentives to support telemedicine and remote care incentives** should be reviewed and refined, to support e-care delivery in a sustainable fashion. Last but not least, despite some much-needed improvements (such as the capacity to include COVID-19 clinical trials participants), the use of the Digital Green Certificate in many countries proved helpful in controlling the pandemic. Moving forward, the Digital Green Certificate could be a first step towards the implementation of an e-vaccination card covering all available vaccines, and of an interoperable, pan-European system of existing or newly created national Immunization Information Systems.

The COVID-19 pandemic has shone a harsh light on the gaps and inefficiencies in national health systems across the globe, which must prepare for increasing health demands

As health systems became overwhelmed during the pandemic, with many operating at or above capacity, addressing the immediate needs of a crisis was the short-term focus. However, that unprecedented pressure is likely to have consequences for the general population, which will stay long after the pandemic has subsided. **A new vision for European health systems is needed, to address current and future demands, moving away from reactive and short-term approaches, and assessing and planning for longer-term health outcomes**. This should include, for example:

- a **real and continuous focus on prevention and early care**, to address the challenges that existed pre-COVID-19, and which have been exacerbated by the pandemic;
- adequate **national funding for prevention and immunisation**;
- the use of **real-world data to understand trends** in future healthcare needs;
- the introduction of **payment models that incentivise the creation of efficient patient journeys**;
- **new approaches to clinical trials**, such as remote patient interactions, as a vital tool to ensure clinical trials are not derailed by future crises, as was the case during COVID-19.