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EU vaccines – a success story on the way to forging a real Health Union

Two years of the Covid-19 pandemic have taught us a hard lesson. Global challenges, like a pandemic, cannot be fought alone because nobody is safe until everybody is safe. While the international fight against the coronavirus goes on and vaccines are administered in Europe and beyond, new policies and instruments need to be developed and implemented in order to make sure that we are equipped to prevent and fight all future health threats, and to ensure universal and equitable access to healthcare. The European Union is in a unique position to design and develop the framework within which health systems and capacities can be strengthened and innovated.

The beginning of a new age

On the last day of 2019, China reported a cluster of cases of pneumonia in Wuhan, Hubei Province. A novel coronavirus was eventually identified, later named SARS-Cov-2. On 13 January 2020, the first recorded case outside China was recorded in Thailand.

A month later, the World Health Organization (WHO) declared a public health emergency of international concern (PHEIC), on 30 January. This was the sixth time, since the International Health Regulations came into force (2005), that the WHO has declared a PHEIC. Rapidly, this new unknown virus began spreading around the globe, with a pandemic being declared on 11 March.

One by one, every country around the globe started containment and confinement measures that had never been seen before, as no treatment nor vaccine was deemed effective against this new coronavirus. The illness resulting from it was named Covid-19 and by March 2020 it had shaken the whole world.

One by one, each national healthcare system was flooded by new cases of SARS-Cov-2, a virus that has proven to be a true headache for healthcare systems. When the pandemic started, 80 per cent of cases presented mild symptoms; the problem lay in the other 20 per

cent. These 20 per cent were severe cases that needed extensive specialised medical care in order to manage the symptoms, as no treatment was available. Older and younger people were both affected, and the only ones that seemed not to be struck by this new virus were children and adolescents.

Almost two years have now passed and much has evolved. Let me guide you through the efforts of the European Union on securing safe and effective vaccines.

Health in the European Union – treaties and history

First, it is important to clarify the competences of the European Union concerning health.

Historically, the EU has worked on the assumption that health is a national policy. However, a closer look into the treaties shows otherwise. According to Article 168 of the Treaty on the Functioning of the European Union (TFEU), the primary responsibility for health protection, and in particular healthcare systems, indeed continues to lie with the member states. However, the European Union has an important role to play in improving public health, preventing and managing diseases, mitigating sources of danger to human health, and harmonising health strategies between member states. Furthermore, a high level of human protection is to be ensured in the definition and implementation of all EU policies and activities.

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In simpler terms, healthcare provision is a competence of each member state. However, the protection of public health is a shared competence between member states and the European Union. It was this shared competence for the protection of public health that led us to the success story of vaccines in the EU.

(Lack of) coordination and measures against Covid-19

At the start of the pandemic, we saw borders closing one by one without any clear coordination, largely out of panic due to the unknown virus and its potential impact. Preliminary data indicated that this virus caused serious respiratory symptoms, with the need for specialised care for those with mild to severe symptoms.

The EU civil protection mechanism was activated for the repatriation of EU citizens, and this ended up returning 500,000 citizens from abroad. In a worldwide search for personal protective equipment, a joint procurement procedure was launched by the European Commission on behalf of the member states. This allowed the EU to act on the market as one big buyer, which encouraged suppliers to scale up and provide the maximum equipment possible at the best price.

March and April 2020 were hectic months when the pandemic hit the EU member states hardest. Solidarity prevailed when the various member states were hit differently and

were in need of specialised medical professionals, equipment and medical products. But we needed to do more – and we did, taking a step forward to find a vaccine that could help us solve this global problem.

Coronavirus Global Response: funding innovation and vaccines

Focusing on the vaccination strategy, the first step was taken on 24 April 2020, when the European Union, together with global partners, launched a pledging effort for the Coronavirus Global Response – a joint call for action to develop fast and equitable access to safe, quality, effective and affordable diagnostics, therapeutics, and vaccines against the coronavirus. This initiative also aimed to strengthen health systems everywhere and to support the economic recovery of the world's most fragile regions and communities. A total of €15 billion was raised for this fund.

Furthermore, at the same time the WHO, EU and global organisations launched the Access to Covid-19 Tools (ACT) Accelerator. The aim was to accelerate the development of treatments, tests, and Covid-19 vaccines, as well as to ensure equitable global access to them, and to strengthen health systems.

Vaccines – 'gambling' together increased our chances

The EU Vaccines Strategy was presented by the European Commission in June 2020, with the goal of accelerating the development, manufacturing, and deployment of vaccines. With this strategy, the Commission supported efforts to make the process more efficient, thus reducing the timeframe to less than a year for the majority of vaccines.

The EU Vaccines Strategy wanted to guarantee timely, equitable and affordable access for member states to safe and effective vaccines and to ensure that EU member states were ready to roll out those vaccines when available, overcoming any transportation and deployment needs. The Vaccines Strategy was also to act as a reference point for member states when formulating their national vaccination strategies, including the identification of priority groups.

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By summer 2020, the European Commission started signing the first contracts with pharmaceutical companies to allow the purchase of a future effective and safe vaccine against Covid-19 for all EU member states, with donations to lower- and middle-income countries. This ensured a competitive negotiation power, which translated into contracts for the European Union as a whole, guaranteeing a large portfolio, which otherwise would not have allowed all the 27 member

states to have equitable access to a safe and effective vaccine when it came onto the market after all the approvals required by the European Medicines Agency (EMA).

Vaccinate the EU

Vaccines started to be distributed in the EU by the end of 2020, following strict authorisation procedures with the highest safety standards.

An early Christmas gift arrived on 21 December 2020 when the European Commission authorised the first vaccine against Covid-19. The first jabs thus started to be administered all across the Union by the end of the year. Finally, after almost a year of the pandemic, a light had begun to shine at the end of the tunnel.

Each member state was responsible for defining its national strategy for vaccination, with the European Union publishing guidelines on how to set up such strategies. Indeed, as soon as vaccines started reaching the masses, a new sense of relief began to arise.

Two months into the roll-out of vaccines, a new European bio-defence preparedness plan was launched – the HERA incubator. The aim was to work with researchers, biotech companies, manufacturers, and public authorities in the EU and globally in order to detect, prepare and respond to new coronavirus variants. By September 2021, HERA was established as a body of the Commission, with the latter activating Article 122(1) of the TFEU, bypassing the European Parliament – a move that we in the Parliament believe was not the most correct, given the important role that all the European institutions, including the Parliament, had during the crisis response. The Commission also proposed sole regulation for HERA to the Council.

By the end of August 2021, 70 per cent of the EU adult population had been fully vaccinated, reflecting the enormous success of the European Union's strategy in the fight against Covid-19. Every European citizen had the equal right and opportunity to have access to a vaccine.

With vaccinations taking place in the EU, a mechanism was sought in order to facilitate free movement in the Union. On 1 July 2021 the EU Digital Covid Certificate Regulation entered into application. This certificate is available to anyone who has recovered from Covid-19, or who has been fully vaccinated, or who has tested negative, to enable them to move freely around to the EU. Today, it has proven to be our safest instrument to allow safe travel abroad, and it has had an enormous economic and social impact – especially in the tourism sector, one of the main economic sectors for some countries. In addition, the certificate has also contributed to stimulating the vaccination process itself.

After the incredible and unprecedented success of the joint procurement and acquisition of vaccines, anyone in the EU, regardless of their location, financial capacity, or social condition, could have access to a vaccine. However, after ten months, disparities are quite visible within the EU, as the rate of full vaccination among the adult population varies between 23 per cent and 91 per cent depending on the member state. Lower vaccination has translated into a higher infection rate, which translates into a higher number of moderate

and severe cases, and consequently more hospitalisations and deaths. It has also contributed to increasing the pressure on health systems, which consequently have more difficulties responding to other diseases. The answer is not yet as straightforward as one would want – as indeed nothing has been since 31 December 2019.

Analysing the motivations of those who have not been vaccinated, a large number are waiting for more data to arise in regard to transparency, side effects and long-term effects. Only a very few are negationists of the pandemic. Focusing on the first, it is clear that the scientific information is not reaching the public as we had hoped. Many of their questions can and should be answered. Unfortunately, this has also become the pandemic of disinformation.

More efforts should be deployed for targeted vaccination campaigns that focus on sharing reliable and evidence-based information. In a globalised and informed world, science needs to be centre stage during a pandemic. Additional efforts should be made to fight fake news on social media. After all, preliminary data show that solely in the EU half a million deaths have been avoided thanks to vaccination.

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Vaccinate the world – our moral failure

By December 2021, any citizen in the European Union who wanted to be vaccinated, and was medically allowed to do so, could get a vaccine quite easily. However, that is not the case when looking at the rest of the globe, especially in low- and middle-income countries.

The European Union has committed to ensuring universal access to safe and effective vaccines as, for now, this is the only known lasting solution to the pandemic. COVAX was created as the vaccines pillar of the ACT Accelerator, and global collaboration through COVAX will help us reach this goal of universal access to vaccines. COVAX includes a mechanism that enables low- and middle-income countries to access donor-funded doses of vaccines. By the end of February 2021, the first deliveries of Covid-19 vaccines through COVAX marked the largest, fastest, and most complex global roll-out of vaccines in history.

However, by 6 December 2021, only 610 million doses had been delivered to 144 countries through COVAX. It was an important milestone but one that was still far from the goal.

It is also important to note that it is not only through donating doses that they will reach people's arms. Together with partners, the European Union needs to support vaccination strategies, and distribution supplies, and to boost the local manufacturing capacity of vaccines. Global leaders from the G20 have committed to ensuring that 70 per cent of the world's population is vaccinated by mid-2022.

As is often repeated loud and clear: we will not be safe until everyone is safe. Despite the European Parliament's position in favour, the European Commission still keeps saying

no to the temporary TRIPS waiver of patent protections and the consequent free use of knowledge of medicines and vaccines against Covid-19.

Until vaccines are rolled out easily across the globe, SARS-Cov-2 will keep mutating in order to survive. That is nature of viruses and that is why we will keep being in danger until everyone is vaccinated.

The challenges remain – five lessons learned

At the time of writing this chapter of the *Progressive Yearbook*, the world is facing the rise of a new coronavirus variant that seems to be the most infectious ever seen, increasing the number of daily cases to historical numbers everywhere – even in the most vaccinated countries of the world. That is why, two years after the beginning of this story, we need to have learned some lessons that we must put into practice as soon as possible.

The first lesson is very clear – we need to vaccinate the world faster. In a few countries we have just started vaccinating children between the ages of 5 and 11, after having already vaccinated older children. Booster doses are also being given to the whole population. We now need to put the same effort into vaccinating all those who have not yet received a single dose of vaccine – either because they are in a country where they have not had access to one, or because they still do not trust science enough. Making vaccination mandatory in some scenarios might seem the right way, but it is a symptom of our failure, as the political and scientific communities, to explain to everyone that vaccines are the only way to protect us from the disease and to protect the world from a virus that is always rapidly mutating, even faster than the mRNA vaccines that can be adapted in one hundred days.

And that is the second lesson – to invest in health literacy and to fight disinformation. It is of the utmost importance to provide citizens with knowledge about health.

We need to keep pushing forward to maintain an innovation environment in the EU, with more transparency and cooperation

The third lesson – we need to keep pushing forward to maintain an innovation environment in the EU, with more transparency and cooperation. This will allow our national and European institutions and organisations, even those that are political, technical, or academic, to exchange knowledge, tools, and technology. Multicentric research and shared knowledge is the way forward to reaching better and faster answers to our current challenges.

The fourth lesson – we need to keep looking for new vaccines and treatments, not only for Covid-19, but for other infectious and non-infectious diseases. The EU is trying to create the necessary framework for this with the European Pharmaceutical Strategy, for example.

The fifth lesson – we need to keep working for a real European Health Union, where every member state competence is respected, but also where our global response and power improves with our synergy. And that is our current political challenge and goal.

The future of health

It is now very clear that the pandemic has enabled everyone to understand the true importance of strong health policies, and that health must be seen as an investment for the whole of society.

Since April 2020, the Group of the Progressive Alliance of Socialists and Democrats (S&D) in the European Parliament has been calling for a true European Health Union: it was and is clear for us that health should have a central role in EU policy.

In the 2020 State of the Union speech by the president of the Commission, the European Health Union legislative proposal was finally mentioned. Negotiations for the EU4Health programme ended in 2021 with a budget of €5.3 billion – a tenfold increase compared to the initial pre-pandemic proposal of only €500 million. EU4Health is the EU's most ambitious health programme ever and it goes far beyond crisis response, to addressing the resilience of healthcare systems. The programme defines the health policies in the EU for the next seven years (2021-27), complementing EU countries' policies and pursuing ten specific objectives under four general goals:[1] "to improve and foster health in the Union"; "to tackle cross-border health threats"; "to improve medicinal products, medical devices and crisis-relevant products"; and "to strengthen health systems, their resilience and resource efficiency".

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We cannot forget all the other diseases and patients – and we need to guarantee that no one is left behind. That is why EU4Health will also invest in urgent health priorities, such as Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe, health systems' digitalisation, antimicrobial-resistant infections, rare diseases and orphan drugs, and overall vaccination.

In addition, a new legislative package to strengthen the EU response to health threats was developed in 2021, with the umbrella file including the revision of the regulation of serious cross-border health threats, the revision of the mandate of the European Medicines Agency (EMA), and the revision of the mandate of the European Centre for Disease Prevention and Control (ECDC). The aim of this package is to build a stronger and more comprehensive legal framework within which the Union can prevent, prepare, and respond to health crisis – as this will undoubtedly not be the last pandemic of our time.

We also have the Pharmaceutical Strategy for Europe. This is one of the pillars of the European Health Union and it seeks to ensure access to innovative medicines at affordable prices for patients, and to address unmet medical needs – for example in the areas of antimicrobial resistance, cancer, and rare diseases. It also seeks to support the competitiveness, innovation, and sustainability of the EU pharmaceutical industry, and the development of high quality, safe, effective, and greener medicines; to strengthen crisis preparedness and

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1   https://ec.europa.eu/health/funding/eu4health_en.

response mechanisms, and address security of supply; and to ensure a strong EU voice in the world. During the discussion of this legislation, we at the European Parliament aimed to ensure that patients are at the centre of all policies; to safeguard the public interest, namely when there is funding and public incentives, in terms of accessibility, price of medicines, transparency and traceability of investments; to establish fair pricing and reimbursement policies that do not compromise the sustainability of health systems; to implement intellectual property policies that put public health first; and to promote more joint public tenders. This is the only way to ensure that everyone has access to the medicines needed, regardless of their illness, age, location, or economic situation.

A final and special word on cancer: we know that Covid-19 has had a major impact on healthcare systems, particularly in the fight against cancer and in ensuring timely access to health treatment – and that is why we need to act now. Europe's Beating Cancer Plan, with €4 billion, aims to prevent cancer and ensure that cancer patients, survivors, their families, and carers can enjoy a higher quality of life. By tapping into a broad array of EU policies, notably digitalisation, and research and innovation, the cancer plan helps EU countries turn the tide against cancer. It includes actions and flagship initiatives covering the entire disease pathway: prevention, early detection, diagnosis and treatment, and quality of life for cancer patients and survivors.

Health as a global commitment

Covid-19 has caused millions of deaths and the socio-economic impact of the pandemic remains extreme. It has taught us that we are stronger together.

The disease is still a global challenge that reminds us of its strength every day. Furthermore, we know that there will be other pandemics and other major health emergencies that do not recognise borders in the future. That is why no single government or institution can address the threat of future pandemics alone.

The level of preparedness and response will never be the same, and in November 2021 the World Health Assembly special session approved a mandate to develop the Treaty on Pandemics – a mechanism to improve global efforts on prevention, preparedness, and response to future threats in order to avoid repeating the heavy human, social, and economic costs of this pandemic.

This virus sees no borders, and nobody is safe until everyone is safe. We need to strengthen national health systems and national, regional, and global public health capacities, including their workforce. We need to improve early detection, prevention, and response to any future pandemic, with clear processes and tasks – in particular by ensuring universal and equitable access to medical solutions, such as vaccines, medicines and diagnostics, and protective equipment. We need better international cooperation, a stronger international health framework, and to restore trust in the international health system.

We need to implement a truly 'Health in all policies' approach, promoting an 'all-of-government' and 'all-of-society' view, integrating health subjects across all relevant policy areas

(eg, research, innovation, financing, and transport). We also need a 'global health' policy approach, which keeps in mind that we are only safe when everyone is safe. And we need a 'One Health' approach, connecting the health of humans, animals, and our planet. Besides health protection, we need to keep investing in health promotion and disease prevention.

Everyone is needed. We must work together and ensure sustained and long-term political engagement at all levels. We need to involve every policymaker, whether at European, national, regional, or local level. We need academia and representatives of health professionals, civil society, patients, and their families.

We cannot abdicate our common goal of delivering health as an individual right for everyone. This is why European citizens are counting on us and we cannot rob them of their expectations nor those of future generations.