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Is the European Health Union ready for the challenges of the 21st century?

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Credit: CANVA

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Executive summary

The COVID-19 pandemic laid bare the unpreparedness and structural weaknesses of national health systems while emphasising the disparities in national capabilities among European countries and the lack of a common European approach against cross-border health threats. To enhance the protection of citizens' health, prevent and prepare for future pandemics, and strengthen the resilience of Europe's health systems, the European Commission set out its plans for a European Health Union.

As we enter a post-pandemic era, this Discussion Paper assesses the proposals under the European Health Union and sets out recommendations to address the identified shortcomings. The following recommendations build on the discussions of the European Policy Centre's Task Force on the European Health Union:

- Adopt a more holistic approach by appointing a Vice President for Well-being.
- Strengthen crisis preparedness by elevating the Health Emergency Preparedness and Response Authority to an agency.
- Promote access and affordability by extending joint procurement.
- Strengthen the European health workforce by tackling shortages and addressing skills gaps.
- Mitigate the cost of inaction by increasing investment in health.
- Ensure planetary health by promoting a Green European Health Union.
- Promote Europe's status as a global leader in health data by harmonising health data regulations with the European Health Data Space.
- Safeguard the EU's strategic autonomy by implementing the Versailles Declaration and strengthening supply chain resilience.
- Build on the EU's Global Health Strategy by exploring global partnerships.

Introduction

In September 2020, during her State of the Union address, the President of the European Commission, Ursula von der Leyen, declared that "for me, it is crystal clear – we need to build a stronger European Health Union".[1] Against the backdrop of the COVID-19 pandemic, the Commission acknowledged the need for greater coordination between member states to better prepare, prevent and respond to future health threats and crises. This would have been unimaginable the year prior with fears that the focus on EU health policy would be significantly diminished due to former Commission President Junker's "big on big things" approach. However, in 2020 and 2021, the impact of the pandemic catapulted health to the top of the political agenda at both the EU and member state levels.

The pandemic brought to the fore the strong correlation between the importance of a healthy population and the resilience of the EU's economy, as well as solid supply chains and the risk of unwanted dependencies on other parts of the world. One of the first European heads of state who seemed to grasp these interconnected challenges was French President Emmanuel Macron, who advocated for the construction of "*une Europe de la santé*".[2] It was in this political environment that the Commission set out its plans to build a European Health Union (EHU).

After months of unwelcome delays, the final building blocks of the EHU have been laid by the Commission, with proposals to extend the mandates of the European Medicines Agency (EMA) and European Centre for Disease Prevention and Control (ECDC) and establish the Health and Emergency Response Authority (HERA). The construction of the EHU has continued with the proposal for a European Health Data Space (EHDS) and the revision of the Pharmaceutical Strategy.

While the impact of the pandemic placed health high on the EU's political agenda and resulted in the previously outlined initiatives, questions remain as to the definition of a health union and the future of health policy in the EU. The World Health Organization (WHO) declared COVID-19 over as a global health emergency on 5 May 2023.[3] As we enter a post-pandemic era, are the EHU initiatives enough or is further action needed to build a true European Health Union? In an era defined by challenges such as the Russian aggression on Ukraine, the cost-of-living crisis, changing demographics and climate change, what should the future of health policy entail? Citizens, via the Conference on the Future of Europe, expressed a desire for an increased role for the EU in health. However, any further action at the EU level depends on member states' political will and ambition to address health policy more holistically. The discussion around a strong European Health Union brings to the fore the contrast between growing demands for more EU action and the much-needed intersection between health and other policy areas and traditional member state resistance to deeper integration in health.

In this context, the European Policy Centre established the Task Force on the European Health Union in Autumn 2022. This EPC Task Force convened EU and national policymakers, academics and representatives from NGOs and industry for a series of closed-door roundtables to discuss the European Health Union and the future of Health in the EU. The EPC Task Force reflected on the state of EU health policy and focused on the initiatives set out under the EHU. Participants identified challenges and shortcomings, putting forward their thoughts on the action needed at the EU level to build Europe's resilience to prevent and protect against future pandemics, address dependencies on other parts of the world as well as promote healthy populations, reduce health inequalities, and build Europe's R&D ecosystem. The authors drew from the findings of the workshops to formulate the policy recommendations set out in this Paper.

EU health policy: Forged in crisis

WIDER IMPLICATIONS AND EVOLUTION OF PUBLIC HEALTH POLICY IN THE EU

Jean Monnet famously claimed that "Europe will be forged in crises and will be the sum of the solutions adopted for those crises". This sentiment holds true when reflecting on the evolution of EU health policy. The EU has been confronted with several public health crises that have impacted and shaped the EU's role in health policy. For example, the 2002 SARS outbreak led to establishing the European Centre for Disease Prevention and Control in 2004. Similarly, the impact of the 2009 swine flu pandemic paved the way for joint procurement and most recently, the COVID-19 pandemic resulted in the proposal for a European Health Union.[4]

The EU has been confronted with several public health crises that have impacted and shaped the EU's role in health policy.

While health has never been at the heart of the European project, there has long been health-related legislation. Already in 1965, the European Economic Community adopted legislation to ensure high standards of research and manufacturing of medicines.[5] However, the 1992 Maastricht Treaty created a legal basis for public health in the EU, albeit with limited scope. The 1997 Amsterdam Treaty further enhanced the role of the EU regarding public health, allowing the EU to adopt measures aimed at guaranteeing a high level of human health protection. Additionally, member states were able to cooperate on causes of danger to human health.[6] The subsequent Lisbon Treaty led to the Treaty on the Functioning of the European (TFEU), which underscored health policy by outlining under Article 168 that "a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities".

While Article 168 provides the legal basis for most health legislation, some legislative initiatives, such as the regulation on Health Technology Assessment, fall under the remit of the internal market, Article 114 of the TFEU. The legal basis for health legislation is broader than Article 168 and is interconnected with the EU's Single Market and Europe's competitiveness. Yet this is often overlooked at the EU level, with a tendency to fall back on a narrow definition of public health, thus missing the broader picture, leading to a lack of direction. This further indicates that health legislation is intrinsically linked to other areas of EU policymaking and legislation, and it is within this legal framework that the European Health Union is being constructed.

Once the worst of a crisis has passed, there is a tendency for health to lose momentum at the EU level.

As needs have arisen, EU health policy has responded and, therefore, has been mostly reactive. However, once the worst of a crisis has passed, there is a tendency for health to lose momentum at the EU level and be regarded as a rather technical domain where the EU has limited competencies rather than an area that brings well-being and economic prosperity to EU citizens and is of relevance for the EU's global competitiveness.

While previous crises have shaped EU health policy, none have perhaps had the same impact as the COVID-19 pandemic. Owing to the global impact of the pandemic, it drastically intensified the importance of health at the EU level. It resulted in stronger cooperation between the EU and member states, with regard to the Vaccine Strategy. The strategy, which leveraged the joint procurement mechanism, saw the Commission negotiate advance purchase agreements with vaccine producers, securing the right to purchase a certain number of vaccines at a certain price for a particular length of time.[7] This facilitated access to vaccines for member states reducing inequalities as is often observed with other medicines and displayed the added value of a more cooperative approach in the field of health.

NO FURTHER EVOLUTION WITHOUT STRONG POLITICAL WILL

Although the Vaccine Strategy was a success and did indeed display the added value of a coordinated approach at the EU level, it is important to note a key reason for its success. The presence of strong political will from member state governments allowed for an environment in which this proposal could succeed to jointly find a way out of the pandemic. Political will is essential and will remain essential as we attempt to define the future role of the EU in health. Citizens during the Conference on the Future of Europe called for health and healthcare to be included among the shared competencies between the EU and member states. They urged for action on the intersection of health and climate change.[8] However, while citizens have expressed a strong desire for increased action on health, some member states continue to be hesitant to question treaty change and further competencies for the EU in health.

In the current era of permacrisis, revising the EU treaties might not be a priority for member state governments or the European Commission. However, as we move away from the pandemic, we must ensure that the momentum and political and economic significance of healthy societies remains high and that safeguarding human health and well-being is linked to protecting the planet. While the pandemic underscored the importance of health for the functioning of our societies, its importance remains true in post-pandemic times with the interconnected challenges the EU is currently facing.

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Responding to the COVID-19 pandemic: Building a European Health Union

KEY PILLARS OF THE EHU

The impact of the pandemic garnered unprecedented political attention for health, placing it high on the agenda at the EU level. With such momentum, the European Commission set out its plans to create a strong European Health Union. The EHU aims to better protect the health of citizens, equip the EU and member states to prevent and address future pandemics, and improve the overall resilience of the health systems across the EU.[9]

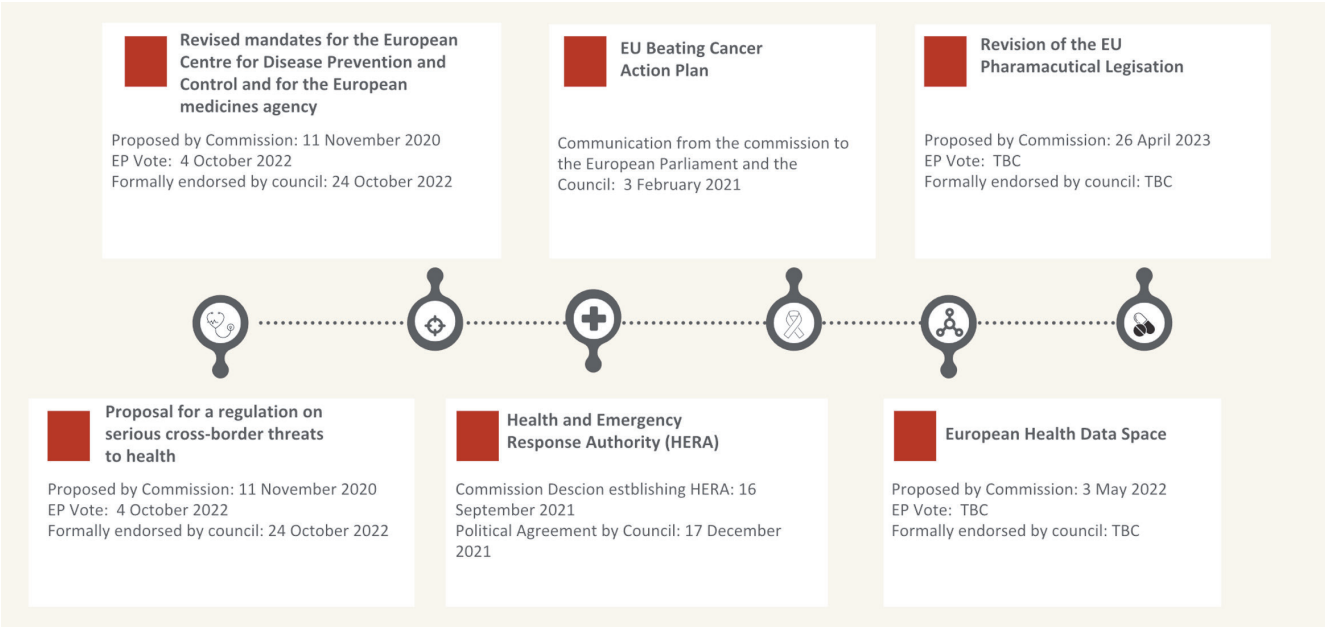
The Commission Communication "Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats'' published in November 2020, outlined the first building blocks of the EHU with the objective of bringing "greater overall impact while fully respecting the member states' competence in the area of health".[10] A core component of the EHU is crisis preparedness with a number of proposals aimed at better preparing for future crises. The early building blocks focused on the need to be better prepared in the face of future health threats.

CRISIS PREPAREDNESS

One of the earliest building blocks was laid in October 2020 with the Commission's proposal to regulate serious cross-border health threats. The regulation was adopted by the Council two years later in October 2022, and set out measures for more robust preparedness planning accompanied by a more integrated surveillance system. It allows for the creation of a Union prevention, preparedness and response plan and will include provisions for exchanging information between EU and member states. Additionally, the legislation provides for the establishment of mechanisms for joint procurement of medical countermeasures, incorporating the possibility of adopting measures at the EU level to respond to future cross-border health threats. The role of the Health Security Committee (HSC) is also strengthened under the regulation. As a coordinating body of EU response, the Committee is afforded further responsibility related to the adoption of guidance and opinions with the view of supporting member states in preventing and controlling threats to cross-border health.[11] This first block paves the way towards a stronger role for the EU in prevention and preparedness for future health threats, all while remaining within the confines of the limited EU competencies in the field.

Fig. 1

EUROPEAN HEALTH UNION



Source: European Policy Centre.

To further strengthen the EU's resilience in the face of health threats, the mandates of the European Medicines Agency and the European Centre for Disease Prevention and Control have been extended under the EHU. This extension allows the ECDC to mobilise and deploy an EU Health Task Force and host a network of EU reference laboratories to assist national responses and issue recommendations to member states. In parallel, the EMA's mandate has been enhanced to monitor and mitigate the risk of shortages of critical medicines and medical devices, provide scientific advice on medicines, and coordinate studies and clinical trials.

This more coordinated approach was, to a certain degree, institutionalised with the establishment of the Health and Emergency Response Authority, which aims to strengthen the ability to prevent, detect and respond to cross-border health emergencies by ensuring the development, manufacturing, and procurement of equitable distribution of key medical countermeasures. However, HERA was established as a service within the Commission instead of an independent stand-alone agency as was initially envisaged. This resulted in criticism from some stakeholders who pointed out that HERA's transparency and accountability would be undermined without agency status. The idea of a stand-alone agency was met with push back by member states, many of whom saw it as a step too far, which may have contributed to the decision to instead house it within the Commission. Doing so was also the most time-efficient way for the service to be set up without the involvement of the European Parliament as co-legislator. However, without agency status, the transparency and independence of HERA remain questionable. It does not have to go under the scrutiny that agencies are subject to under the Common Approach of the Commission, Parliament and Council to EU agencies, which includes impact assessments before establishment, annual report of the agency to the Commission, Parliament, Council and Court of Auditors and audits undertaken by the European Court of Auditors, among others. Without such mechanisms, transparency, governance and accountability remain somewhat murky. The planned review of HERA (expected in 2024) offers an opportunity to re-evaluate its status within the Commission to elevate it to an independent agency.

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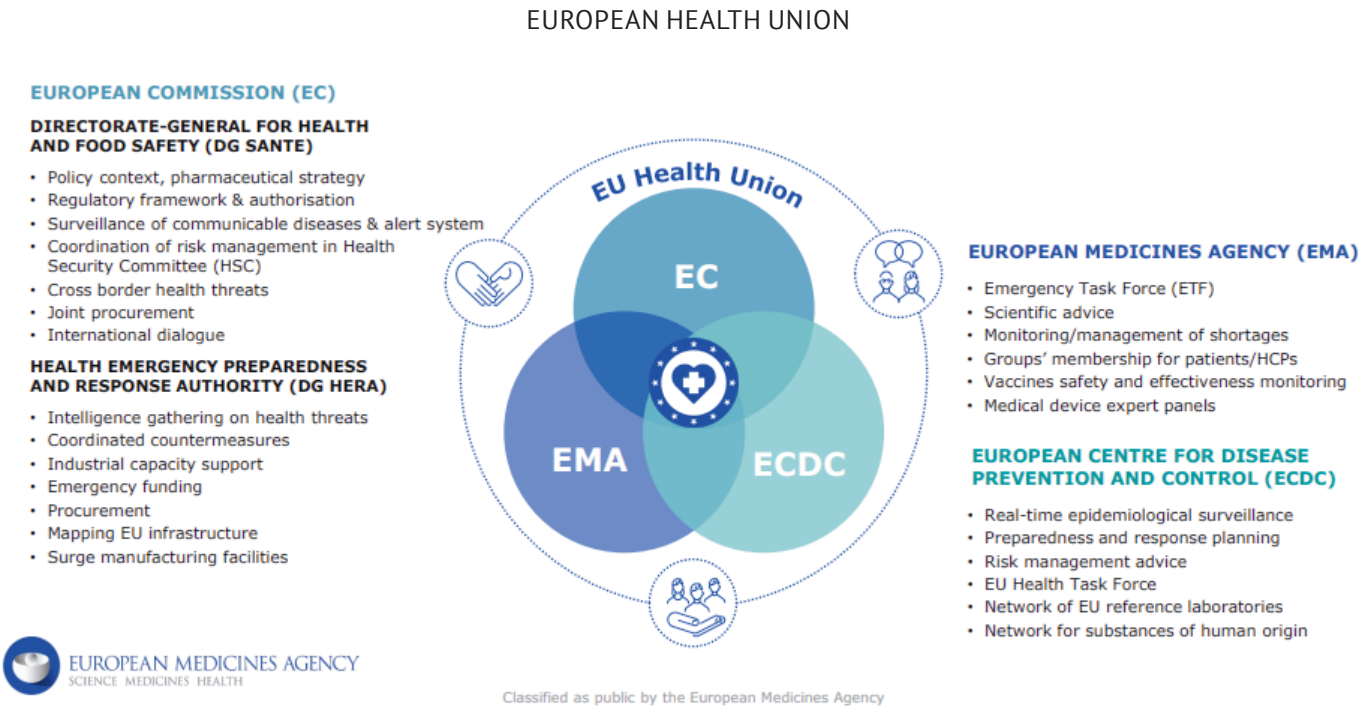
Fig. 2



Source: European Medicines Agency

GOING BEYOND CRISIS PREPAREDNESS

While the EHU was set out in response to the impact of the pandemic, it also contains initiatives with aims that go beyond crisis preparedness. In November 2020, the Commission laid out Europe's Beating Cancer Plan. The flagship plan seeks to prevent cancer with initiatives that cover the entire disease pathway, including prevention, early detection, diagnosis and treatment, and quality of life for cancer patients and survivors. The plan focuses on these four key pillars and sets out ten flagship initiatives and multiple supporting actions, and has an allocated budget of €4 billion.[12]

While the cancer plan was already planned prior to the pandemic, its inclusion under the umbrella of the EHU indicates that the Commission, to at least some degree, sees the Union as more than just an instrument to better prepare the EU in the face of another pandemic or health crisis. Measures such as the EU supported Cancer Screening Scheme illustrate how the cancer plan and, thus, the EHU aim to reduce inequalities and increase convergence between member states on cancer screening. The plan aims to ensure that 90% of the EU population who qualify for breast, cervical and colorectal cancer screenings are offered screenings by 2025.

Further initiatives, such as the proposal for the European Health Data Space, illustrate that the scope of the EHU is broader than pandemic preparedness. The EHDS aims to enable the sharing of primary and secondary data across member states borders. Unveiled in May 2022, the proposal sets clear guidelines, standards and practices, infrastructures, and a governance framework for using electronic health data by patients and research, innovation, policymaking, patient safety, statistics, or regulatory purposes. The Commission proposal aims to promote the safe exchange of patient data and provide citizens with control over their own health data, referred to as primary use. The proposal also sets out to support the secondary use of data to encourage access to and use of health data for research, policymaking and regulation.[13] The latter is perhaps more contentious and will be more difficult to find agreement between the Council and Parliament. Cited issues of concern for member states include the division of competencies, funding and the timetable of implementation which is thought by some to be unrealistic. Further issues raised by the Parliament include concerns related to AI and GDPR.

Further initiatives, such as the proposal for the European Health Data Space, illustrate that the scope of the EHU is broader than pandemic preparedness.

The Commission published the following building block of the European Health Union on 26 April 2023. Initially anticipated in late 2022, the revision of the Pharmaceutical Strategy was subject to several months of delay. The package aims to align and update the EU's pharmaceutical framework with recent technological developments. Still, it also addresses the importance of reducing inequalities by ensuring patients across EU member states have equitable and timely access to effective and affordable medicines. Owing to the lessons learned from the pandemic, it equally seeks to secure greater security of supply to ensure the availability of medicines across the EU. The revision consists of proposals for a new Directive and a new Regulation to replace the current legislation. They are accompanied by a council communication to step up the fight against antimicrobial resistance (AMR).[14]

The revision of the pharmaceutical legislation attempts to incentivise the industry to make innovative medicines available at the same time across all EU member states.

The revision of the pharmaceutical legislation attempts to incentivise the industry to make innovative medicines available at the same time across all EU member states. Incentives include increased time for market exclusivity for a product if launched across all member states. This, together with proposals to ensure that the EU's regulatory approval process is fit for purpose, signals a positive step in providing access and availability of medicines for patients in all corners of the EU. However, while creating an ecosystem for innovation is in the EU's remit, access to innovation is a national competence. To guarantee the success of the Strategy and ensure access to medicines and novel therapies, some member states governments will be required to increase their health budget and rethink their spending and budget allocation for health. Given the varying level of access between member states and the political trade-offs between different policy areas the current geopolitical situation requires, this may be a sticking point during negotiations at the Council level.

While overall the proposal offers potential, the strategy lacks concrete proposals to address access to medicines and innovative therapies such as advanced therapy medicinal products (ATMPs). The strategy does not address complex and advanced medical treatments such as cell and gene therapies (CGT). Joint procurement could be a valuable tool to address access to medicines and recommended to broaden its scope beyond serious cross-border health threats, considering the success of the Vaccine Strategy. The use of the joint procurement

instrument could, for example, be explored for rare diseases and orphan medicines. This would not only address the price tag of orphan medicines, but also their small volumes, which make it very hard for member states to individually negotiate these medicines with the industry. However, one of the lessons learnt from the pandemic is that exclusivity provisions are needed to ensure that joint procurement is centrally concluded by the European Commission instead of member states in parallel conducting their own negotiations (as we have seen at the start of the pandemic). This would mean broadening the regulation on serious cross-border health threats which is likely to get push-back from member states.

Joint procurement could be a valuable tool to address access to medicines and recommended to broaden its scope beyond serious cross-border health threats, considering the success of the Vaccine Strategy.

More practically, timing is an issue with this proposal, which was subject to many delays. This will more than likely have consequences in terms of the ability to finalise the package before the end of the current mandate of the European Parliament. With the elections in June 2024, there is much doubt about the feasibility of an agreement in the coming months. Not only does this delay the enactment of the legislation, but it also makes it difficult to determine the outcome of the negotiations owing to the likely change in the makeup of the European Parliament after the election. This uncertainty is combined with likely changes in the Council with a number of elections due to take place in member states in the coming year.

On 7 June 2023, the Commission added a final pillar to the EHU: a new comprehensive approach to mental health. This welcome development demonstrates that the Commission recognises the need for EU action on mental health. It also further demonstrates that the EHU should be more than a crisis preparedness instrument. The Mental Health in All Policies approach is most welcome. However, it remains to be seen how this will be implemented across member states owing to the lack of tangible targets. Nonetheless, it is a positive first step, and the EHU should be the umbrella under which further action on mental health occurs.

THE EXTERNAL DIMENSION OF THE EHU: GLOBAL HEALTH STRATEGY

Health threats do not just exist within the parameters of the EU but cross borders, marking the importance of global health. In parallel with the mentioned initiatives, the EU launched its Global Health Strategy, setting out three main priorities to deal with global health challenges. The strategy aims to deliver better health and well-being to people across the life course, strengthen health systems and advance universal health coverage, and prevent and combat health threats, including pandemics, applying a One Health approach. This strategy sets out twenty guiding principles to achieve the aims and improve global health, reducing health threats. While the goals and principles contained within the strategy are welcome, questions remain as to how they will and can be implemented.

What is certain is the importance of relationships and cooperation with other global actors. To achieve the aims set out in the strategy, international cooperation will be critical, especially after the COVID-19 pandemic. The negotiations on the International Pandemic Treaty show that data-driven decisions and better health outcomes do not always go hand in hand with international policies and clash with different concepts of sovereignty at a global level. Speaking at the EPSCO Health Council meeting in June 2023, Commissioner Kyriakides noted that there is a risk for the process to be derailed by the current geopolitical dynamics. This does not bode well for negotiations or the broader relations in the global public health context.

Assessing the European Health Union

The European Health Union is undoubtedly the most ambitious health initiative introduced at the EU level. Accompanied by the largest EU budget for health to date, the EU4Health programme, there has been a significant increase in the emphasis placed on health at the EU level. The budgetary increase from €452.3 million in the previous cycle to €5.1 billion for 2021-2027 demonstrates the extent of the increased ambition at the EU level.

The construction and political support for the European Health Union signals a push towards greater cooperation and coordination of health at the EU level. The outlined initiatives should result in an EU that, with its member states, continues to prioritise health security in the current geopolitical context and is better prepared in the face of future crises.

DEFINING THE EHU

Nevertheless, questions remain about how to define a true European Health Union. The initiatives, focusing on crisis preparedness measures, are welcome and much needed. However, while allowing for increased coordination and cooperation between member states, they do not expand the power of the EU in times of crisis beyond the extended roles of the ECDC, EMA and HERA. While Europe's Beating Cancer Plan, the European Health Data Space and the review of the pharmaceutical legislation extend the remit of the European Health Union, their success, of course, will be determined by the willingness and commitment of member states to see synergies between the different pieces of legislation and to fully implement these proposals in time.

Questions remain about how to define a true European Health Union.

Perhaps the European Health Union does not constitute a 'Union' in the typical sense, which would infer greater integration, for example, as was the case with the establishment of the Customs Union or the Economic and Monetary Union.[15] While it does not carry as much weight as other Unions present in the EU, it does have strong political significance and could pave the way for further integration in the field of health. In this way, the EHU should not be seen as a stagnant project but one that evolves over time to address the health issues facing EU citizens and member states. Therefore, it should not be viewed as a package that has been delivered but rather something that can further encapsulate health in the broadest sense. Defining the EHU for the next mandate of the European Commission will be paramount to avoid the intersection between health and other policy areas being overlooked as we move further away from the pandemic.

EHU: MORE THAN PUBLIC HEALTH

The impact of the pandemic placed a spotlight on the debate around health security and the EU's strategic autonomy. The shortages of masks and critical medicines encountered at the start of the pandemic meant Europe was heavily reliant on China, promoting discussions in the EU on the potential repercussions of global supply chains. This debate, further aggravated by the Russian invasion of Ukraine, has led the EU, along with the US, to rethink unwanted dependencies on other parts of the world. As evidenced by the Versailles Declaration, adopted in March 2022, the EU has recalibrated its focus on strategic sectors expressing the desire to make "Europe a leader in biomedicines" and avoid new dependencies in science and health technology.

A healthy population impacts Europe's growth model, especially in times of changing demographics. Pharmaceutical and industrial policy are intrinsically interlinked, as access to health and innovation can only be maintained by providing the right infrastructure for developing R&D and if manufacturing conditions are met in Europe. Whether Europe will remain an attractive place to invest compared to other parts of the world depends on its ability to create an innovation ecosystem that is inherently linked to the twin green and digital transition. The US Inflation Reduction Act clearly shows that health, security and environmental policies are interconnected, and the pressure is on for the EU to achieve the same with its Pharmaceutical Strategy.

Not only are health and the economy deeply interlinked, but there is also increased recognition that the healthcare sector contributes to the world's CO_2 emission, accounting for 4-5% of the total global carbon emission. Thus, the healthcare sector should be considered as an important part of the EU's green agenda and decarbonisation strategy. The pandemic allowed for increased recognition of the nexus between health and the environment, giving prominence to concepts such as planetary health, which advocates for "a solutions-orientated, transdisciplinary field and social movement focused on addressing analysing and addressing the impacts of human disruptions to Earth's natural systems on human health and all life on Earth". While environmental determinants significantly impact people's health, the health of the planet is impacted by human activity. This demonstrates the need to incorporate health into the EU's green agenda and further integrate into the EHU.

While we may be moving away from the COVID-19 crisis, we are by no means entering a period free of health threats. One of the most pressing issues facing health in Europe and beyond is antimicrobial resistance, which is deemed the 'silent pandemic'. Within the context of the Pharmaceutical Strategy, the EHU attempts to address the challenge of AMR using a One Health approach. This more holistic approach to tackling health threats is welcome. However, it should not be limited to AMR. Instead, it should underpin all initiatives under the EHU. While there is merit to the One Health approach, the scope should be extended towards a planetary health approach. Such an approach should be incorporated into policies not only in reaction to health crises but also regarding health promotion and prevention.

LACKING HEALTH PROMOTION AND PREVENTION

The EHU falls short when it comes to measures or initiatives that aim to address health promotion and prevention. The Beating Cancer Plan addresses determinants associated with cancer, including alcohol, tobacco, diet, and exercise, which, of course, are also defined as risk factors for other non-communicable diseases. However, a more overarching approach to health determinants with the aim of health promotion, also in

light of environmental concerns, should be considered as important to improving public health in the EU and thus should feature more prominently in the EHU. There is a need for a more holistic vision towards health prevention and promotion with the need to integrate 'health for all policies' approach to tackle health inequalities. While the EHDS and the review of the Pharmaceutical Strategy offer opportunities to address specific health inequalities, such as access to medicines and treatments, the EHU should go further to tackle the persistent health inequalities across the EU. The heterogeneity of EU health systems often presents a challenge here, especially concerning the varying levels of investment in health between countries across the EU. This, too, will be an important feature in the implementation of Europe's Beating Cancer Plan, and as well as perhaps a roadblock when it comes to negotiations on the review of the pharmaceutical legislation in the Council.

EU HEALTH SYSTEMS HETEROGENEITY

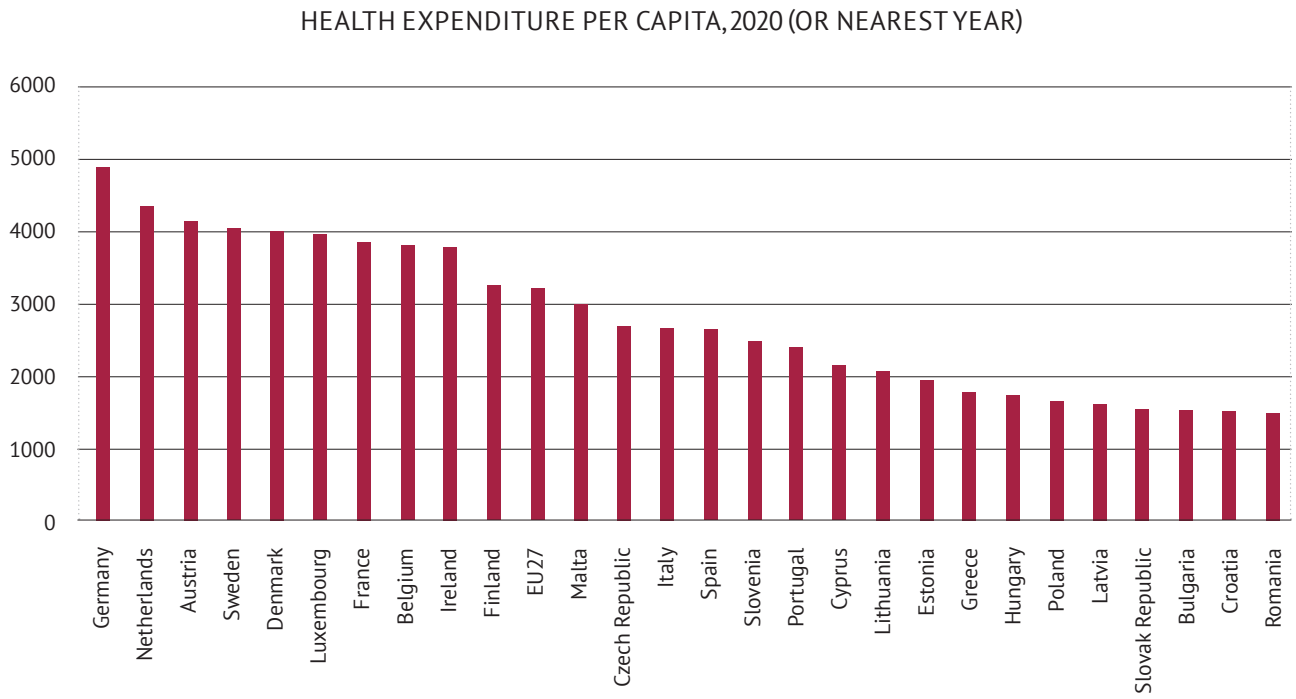
The heterogeneity of health systems also extends to the level of funding member states allocate to their health budget, which varies greatly across the EU. Research by the OECD[16] found that health spending differs three-fold between high-income countries in Western and Northern Europe and low-spending countries in Central and Eastern Europe, an outcome also reflected in the Country Specific Recommendations of the European Semester Process. Introduced in 2011 in the wake of the financial crises, this process has emphasised health systems as a significant area of public expenditure. However, cost containment measures have often focused on hospital services and pharmaceuticals without a comprehensive long-term vision of reforming their healthcare systems.

The current geopolitical context will likely only lead to more difficult trade-offs between different policy areas. This creates challenges, particularly when it comes to reducing inequalities, with some member states either pursuing cuts in healthcare budgets or unwilling or unable to increase health spending due to budgetary constraints. However, we need to consider the cost of non-action in health, in the context of changing demographics. An ageing population will result in increased pressure on health and long-term care combined with a smaller working-age population to finance expenditures. There will be increased demand for medicines and treatments, and without adequate planning and financing, the inequality gaps will widen.

The current geopolitical context will likely only lead to more difficult trade-offs between different policy areas.

The difference in member states health systems can also pose a challenge to implementing initiatives under the EHU. With regards to the European Health Data

Fig. 3



Data source: OECD Health Statistics 2022; Eurostat Database; WHO Global Health Expenditure Database.

Space, countries are starting at very different points of departure with inconsistent levels of digitalisation across member states. Research shows that Nordic countries lead the way, while the health systems in Eastern member states tend to be less digitalised.[17] Therefore, the envisaged timeline of full completion of 2025 is somewhat ambitious as member states may require more time for full implementation. Digitalisation will also require investment in the digital literacy of populations to ensure the full potential of health digitalisation is harnessed. While digitalisation offers the opportunity to reduce inequalities, without adequate skills and knowledge, it could have the opposite impact. However, while differences may present challenges in implementation, they also offer opportunities to share best practices and knowledge exchange that can and should be further emphasised.

WORKFORCE CHALLENGES

To realise the ambitions of the EHU and ensure the functioning of Europe's health systems and high-quality healthcare, qualified, trained and skilled healthcare workforce is essential. As promising as new technological developments may be, the right skills will be needed to make them reach patients. However, health systems across Europe are facing great challenges in relation to the hiring and retention of healthcare professionals. Shortages are prevalent across the EU, with an average of 3.9 doctors and 8.4 nurses per 1000 population in the EU. While all member states are faced with shortages, the issue tends to be greater in Eastern and Southern countries. Differences in working conditions result in high volumes of mobility to other parts of Europe, resulting in shortages. High levels of mobility can often be further explained by budgetary constraints resulting in a lack of investment in health services and their workforce.

To realise the ambitions of the EHU and ensure the functioning of Europe's health systems and high-quality healthcare, qualified, trained and skilled healthcare workforce is essential.

The diminishing capacity of the healthcare workforce can be attributed to several factors including poor working and pay conditions. The impact of the COVID-19 pandemic highlighted these ever-persistent issues with healthcare professionals exposed to threats to their physical and mental well-being as well as violence, leading to increased levels of anxiety among healthcare professionals.[18] Healthcare systems are also faced with skills gaps, in relation to green and digital skills. Artificial intelligence and digitalisation offer much potential for health, in particular for the healthcare workforce. They have the capacity to simplify and automate arduous and repetitive responsibilities, thus lessening the burden on healthcare professionals. Nonetheless, the full benefits can only be achieved if these tools are used appropriately and if ethical standards are upheld. In the absence of the necessary expertise and understanding, digital tools have the potential to impose extra challenges on healthcare workers, ultimately negatively impacting patient care.

The EHU fails to address the workforce challenges and ignores it is essential to ensure access to care for EU populations. Without action, it is difficult to imagine that the ambitions of the EHU will be achieved and that citizens and patients will get the future care they need. The need to address these challenges is paramount in the context of Europe's changing demographics. With an ageing population comes an increased need for healthcare and the provision of medicines and patients. While this is acknowledged, debates at the EU level seem to neglect the urgency of the matter. Without preparing for this demographic change, Europe's health systems will be incapable of matching the increased demand for health and care with adequate supply. An ageing population also means an ageing labour force which will inevitably present increased challenges in terms of workforce capacity, which, as previously mentioned, is already under pressure.

PROMOTING HEALTH LITERACY

While workforce skills are important, so too is the health literacy of the EU populations. As health systems move towards digitalisation, citizens must be equipped with the necessary digital skills to reap the benefits of digital tools and overall benefits for public health and health systems. This will be essential for the implementation of initiatives such as the EHDS. Meeting the targets of the European Pillar of Social Rights (EPSR) will be key to this. Under the European Pillar of Social Rights, the Commission has set a target to ensure that at least 80% of people aged 16 to 74 have basic digital skills. Initiatives such as the European Skills Agenda, the Digital Education Action Plan and the European Year of Skills can help increase digital literacy. However, further targeted programmes are required at the member state level to ensure that the most vulnerable are not left behind, avoiding the risk of increased health inequalities.

Recommendations

The current proposals under the European Health Union are a step in the right direction to protect the EU against future health threats while at the same time attempting to promote better access to care for citizens. However, it is merely a step with many more required before the European Health Union can truly become a reality. We put forward the following recommendations:

Adopt a more holistic approach by appointing a Vice President for Well-being

Strengthen crisis preparedness by elevating HERA to an agency

Promote access and affordability by extending joint procurement

Strengthen the European health workforce by tackling shortages and addressing skills gaps

Mitigate the cost of non-action by increasing investment in health

Ensure planetary health by promoting a Green EHU

Promote Europe's status as a global leader in health data by harmonising health data regulations with the European Health Data Space

Safeguard the EU's strategic autonomy by implementing the Versailles Declaration and strengthening supply chain resilience

Build on the EU's Global Health Strategy by exploring global partnerships

- **Adopt a more holistic approach by appointing a Vice President for Well-being.**

  A more holistic vision is required when it comes to health promotion and prevention. The implementation of health in all policies approach must be strengthened at the EU level and should be further encouraged at the member state level. This requires a shift away from the traditional siloed-based approach to policymaking to a more collaborative approach across policy areas including, environment, agriculture, employment, economic, transport and education.

  The EHU should reach beyond the current measures to include initiatives related to health, which are outside the traditional health domain. For example, environmental policies and legislation are also vehicles, which can also be used to bring forward ambitious measures to improve human health. The intersection between human health, animal health and the environment garnered recognition during the pandemic. The EHU should embed a planetary health approach into all initiatives to ensure the best outcomes for people, places, and animals. This approach should also feature predominately in the EU's external actions.

  A well-being framework should be adopted to promote a more holistic approach and to ensure the health of citizens, along with animal and planetary health, are integrated across all policy areas. Achieving policy coherence and alignment across silos will require strong political leadership. To this end, the European Commission, in its next mandate, should appoint a Vice President for the Well-being Economy with responsibility for coordination and political leadership promoting a more holistic approach.[19] Such an approach should work to reduce health inequalities by better addressing health determinants and arriving at better outcomes for citizens across the EU.

- **Strengthen crisis preparedness by elevating HERA to an agency.**

  The Health and Response Authority should be granted agency status moving outside of the remit of the Commission. An independent authority would be better suited to prepare for future health emergencies and to undertake epidemic forecasting to ensure the EU is building up its capacity for future crises. Being subject to the Common Approach of the Commission, Parliament and Council to EU

agencies would strengthen the transparency and independence of the entity. Such scrutiny could only enhance the legitimacy of HERA, and strengthen its position in preparing for future crises. Given the interconnectedness of health and the planet, with regard to health threats, a holistic planetary approach should be embedded into the activities of the agency. In this context, there should be close collaboration between HERA and other EU agencies such as the European Centre for Disease Prevention and Control, European Medicines Agency and European Environment Agency (EEA). This would mean that monitoring and forecasting could be conducted in a transdisciplinary manner to better prepare and protect against future threats.

- **Promote access and affordability by extending joint procurement.**

  While the revision of the Pharmaceutical Strategy attempts to narrow the gap in access and availability of medicine and treatments across the EU, it fails to put forward additional measures to facilitate access to medicines and new treatments such as ATMPs. Joint procurement at the EU level should be harnessed under the EHU to reduce access inequalities, particularly concerning medicines and treatments for rare diseases.

  Joint procurement enables member states to combine their demand for certain medicines or treatments and, by aggregating the demand, offer the opportunity to negotiate better prices and improve availability. Joint procurement could help promote access and affordability and also offers an avenue for increased coordination and cooperation on health at the EU level without any need to revisit treaties.

  The Joint Procurement Mechanism should be extended to include orphan drugs to ensure that those suffering from rare diseases across the EU have greater access and availability to the drugs they need. Broadening the scope of joint procurement can help to reduce inequalities, a value which should be at the centre of the European Health Union. In order to facilitate the use of the instrument, exclusivity provisions are needed to ensure that joint procurement is centrally concluded by the European Commission and does not lead to burdensome procedures where member states are conducting their own procurement procedures in parallel.

- **Strengthen the European health workforce by tackling shortages and addressing skills gaps.**

  The EHU can and should be used as a vehicle to address the challenges confronted by the healthcare workforce across Europe. Under the EHU, initiatives should be established to monitor the situation across the EU using common definitions of healthcare workers in all member states. This will require timely, accurate and comparable data that can help identify shortages and their implications in terms of healthcare delivery and mobility. Member states with the greatest shortages must be encouraged to address low attrition and retention rates with financial incentives along with measures to improve working conditions, promote work-life balance and invest in skills.

  Initiatives should be established and streamlined under the EHU to support member states with the upskilling and reskilling their healthcare workforce. The Recovery and Resilience Facility (RRF) can be a useful mechanism to achieve this. All member states should be encouraged to engage with Commission services and avail of the available support. This includes the exchange of best practices whereby member states can collaborate on challenges to identify solutions together. An EU-level skills programme dedicated to green and digital skills should be incorporated into the EHU to promote cross-border training for healthcare professionals across the health ecosystem. This could enhance the sharing of knowledge and best practices and help reduce inequalities in healthcare across the EU. The Skills Strategy, set to be developed as part of an ongoing Erasmus+ project, could act as a roadmap to address the current skills gaps across the 27 EU member states.

- **Mitigate the cost of non-action by increasing investment in health.**

  In order to achieve the aims of the European Health Union and prepare for an ageing population, member states should re-evaluate their health expenditure and protect healthcare spending from cost cuts and reform the European Semester process accordingly. Indicators related to health should be streamlined across different EU initiatives, such as the Semester and the RFF. Healthcare spending, which provides long-term value, should be defined as an investment rather than a cost, and the current reform of the EU economic governance framework offers an opportunity to do just that. For example, interventions aimed at prevention and health promotion should be categorised as investments across member states and sustainable and inclusive economic growth through investment and reform should be promoted. Evidence shows that health promotion and disease prevention, delivered both within the health systems and in coordination with other sectors, are extremely cost-effective. Further evidence and data are required to determine how much is lost by failing to invest in health promotion and disease prevention.

- **Ensure planetary health by promoting a Green EHU.**

  Planetary health must be deeply embedded into the EHU. Stronger links between the EHU and European Green Deal should be established for the benefit of human health and the environment. The green transition under the RRF should incorporate health considerations with investment and reform in

measures that advance planetary health. Environmental factors such as climate change have negative implications for health with evident impacts on health systems. However, these systems are contributing to the symptoms they are trying to treat, with healthcare accounting for 4-5% of the total global carbon emissions. Health systems across the EU must strive to reduce emissions. Hospitals emit 2.5 times more greenhouse gases than commercial buildings. As such, efforts must be made to transition to renewable energy sources. Member states should ensure that public hospitals use renewable energy in line with the objectives of the RFF. This should be complemented with criteria for energy efficient medical equipment across all public health settings.

- **Promote Europe's status as a global leader in health data by harmonising health data regulations with the European Health Data Space.**

  The EHDS is the first data space of its kind. It offers the potential for the cross-border sharing of data between EU member states with benefits for patients, and professionals along with research and innovation. In addition, it provides an opportunity for the EU to become a global leader in health data in terms of setting standards for the use of digital health data. Not only does the EHDS have the potential to enable the sharing of data for better outcomes for patients and boost research and health innovation, but it will also be crucial for the creation of further data spaces. To truly harness the potential of EHDS and promote the EU as a world leader of data spaces, alignment with other legislative initiatives is required, as well as awareness about what is happening at a global level, e.g. in the US and Asia. The EHDS regulation must be harmonised with other legislation, including the proposed AI Act, GDPR legislation and the measures on AI-based applications provided for under the Medical Device Regulation.

  The EDHS could be used as a blueprint in other areas where data spaces are envisaged, such as agriculture and finance. Therefore, it is paramount that the European Parliament, the Spanish and upcoming Belgian Presidencies prioritise negotiations on the EHDS to ensure an agreement before the Parliament elections, allowing for the implementation of the EHDS across member states.

- **Safeguard the EU's strategic autonomy by implementing the Versailles Declaration and strengthening supply chain resilience.**

  Initiatives under the EHU should not be viewed in isolation as a means to merely achieve better public health. Lessons learned from the pandemic on the importance of supply chains and unwanted dependencies on the rest of the world must be used to safeguard the EU's strategic autonomy. The Russian invasion of Ukraine has accelerated the need to strengthen supply chain resilience. The EHU and more specifically the Pharmaceutical Strategy should be used to secure supply chains and should be further linked to the industrial strategy and trade strategy to expand its strategic autonomy, enforce Europe's health security and secure its place in the global arena.

  To further ensure health security and advance Europe's strategic autonomy to avoid future dependencies, the European Union must be at the fore regarding health research and innovation. The EHDS should enhance research capabilities while the revision of the Pharmaceutical Strategy attempts to incentivise innovation for new medicines by simplifying the regulatory framework. Pharmaceutical and industrial strategy should mutually strengthen the EU's leading role in health technology. Therefore, investment and funding in R&I are essential and must continue to be a key component of the next Multiannual Financial Framework. Additionally, public-private relationships can play a central role in R&I and thus should be encouraged across the EU. Adhering to the Versailles Declaration, the EU and member states must concentrate on supporting innovation and sustainable European manufacturing of medicines, financing research and development and building production capacity for critical products to respond to health crises.

- **Build on the EU's Global Health Strategy by exploring global partnerships.**

  The aftermath of the pandemic offers an opportunity for the EU to solidify itself as a strong global actor and further enhance its relationships with other global actors. The EU Global Health Strategy sets out to address global health challenges to deliver health and well-being of people across the life course, strengthen health systems, advance universal health coverage and prevent and combat health threats, including pandemics. In order to achieve these aims, strong relationships with international partners are required. In the context of the ongoing negotiations on the pandemic treaty and the challenges in negotiations, it is important that the EU builds strong relationships with other international actors to advance their global health priorities. Attention should be given to an array of actors including the US and Asia, but also actors in the Global South. The global nature of health, which acts across and between borders, requires strong international cooperation in fora, such as the WHO, UN, G7 and G20 to ensure the best outcomes for public health.

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The **European Policy Centre** is an independent, not-for-profit think tank dedicated to fostering European integration through analysis and debate, supporting and challenging European decison-makers at all levels to make informed decisions based on sound evidence and analysis, and providing a platform for engaging partners, stakeholders and citizens in EU policymaking and in the debate about the future of Europe.

The **Social Europe and Well-being** (SEWB) programme is structured around the following priorities:

(1) strengthening the social dimension of EU policies and governance for upward social convergence;

(2) moving towards a modern and inclusive labour market;

(3) making European welfare states and social protection systems 'future-fit' in the light of ongoing labour market transformation; and

(4) investing in human capital for greater well-being and less inequality, with a particular focus on health.

The activities under this programme are closely integrated with other EPC focus areas, especially those related to migration and the economy, with a view to providing more 'joined-up' policy solutions.

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