A Europe that cares, prepares, protects: Strengthening the EU Health Union

- Building health system resilience
- Tackling the health workforce crisis
- Ensuring affordable access to healthcare
- Action on non-communicable disease prevention
- Fostering needs-driven Innovation
- Managing future health crises
- Securing resources for health systems
- EU Joint Actions 2.0
EUROHEALTH

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CONTENTS

Belgium EU Presidency 2024

FOREWORD – Stella Kyriakides

EDITORIAL – Editors of the Eurohealth special issue

THE PROMISE OF A EUROPEAN HEALTH UNION – Frank Vandenbroucke

ENSURING AFFORDABLE ACCESS TO HEALTHCARE FOR EVERYONE IN THE EUROPEAN UNION: WHAT GAPS REMAIN AND HOW CAN THE EU SUPPORT MEMBER STATES TO OVERCOME THEM? – Jessica Martini, Giorgia Fleischmann, Sebastiano Sabato, Jonathan Cylus, Sarah Thomson, Nicolas Bouckaert and Carine Van de Voorde

A RENEWED CALL TO ACTION: HOW CAN THE EUROPEAN UNION SCALE-UP ACTION ON NON-COMMUNICABLE DISEASE PREVENTION? – Judith Lambert, Ann Marie Borg, Gauden Galea, Kremlin Wickramasinghe and Caroline Costongs

ENSURING THE AVAILABILITY OF A SUFFICIENT HEALTH AND CARE WORKFORCE WITH THE RIGHT SKILLS – Karl Lauterbach

FINANCIAL ACCESS TO HEALTHCARE – Popi Kanari

COMPREHENSIVE APPROACH TO HEALTH AND WELLBEING – Kaisa Juuso

TOWARDS NEEDS-DRIVEN INNOVATION AND HEALTHCARE POLICIES – Ernst Kuipers

EUROPEAN HEALTH INVESTMENT HUB – Johannes Rauch

IDENTIFYING DISEASE-SPECIFIC PATIENT AND SOCIETAL NEEDS TO FOSTER NEEDS-DRIVEN HEALTHCARE AND INNOVATION POLICIES IN THE EU – Irina Cleemput, Charline Maertens de Noordhout and Wim Goettsch

REVAMPING THE EU’S HEALTH SECURITY FRAMEWORK TO MANAGE FUTURE HEALTH CRISIS – Andrea Renda, Timothy Yeung, Hien Vu, Jane Arroyo, Amy Kokalari and Panka Rékasy


EU JOINT ACTIONS 2.0: A BOOSTER FOR HEALTH IN THE EU? – Laurence Ballieux, Silke Baumann and Guy Dargent

Contributions from
EU Health ministers

ENSURING THE AVAILABILITY OF A SUFFICIENT HEALTH AND CARE WORKFORCE WITH THE RIGHT SKILLS – Karl Lauterbach

FINANCIAL ACCESS TO HEALTHCARE – Popi Kanari

COMPREHENSIVE APPROACH TO HEALTH AND WELLBEING – Kaisa Juuso

TOWARDS NEEDS-DRIVEN INNOVATION AND HEALTHCARE POLICIES – Ernst Kuipers

EUROPEAN HEALTH INVESTMENT HUB – Johannes Rauch

A Europe that cares, prepares, protects

WHAT COULD THE EU DO TO BUILD RESILIENT HEALTH SYSTEMS AND RESILIENT, HEALTHY SOCIETIES? – Scott L. Greer, Julia Zimmermann, Anna Sagan, Katherine Cooney and Josep Figueras

TACKLING THE HEALTH WORKFORCE CRISIS: TOWARDS A EUROPEAN HEALTH WORKFORCE STRATEGY – Matthias Wismar and Tom Goffin
FOREWORD

Embracing the European Health Union – A Europe That Cares, Prepares, and Protects

As we enter the Belgian Presidency of the European Union and a new year ahead, we have an opportunity to reflect on the path we have embarked on to change the paradigm of EU health policy.

Despite the challenges we faced at the start of the COVID-19 pandemic, with the support of Member States we have broken down the taboos of the past and have begun charting a new course by putting in place the foundations of a strong European Health Union.

We already have in place a stronger EU health security framework, underpinned by a reinforced European Centre for Disease Prevention and Control (ECDC) and European Medicines Agency (EMA), as well as a new Health Emergency Preparedness and Response Authority (HERA).

We have an ambitious and well-funded Cancer Plan that is already delivering on its promise to change the realities of cancer for EU patients.

We are aiming to fully unleash the potential of health data through a European Health Data Space to produce better treatments for patients.

Through the Health Union and the events of the last few years, health is at the top of the political agenda, with Member States having committed more than €43 billion in their Recovery and Resilience Plans as part of EU support through NextGenerationEU to strengthen their health systems.

Taken together, these flagship initiatives have kickstarted a new era for health in the EU, for today and for tomorrow.

A strong European Health Union is a Union in which all Member States prepare and respond to health crisis together and in solidarity. A Health Union that puts patients at the centre of every policy and ensures the highest standards of prevention, treatment and care for every citizen. A Health Union that leaves nobody behind.

I look forward to continuing this mission, hand-in-hand with the Belgian Presidency, which I know shares many of these goals. Let us work together for stronger and healthier societies, and modern, sustainable health systems that deliver for our citizens.

Last but not least, our new comprehensive approach to mental health puts people at the centre by aiming to break the stigma and make a positive difference for every citizen facing mental health challenges.

Stella Kyriakides,
Commissioner for Health and Food Safety,
European Commission

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The Belgian EU Council presidency is coming at a crucial time: at the end of the current EU commission’s term of office and coinciding with European elections. This provides an opportunity to reflect on Europe’s health agenda for the next five years (2024–2029). Therefore, the Belgian health presidency commissioned the special issue of Eurohealth that you have in front of you. We hope that it will contribute to the discussion on a number of key topics for a Europe that cares, prepares and protects.

To start, we present contributions from a number of EU health ministers underlining the importance of some of these key topics. The following section contains articles from experts who were invited to provide analyses on chosen key topics and to come forward with policy proposals for action at EU level. While the Belgian health presidency team defined the scope of the articles, the authors are solely responsible for the content; the policy recommendations they present do not necessarily reflect the views of the presidency. Nevertheless, together with the events planned during the Belgian EU Council presidency, they should encourage debate on the potential ways forward.

The first article “What could the EU do to build resilient health systems and resilient, healthy societies?” offers an overview of key lessons from comprehensive evaluations of the COVID-19 crisis, with a view to addressing future crises. The article identifies areas where EU initiatives have the greatest added value in terms of implementation.

The following articles delve into some of the themes that will gain prominence during the Belgian presidency.

The article “Tackling the health and care workforce crisis: Towards a European Health Workforce Strategy” analyses how the EU can support Member States in ensuring the availability of sufficient health workforce with the right skills to sustain their healthcare systems. The authors pay particular attention to the EU legal frameworks and how they can be revised to better accommodate national health workforce policies.

Principle 16 of the European Pillar of Social Rights grants “everyone (…) the right to timely access to affordable, preventive and curative healthcare of good quality.” However, much work remains to be done in order to put this principle into action as explored in the article “Ensuring affordable access to health care for everyone in the European Union: what gaps remain and how can the EU support Member States to overcome them?”

The EU has important legal competences to prevent and tackle non-communicable diseases, in particular by its regulatory powers on tobacco, alcohol and food. We believe that the EU should use these levers, so that many more people in the EU can make healthier choices. This is explored in the article “A renewed call to action: How can the EU scale-up action on non-communicable disease prevention?”

In a response to the COVID-19 crisis, the EU adopted new legislation and created the Health Emergency Preparedness and Response Authority (HERA). During the Belgian presidency, we want to take a critical look at these initiatives. The article “Revamping the EU’s health security framework to manage future health crises” is a first attempt to take stock of this post-pandemic EU health emergency governance framework.

Finally, this publication addresses two key EU-level health instruments whose impact could be improved through revision. The article “Building capacity and identifying appropriate support: How can the EU contribute to securing resources for health systems?” addresses aspects to facilitate access to (non-health-specific) European funds for health; whereas the article “EU Joint Actions 2.0: a booster for Health in the EU?” analyses the strengths and weaknesses of the current European Joint Action mechanism.

We hope that the thoughts presented in these articles can feed into the policy debate during the presidency and wish you an inspiring read.

The Editorial teams of the Eurohealth special issue
THE PROMISE OF A EUROPEAN HEALTH UNION

By: Frank Vandenbroucke

Summary: In order to cope with current and future crises, individual welfare states need transnational collective action, that is, solidarity. The 'European Health Union' should organise such collective action in support of shared goals of public health and national healthcare systems. The Belgian presidency will give a strong signal that health should be a top priority for the next European Commission’s agenda. The key policy challenges to be addressed by the future Commission answer three broad and interconnected aspirations: a Europe that cares, prepares and protects.

Keywords: European Health Union, Solidarity, Health Workforce, Needs-driven Innovation, Medicines Shortages, Access to Healthcare

Introduction

At the time of writing, the Ukrainian war has been going on for a year and a half, armed conflict has erupted in the Middle East, the world is experiencing record temperatures, and patients face severe medicines shortages. Meanwhile, we are still dealing with the aftermath of the most serious health crisis in a century, which has added to the fatigue of a health and care workforce already under stress. Such international crises and emergencies are no longer an exception, they have become part of life as we know it. No country can overcome large-scale transnational crises on its own: they require international collective action or, in other words, solidarity.

Solidarity proved to be essential to respond to the COVID-19 pandemic, both at the national and the European level. At the national level, the in-built solidarity of inclusive welfare states with accessible healthcare and universal sickness benefits is crucial for a society to be economically and socially resilient when it is hit by such a shock. However, European solidarity was needed to complement and reinforce the response capacity of the individual European welfare states. Fortunately, the EU’s reaction to the pandemic was a deliberate choice for collective action and solidarity, more explicitly and more boldly than in previous economic and financial crises. Traditional concerns about the risk that solidarity might be ‘misused’ were quickly – and rightly – set aside. This crisis was caused by a public health shock which hit all countries in the same way, no country could be held ‘responsible’. There was no issue of moral hazard, the adequate response was straightforward solidarity.

A European Health Union

In the past I coined the expression ‘a European Social Union’ to describe the role the EU should play in the domain of social policy: the EU should be a true
union of welfare states, notwithstanding their different historical legacies and institutions. In a Social Union, the EU should support national welfare states and guide their substantive development on the basis of common social standards and in pursuit of upward convergence. Simultaneously, a European Social Union maintains subsidiarity as an organising principle with regard to the ways and means of welfare state solidarity. The European SURE initiative*, which was launched to support national job retention schemes, such as short-time working arrangements, when the pandemic hit, is a prime example of what a true Social Union is about. SURE could be understood as the prefiguration of a European ‘interstate insurance’ to buttress the stabilisation capacity of national welfare states. Next to providing such systemic support, a Social Union should be a norm-setter that defines common social standards, so I argued.

population’s overall well-being, including mental health, enhances its resilience to emergencies and stress.

The mission of a European Health Union, as presented in official EU documents, indeed refers to a broad range of actions on health, “in which all EU countries prepare and respond together to health crises, medical supplies are available, affordable and innovative, and countries work together to improve prevention, treatment and aftercare for diseases such as cancer”.[2] Notwithstanding its broad mission statement, the initiatives taken under the umbrella of the European Health Union mostly focused on preparedness and response, and less on the overall resilience of public health systems.

The Conference on the Future of Europe noted this strong emphasis on crisis-related aspects of health policy and called for the establishment of a “right to health” by ensuring that all Europeans have equal and universal access to affordable, preventive, curative, and high-quality healthcare, by improving the quality and resilience of our healthcare systems, and by adopting a holistic approach to health, and ensuring access to healthy food.[3] The Conference also called for the integration of health and healthcare among the shared competencies between the EU and EU Member States.

Still, I believe that the key, above all else, is political will, with consensus-building as the essential component. A change of the Treaty on the Functioning of the European Union (TFEU) would certainly provide the occasion to create a stronger legal basis for the work on health, but COVID-19 showed us that EU collaboration in health can already be extensive within the current legal framework.

Moreover, we know that the EU’s current impact on health policy is much broader than what one might expect when reading article 168 of the TFEU. Many health-related provisions can be found in the legislation of other policy areas (such as food safety, safety at work, chemical products, environment …). In particular, the internal market legislation and the EU fiscal policy framework have a crucial impact: think about pharmaceutical products, health professionals and the European Semester (the EU’s framework for the coordination and surveillance of economic and social policies). Furthermore, the EU’s various funding instruments are also of increasing importance, especially when they are used to leverage the implementation of policy priorities defined in the European Semester.

In short, if we argue for a broad understanding of the European Health Union’s mission, we are in good company when reading the results of the Conference on the Future of Europe. But such a broad understanding does not presuppose Treaty change acknowledging that the current Treaty already grants important legal competences to the EU in policy domains that bear significantly on national public health and healthcare policies.

**A Europe that cares, prepares and protects**

The Belgian Presidency of the Council of the European Union coincides with the conclusion of the von der Leyen Commission’s term. Hence, during our presidency we propose to identify and discuss the priorities for the next Commission’s agenda with regard to the European Health Union. These priorities can be grouped in three thematic clusters: “care”, “preparedness” and “protection”.

**A Europe that cares**

All countries face health workforce challenges: shortages associated with the increasing needs of an ageing population and waves of retirement of health workers in changing labour markets, uneven geographical distribution, mismatches in skill-mix, difficulties to develop skills to meet new healthcare needs and new technologies.[4] To face the health workforce crisis, action is necessary at all levels, both national and European. Whilst fully respecting national competences, the EU can do much more to support Member States in the development of strategies to ensure the availability of sufficient and well-skilled healthcare workers.

What is an optimal division of tasks between professionals with different qualifications? What is the role of

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* SURE is the European instrument for temporary Support to mitigate Unemployment Risks in an Emergency.
technological innovation and new medical devices? To address such – shared – questions national policy-makers can learn much from each other, and the EU can contribute significantly to the exploration of new frontiers of innovation. However, next to taking up such a supportive strategic role, the EU already has a crucial legal impact on the organisation of the healthcare professions, through the EU legal frameworks regulating health professions, in particular – but not only – the Professional Qualifications Directive (PQD). We call for a critical examination of these legal frameworks from different angles, even if they might seem to pull the debate in opposite directions. On the one hand, the PQD may be too rigid and formalistic to accommodate the continuous dynamic development of competencies and the flexibility and new models of cooperation needed in the future organisation of the health workforce. On the other hand, the current legal frameworks seem ill-equipped to address challenges related to specific contexts, in particular short-term mobility of health workers and telemedicine, which raise specific issues of quality assurance and patient protection.

Priorities can be grouped in three thematic clusters: care, preparedness and protection

Research and development are obviously crucial to continuously improve healthcare systems and shift their frontier. However, research and development must not be driven by what can generate significant profits, but rather by current (unmet) health-related needs in society, and therefore needs from patients. The EU plays an important role in orienting research and development through its research funding programs and through regulatory incentives built into the pharmaceutical legislation. Therefore, the Belgian presidency will launch a debate on the notion of a ‘needs-driven approach’ of healthcare policy and research and development. That is, we need a common methodology to identify and assess disease-specific unmet needs and define priorities in an evidence-based manner. On that basis, the Commission must be able to draft an EU strategic plan to adequately and effectively respond to the identified patient and societal needs. Such a strategic plan should consider all types of health interventions (rather than only pharmaceuticals), and coordinate all kinds of public support and incentives.

While there are already many sound arguments for the prevention of non-communicable diseases (related to health, budgetary matters and economy of well-being), COVID-19 added one more argument to this list: healthy populations are also more resilient to different types of crises. But then, first of all, people must have the opportunity to lead a healthy life. Here too, the EU has an important role to play given its already existing legal competences: just think about its policy levers with regard to food, tobacco and alcohol. There is a significant acquis, but the EU must continue to work on the prevention of non-communicable diseases and raise its level of ambition. More concretely, we want to bring the negotiations on the Council Recommendation on vaccine-preventable cancer and the Council Recommendation on a smokefree environment to an adoption by the Council, as well as organise a stock-taking exercise on the Europe Beating Cancer Plan, with a specific focus on legislative measures. Consequently, this could lead to a call to continue action on non-communicable diseases.

A Europe that prepares

We need to implement the lessons learned from the COVID-19 pandemic in order to be ready for the future. With the adoption of the Health Union legal package and the creation of the Health Emergency Preparedness and Response Authority (HERA), the work related to health emergency preparedness has only started. These swift initiatives were badly needed, but are we now really prepared for the next crisis? The Belgian Council Presidency will launch a stock-taking exercise of the post-pandemic EU health emergency governance framework. We propose to address five sets of questions. In the event of a new health emergency, will the EU be able to rely on: (i) the right tools and procedures to deal with the crisis; (ii) the financial means to effectively secure adequate resources; (iii) the structures and institutions to develop coordinated, multi-level response strategies; (iv) the means and advice to speak with authority and legitimacy to the general public; and (v) sufficient intelligence to collect data and relevant information, and translate it into actionable insights? In a nutshell, who does what exactly at what time? And how do we ensure that everyone is on board in time?

In this context, we will also examine how the EU’s capacity to conduct large scale clinical trials can be expanded. During the pandemic, the World Health Organization (WHO) recorded over 18,000 COVID-19 clinical trials, the vast majority (95%) of which are thought to have contributed nothing to the evidence base due to failure to complete enrolment or poor design features. An unprecedented number of academic clinical trials have also been launched in the EU to speed up COVID-19 treatment and prevention. Despite these efforts, a lack of coordination across Member States resulted in a chaotic landscape with numerous underpowered trials that could not provide meaningful results and a duplication of research activities. The Presidency will work on the development of concrete actions for strengthening the European ecosystem for public clinical trial platforms.

Additionally, the Presidency will continue the work of the Swedish and Spanish Presidencies on the silent pandemic of antimicrobial resistance (AMR). The European Centre for Disease Prevention and Control (ECDC) estimates that 35,000 people die each year in the EU from antimicrobial-resistant infections. We intend to discuss the EU’s AMR governance, the development and implementation of effective, results-driven, policy measures to optimise use of
antibiotics, how to stimulate the research and development of new antibiotics and sustainable access to existing ones.

Finally, the Presidency will prioritise the finalisation of the negotiations on the International Pandemic Treaty and the International Health Regulations, which fall under the WHO’s purview.

A Europe that protects

The EU has been confronted with severe medicines shortages over the past few years. According to the most recent survey conducted by the Pharmaceutical Group of the European Union (PGEU), all European Member States experienced shortages in 2022. The study also found that shortages had gotten worse than during the peak of the COVID-19 pandemic, with three-quarters of respondents reporting a further deterioration of the situation compared to 2021.

To tackle these problems, Belgium launched a non-paper on security of medicines supply, which was signed by 23 Member States. The non-paper proposed three measures to help relieve the worst effects of shortages on patients, as well as to provide a structural answer to the underlying causes, namely: 1) a voluntary solidarity mechanism to address acute shortages, 2) a European list of critical medicines whose supply, production and value chains must be monitored, and 3) a Critical Medicines Act to strengthen Europe’s manufacturing base for critical medicines and reduce dependencies and market consolidations. The initiative has been followed up by a comprehensive Commission Communication, published on 24 October 2023. The Communication puts forward a broad set of short-term and longer-term actions to address shortages of medicines and enhance their security of supply in the EU. Concretely, the Commission immediately put into action proposals to establish a voluntary solidarity mechanism to share medicines between Member States in case of acute shortages and to carry out a risk assessment of the supply chains of a list of critical medicinal products. The Commission also announced an industrial plan for the production of older, less-profitable but critical medicines, the launching of a public-private cooperation under a ‘Critical Medicines Alliance’ and of a study to prepare a future ‘Critical Medicines Act’.

Putting these actions into practice will be challenging, yet necessary. For instance, several Member States have started rigorous stockpiling programmes as a response to shortages, which can have further negative consequences for the fair distribution of medicines on the European market. A solidarity mechanism should be able to counteract some of these problems, but only provided that Member States do not have export restrictions in place to put up a barrier for solidarity, and that there are procedures in place that can efficiently move stock without excessive legal and logistical burdens. In a nutshell, in an interconnected market we must help each other out: the stockpiles of the rich must not create the shortages of the poor.

The same goes for the government support programmes under the ‘Critical Medicines Alliance’ and the future ‘Critical Medicines Act’, which will require tight coordination on the medicines that are primarily targeted, finding the necessary public and private financing, and defining the public services that are asked from producers in return.

Healthcare as a social right and a social investment

During the Belgian Presidency, we want to reaffirm the European Pillar of Social Rights as an overarching compass for the EU’s action in the social domain. Principle 16 of the Pillar proclaims that “everyone has the right to timely access to affordable, preventive and curative healthcare of good quality”. The Pillar has generated highly valuable policy spinoffs since its first proclamation in 2017, but, so far, principle 16 has not triggered specific implementation initiatives. In our view, a European Health Union should also be inspired and driven by this important principle 16 of the Pillar. A Health Union is also about access to healthcare and equity: therefore, the Pillar of Social Rights should be one of the key references and benchmarks of the European Health Union.

Linking the European Health Union to the Pillar not only underscores the importance of equal access to healthcare as a fundamental social right. Establishing that link will also bear on the way healthcare spending is treated in the EU’s economic and budgetary governance; at least that is our ambition. During our Presidency, we will argue that the EU’s economic governance and budgetary policies should now take due consideration

† This work will be carried out under the Belgian Council Presidency, but not be further elaborated on in this publication.

‡ A non-paper is an unofficial document, a paper that has not been through a formal adoption procedure.
of the European Pillar of Social Rights. The review of the EU’s Economic Governance, which is currently on-going, has to recognise that investments in well-organised social policies are an asset and not a liability, a productive factor rather than a cost. The concept ‘social investment’ is well-known in the European policy debate, but it has been used most often with reference to early childhood education and care, education, training and active labour market policies. Investment in health and healthcare are prime examples of investment in human capital and should be included in the concept of social investment. The review of the EU’s Economic Governance offers an opportunity to highlight the role of investment in healthcare as a condition for growth, competitiveness and sustainable public finance. That opportunity must not be missed.

Conclusion

As we navigate global challenges, from conflicts to health crises and climate emergencies to medicine shortages, it is evident that European collective action on health – a true European Health Union – is not optional but imperative. We urgently need more debate on the ways forward to a Europe that cares, prepares and protects. That is why we commissioned this special Eurohealth issue. It is an invitation to dialogue, highlighting some key areas where the Union can make a substantial impact, from bolstering the healthcare workforce to adopting a needs-driven approach to research and development. The contributions also emphasise the importance of reinforcing prevention and promoting healthier lifestyles. And while the views presented are solely those of the authors and do not engage the Presidency, we will work hard with the Commission, the Parliament and Member States to take the objectives that inspire these contributions on board in our work on the European Health Union.

References

5. See WHO Europe Bucharest Declaration on the health and care workforce, March 2023. https://www.who.int/europe/publications/i/item/Bucharest-declaration
Health and care workers are the mainstays of high-quality, universal and needs-based health and long-term care. Due to the profound structural and demographic changes EU countries are facing, many of which have been exacerbated by the pandemic, these professions are particularly challenged. Long-term care facilities and hospitals frequently struggle to ensure sufficient staffing. The situation is expected to become more challenging as the number of people with (long-term) care needs in Germany is projected to rise to approximately 6.8 million by 2055 (26% increase since 2021). Without necessary reforms, e.g., in the field of inpatient care, we run the risk of getting caught in a downward spiral: lack of personnel, fewer cases treated and increasing waiting lists, financial constraints, further decrease in personnel. The same applies to working conditions: Understaffing leads to more stressful work environments for the remaining staff, thus leading to more employee attrition. Policy-makers therefore need to take further action to retain the skills base, boost recruitment and improve working conditions for the health and care workforce.

The work of professionals must be organised according to their skills and qualifications. Better dovetailing of ‘inpatient care’ and ‘outpatient care’ as well as ‘medical treatment’ and ‘long-term care’ sectors, e.g. by way of cross-sectoral healthcare facilities, are key, an aspect considered in the Federal Ministry of Health’s plans for hospital reform. These facilities will combine inpatient medical services with outpatient medical and nursing care.

In addition, the German Federal Government has taken numerous concerted measures to secure the continued availability of skilled staff in the health and care sector. In addition to promoting fair and ethical immigration of skilled staff, legal initiatives were implemented to ensure adequate remuneration and instruments for assessing staffing requirements for nursing staff. Digital innovations that ease the workload burden and improve the quality and efficiency of healthcare provision need to increasingly be integrated into this work. This issue is also stipulated in the Digitalisation Strategy for Health and Care. The collaboration of Member States within the European eHealth network and the establishment of the European Health Data Space also play a vital role.

The number of sick days in the nursing profession caused by physical strain and emotional stress has increased over recent years and represents an additional challenge for health and long-term care facilities. In response, the statutory health insurance funds support nursing staff and their employers by providing specific workplace health promotion services to strengthen employees’ resources and maintain their health.

An urgent question and societal challenge concerns us all: How can we continue to ensure high-quality, universal healthcare in view of current demographic developments? In this context, the EU plays an important role as a mediator which can establish and expand spaces for knowledge transfer and the sharing of ideas so that Member States can effectively learn from measures that were successfully implemented elsewhere.
While the regulatory framework within the European Union (EU) still allows Member States to have considerable flexibility in managing their healthcare sector, it is evident that all Member States have taken significant steps toward financial access to healthcare, guided by the principle that citizens should not be burdened with disproportionately high healthcare costs that force them to make choices regarding their health based on their financial position.

**Universal Coverage** – In order to give citizens equal access to healthcare, we need to ensure that everyone is covered under a national health system. If for any reason cover is not provided to part of the population, it adversely affects the national health system, as health issues affecting minorities are connected to the whole population.

This problem has become even more intense given the large flow of refugees coming into the EU. We need to formulate a policy on this matter and support EU Member States, especially Member States on the borders. Also, funds should be directed to address the special needs of vulnerable populations requiring special attention, such as the older people, children, and those with chronic illnesses.

**Solidarity** – We should make sure that our national health systems cover all the essential healthcare services. We should consider incorporating services like dental care and supporting medical services that are usually excluded.

We also need to ensure that all drugs are provided at reasonable prices. We should reconsider the possibility of procuring drugs at an EU level rather than at a local level. Copayments should be used with caution, and where applied, should be set at low rates and with yearly caps.

**Sustainability** – We should introduce new ideas and incorporate several economic mechanisms into our healthcare systems. This way, we can make sure every euro spent on healthcare is spent effectively.

We must recognise that healthcare systems do not operate according to traditional market forces where services are directed towards those who have the means to pay, given that healthcare consumption is not connected to one’s ability to pay. Understanding this and its consequences, e.g., moral hazard, will lead to us to recognise the need to adapt several dynamic policies within our healthcare systems to optimise their efficiency.

In addition, unifying our knowledge on fraud detection and minimising the misuse of our healthcare systems is vital.

**Investing in areas with higher added value** – Investing in preventive care and promoting good health is important. When there is good health status in the population and the number of chronic diseases is decreased, the result would obviously be better quality of life and fund saving on healthcare in the future.

We should enhance primary care by bringing together general practitioners under properly equipped and staffed primary healthcare centers. Doctors should be relieved of secondary duties, and more responsibilities should be given to nurses and other support staff. This way, doctors will use their time more efficiently.

It is even more important now than in the past to give emphasis on capacity planning at both national and EU level.

**E-Health** – We need to make use of technology to further enhance access to healthcare. Telemedicine, e-prescribing and electronic records have become invaluable tools especially during the COVID-19 pandemic. These innovations reduce the financial burden of having to travel abroad to reach healthcare facilities, make healthcare accessible even to remote areas and our healthcare systems more efficient.

In conclusion, every European citizen should have access to healthcare services when needed, without financial hardship. It is our duty to create a flexible and innovative environment that will accommodate this principle.
In Finland, we believe in a comprehensive and cross-sectoral knowledge-based approach to improving health and wellbeing. Activities in the sector focus on, for example, health promoting lifestyles and clean, safe and accessible living environments, promoting mental health and inclusion.

Reducing health inequalities is a prime objective for us. We recognise that there is inequality in terms of health and wellbeing both geographically and between socioeconomic groups. These disparities can be reduced by national, regional and local policies that take into account the interlinkages between economic, environmental and social sustainability.

In Finland, cross-sectoral collaboration supports the implementation of measures to develop wellbeing, health and safety in different sectors of society, also outside the healthcare and social welfare sector. In addition to various administrative branches representing different ministries, Regional State Administrative Agencies, towns and cities, NGOs, private organisations, universities and research and development institutes are needed to improve the effectiveness of the promoting health and wellbeing. The Economy of Wellbeing approach builds on a continuum of promoting health and wellbeing and takes into consideration the challenges of climate change, digitalisation, new forms of work and ageing population.

Finland’s long-term investment in health promotion has yielded good results in reducing non-communicable diseases (NCDs). We recognise that worsening health and inequality influences people’s ability to work and their capability to be involved in society. In the long run, unaddressed problems also influence the economy.

Alcohol use and smoking are major risk factors for mortality and burden of disease. Finland has been active in implementing evidence-based alcohol and tobacco policy measures to diminish this burden. We have been reducing alcohol related harm by implementing the so called “best buy” policies as defined by the World Health Organization. In 2010, Finland was the first country in the world to set a goal of a tobacco free Finland by 2030 in its national legislation. This goal also applies to other nicotine products. Due to comprehensive and systematic implementation of evidence-based tobacco control policies we have been successful in reducing smoking. However, novel nicotine products require special attention, as we are noticing an increase in their use among adolescents. Tackling this needs attention at European Union (EU) level.

EU cooperation, such as Cancer Joint actions, the European Beating Cancer Plan and Mission on Cancer, has accelerated our national processes and put further emphasis on cross-border cooperation.

Cancer is a focus area in our national health sector growth strategy for research and innovation activities supported by the Government. The Finnish Cancer Center (FICAN) was established in autumn 2019, and is a national joint effort.

Our goal is to create a well-functioning ecosystem that is based on seamless collaboration between academia, regulatory authorities, healthcare providers and private enterprises and, in particular, patients and their families. We strongly believe that the Government’s role is essential in safeguarding the ecosystem’s stability and in ensuring that both patients and the population benefit from these efforts. National guidance aims to ensure equal treatment for cancer patients regardless of their place of residence, promotes research in the field, the quality of treatments and cost-effectiveness.

NCDs, including mental health problems, account for the overwhelming majority of the disease burden in the EU. Although the provision of healthcare is a national competence, exchanging good practices is beneficial at EU level. The Union also regulates many risk factors, such as nutrition, through legislation and funding. A way of better encompassing public health in these policies could be including health impact assessments in all decision making.

International collaboration, especially between the EU Member States, is essential. Innovation-positive and enabling policies will be required to enable a good operational environment and cross-border cooperation.
Thanks to ongoing innovation, many diseases that were incurable 30 years ago can now be treated medicinally. And many diseases that we cannot cure today will undoubtedly be curable within the next 30 years. Pharmaceutical innovation is key to improving patients’ lives, since it leads to medicines with fewer side effects, to breakthrough therapies and to improved methods of drug administration and other developments.

The pharmaceutical industry has developed numerous valuable treatments that have had a profound impact, not just on individuals but on society as a whole. To a large degree, these therapeutic benefits and equal access to innovative treatments have been possible thanks to the solidarity that is built into our healthcare systems. But today more than ever, this solidarity is threatened by strongly increasing healthcare costs, due in part to high drug prices.

The process of developing medicines is complex and expensive, but it offers a fair return on investment. Despite the considerable chance of failure, drug development is also a lucrative business in which double-digit profit margins are often the norm. To gain insight into the financial ecosystem for pharmaceutical research and development (R&D), I commissioned a comprehensive international study. One of the main conclusions was that potential financial gain is a bigger driver of R&D than societal or therapeutic needs. The study also showed a gap between which medicines are developed and which are most needed. In short, investments in new medicines do not always align with the most significant unmet medical needs.

It is up to us to direct efforts towards developing the treatments that are needed most. We need to move away from the current supply-driven innovation model to a needs-driven one in which research priorities are determined by society’s requirements. The objective is to establish a framework in which pharmaceutical R&D aligns with what society needs in terms of medical therapies, particularly those which offer little commercial reward or have been hindered by scientific limitations.

Ultimately, all new medicines are financed from the public purse: government funds basic research, offers market incentives where necessary and pays for people to receive these treatments. But can we agree on which medicines society needs most? For example, we seem to be more willing to pay for medicines that save or prolong lives than for ones that improve quality of life. But is this how our healthcare budget will best benefit society? I believe Europe needs to send a clear message to the pharmaceutical industry about what we are willing to pay, and what we are willing to pay for. This requires a more collective, comprehensive approach to determining our unmet needs.

Cooperation is essential if we are to change this paradigm. Member States operate within the reality of a global pharmaceutical market, and have limited individual influence and financial resources to effect change. But by joining forces, we will have more power to steer towards a more needs-driven model for medicine development. This will include bilateral and regional cooperation, such as through the Beneluxa Initiative, and cooperation at the European and global levels. Together, we can coordinate public funding for research and communicate what our societies need. Together, we can send a strong signal to the pharmaceutical industry to focus on innovations with long-term benefits for individual patients and for society as a whole.
Health systems all over the world experience a great deal of stress and pressure. The challenges during and the aftermath of the COVID-19 pandemic have revealed how fragile and vulnerable our healthcare systems are. Considering also the persistent challenges facing public health systems in Europe, such as demographic shifts, shortages in the health workforce, and the prevalence of non-communicable diseases (NCDs), it is crucial to acknowledge the pressing need for strategic investments and structural reforms. At the same time securing funding for the healthcare sector and the necessary reforms is a challenging task. One crucial aspect is the challenge to present healthcare expenditure as an investment into a healthier society and consequently a more prosperous and productive economy and not as a cost.

In the specific case of Austria, the latest negotiations between all relevant stakeholders provide an important example of the need to do a great deal of persuading for smart investments in health and its usefulness beyond the health sector. As a result of these cyclical negotiations, the allocation of financial resources within the healthcare system is determined on a five-year basis. Hence, these discussions are crucial to steer healthcare system reforms such as further strengthening the area of primary healthcare or shifting from in-patient to out-patient care.

Additionally, the aftermath of the COVID-19 pandemic is still present in the public perception of healthcare expenditure. While COVID-19 highlighted weaknesses of our healthcare systems, it also demonstrated the necessity for sustainable, long-term and strategic investments in health. It is clear: in order to become more resilient and to be better prepared for future crises, we need a well-functioning, solidarity-based healthcare system as well as a strong and healthy society. Therefore, making the case for investing in health as well as securing funding is crucial for successfully dealing with challenges and crises ahead of us.

In this regard, the European Union (EU) plays a vital role in supporting Member States in transforming health systems and addressing common challenges, having already established important frameworks and structures. Austria is currently utilising several mechanisms at the EU level to support healthcare reforms, such as the Recovery and Resilience Facility (RRF) and the Technical Support Instrument (TSI). Within its Recovery and Resilience Plan, Austria invests €100 million to roll-out primary healthcare units and further strengthen primary healthcare.

While the allocation of these funds is a great asset in strengthening the healthcare sector, investments in health still need to increase on EU level and health in all policies needs to be prioritised.

To effectively access and manage available funds, for the first time, several Member States have decided to plan and implement a joint TSI project together. The “Resources Hub for Sustainable Investing in Health” is a joint TSI project by Belgium, Slovenia and Austria with a strong support by the European Commission. The project goal is to strengthen the capacity for making the case for public investment in health at national and EU level as well as to facilitate the use of EU funding mechanisms for health systems. Furthermore, it provides an excellent opportunity for mutual learning and exchanging best practices.

The experiences and results of this project should inform the next steps taken by the EU in further supporting its Member States. Austria is convinced that establishing a “Health Investment Hub” at the European level is crucial to assist Member States in identifying and accessing appropriate funding mechanisms. Additionally, further support from the European Commission will allow for larger, structural reforms in health.

Only with a holistic approach we can overcome silos and think about health jointly with other relevant sectors. Let’s use this window of opportunity and get stronger and more resilient together by securing sustainable and solidarity-based healthcare systems all over Europe.

EUROPEAN HEALTH INVESTMENT HUB

Johannes Rauch – Minister for Social Affairs, Health, Care and Consumer Protection, Austria
WHAT COULD THE EU DO TO BUILD RESILIENT HEALTH SYSTEMS AND RESILIENT, HEALTHY SOCIETIES?

By: Scott L. Greer, Julia Zimmermann, Anna Sagan, Katherine Cooney and Josep Figueras

Summary: The COVID-19 pandemic tested the resilience of our health systems and society, laying bare any pre-existing vulnerabilities. As part of recovering and learning from the COVID-19 pandemic, several public authorities have carried out reviews to learn lessons from the crisis. This article provides a high-level summary of the main findings of the large, international reviews on resilience lessons from the COVID-19 pandemic, relevant to health policymaking in a European context. From this overview, opportunities for EU action are identified. The EU has a range of options to improve health system resilience that can build momentum, while achieving goals right now.

Keywords: COVID-19, Governance, Healthy Societies, Resilience

Introduction
The COVID-19 pandemic was a test for the resilience (see Box 1) of our health systems and societies as a whole, laying bare any pre-existing vulnerabilities in Europe and globally. As part of recovering and learning from the crisis, expert groups have been commissioned to review the evidence of what worked and what did not work to weather the crisis and formulate lessons for the future. This article is a summary of the main findings of a literature review of expert reviews from major institutions in the European region relevant to health policymaking in a European context.

Health systems are the resources, actors and institutions related to the financing, regulation, and provision of health

Box 1: What do we mean by resilience?
Resilience is about the ability of a system to respond to unexpected and compounding threats. It goes beyond traditional risk analysis, which identifies likely threats (e.g., pandemic, wildfire) and plans to manage them. Resilience analysis focuses on building healthy systems, organisations, and people who can respond, adapt and transform when faced with a shock. The many definitions of health systems resilience tend to converge on, broadly, health systems’ ability to manage, prepare for, respond to and learn from a sudden and extreme disturbance.
A summary of large international expert reviews on lessons from COVID-19 to improve health systems resilience

The reviews considered were commissioned or carried out by public authorities such as the World Health Organization (WHO), European Commission, European Observatory, OECD, World Bank, European parliament, among others and either had a global or European perspective. The academic literature on resilience is vast, but our focus was specifically on the reports of major institutions in the European region, to identify key areas of consensus and important items on the agenda.

A search of the grey literature was conducted to identify relevant documents. In addition to a google search, the websites of key international organisations were searched using the keywords “Resilience, Health System Resilience, Pandemic Resilience, Pandemic Preparedness, COVID-19 Resilience”. Experts at the European Observatory on Health Systems and Policies and the Belgian presidency examined the full list of reviews to identify whether any relevant documents had been missed. We have referenced points that were included in the executive summary of review documents and clustered the results, which fall into categories that mirror the Health Systems Performance Assessment (HSPA) framework (**Figure 1**). From this overview, we identified opportunities for European Union (EU) action to improve health system resilience. This is meant to give a concise, broad overview of areas of consensus and emphasis.

COVID-19 reviews agree that working across sectors was key

Many of the international expert reviews identified the importance of working effectively across government sectors, within governments and between governments. Intergovernmental coordination was crucial to aligning the...
efforts of different governments with different resources during the pandemic, and benefitted from both energetic political leadership at the centre and strong existing systems of intergovernmental coordination and communication. Frameworks for such intersectoral or whole of government working include Health in All Policies (HiAP) and Health for All Policies (H4AP) and Sustainable Development Goals (SDGs) approaches. Many reviews also emphasised the importance of equity and supporting vulnerable groups as well as building a strong society. Particular emphasis was placed on working with the transport, social, labour and economic sectors. Also, adopting a One Health approach that integrates environmental, animal, and human health was deemed important, as was working across sectors to combat climate change, antimicrobial resistance (AMR) and to improve food safety and quality.

The reviews also emphasised the importance of developing preparedness and health systems across national borders and beyond the EU. Approaches that were suggested include promoting public goods at a global level, strengthening Global Health, and WHO Expert reviews suggested to develop an International Pandemic Treaty or a set of international rules of another form to prepare for future international health threats, develop a global health threats council or form a global health board at G20 level to improve the global response to future health crises. A pandemic financing facility or other international financing mechanism was also suggested.

The EU can set the benchmark for working across sectors and borders

Leading and Governing means working across sectors. With regards to working across sectors, EU commitments to the SDGs and One Health, treaty commitments to promote health in multiple sectors (Art. 9 Treaty on the Functioning of the European Union (TFEU), Art. 122 TFEU, but also articles in Social Policy, Environment, and Consumer Protection and Art. 168), and collaborative instruments form a solid base for further action. The EU’s biggest health effects have often been grounded in those areas, as with regulation of polluting chemicals. These powers shade over into the ‘broader determinants’ agenda, which is currently particularly salient with regards to the Europe Beating Cancer plan, but which contains much that is relevant to addressing non-communicable diseases (NCDs) as a whole. Dossiers in areas such as workplace safety or chemicals regulation are understood as health policies in the EU. This shows both the extent of EU effects on health and the importance of understanding and aligning with these efforts to address health determinants. Relevant EU instruments could include internal processes such as impact analyses for proposals, funders, and lenders focused on Health for all policies (e.g. greening healthcare infrastructure), stronger and more rigorous incorporation of intersectoral action for the SDGs into the Semester, and legislation in areas associated with One Health such as expanding beyond food safety into consideration of the full range of impacts of agriculture on health.

Leading and governing also means working across borders. The EU’s new global health strategy, a Commission Communication, does two important things: First, it provides a base for incorporation of more policy areas that affect health. EU policies affect the world’s health and health policies in many areas beyond international development and health as defined in its treaties. Agricultural, trade, food and product standards, research, training and education, and intellectual property are all areas in which the EU is globally influential and shapes other countries’ policy options. For example, the EU is one of the most important players in international trade law, which in turn affects the ability of countries to enact and defend public health regulations, control a race to the bottom in social standards, or intervene to manage markets. Second, it can enable a more unified European voice in multilateral organisations such as the IMF, and negotiations such as a pandemic treaty. The collective influence of EU Member States in international forums is considerably greater than the influence of any of the Member States on their own, and coordination magnifies the importance of them all. The international forums that matter include the United Nations, both the General Assembly and agencies such as the WHO, UNICEF, UNED or the World Food Program, and the international financial institutions – the IMF and the World Bank. European influence on the standards and agendas of these agencies can shape the prospects for global health and the place of Europe in the world.

Effective leadership, evidence-based decision making and communication form the basis of a resilient health system

Leading and governing also means strengthening preparedness, health systems resilience and response. Almost every analysis highlighted the role of effective political leadership, with important underpinnings including adequate legislative frameworks, preparedness planning, and coordinating mechanisms. Countries that fared well during the COVID-19 pandemic tended to have effective political leadership supported by a clear and timely response strategy, a preparedness plan and appropriate legislation. Engagement with scientific advice and civil society was important to anticipate problems and reach different parts of society. To support effective political decision making, the reviews suggest strengthening the evidence base and transferring insights from evidence to policy. It was also suggested to define the process for reviewing preparedness plans to ensure they are being kept up-to-date.

Consistent, coherent, and clearly evidence-based communication from governments was crucial in the pandemic and an area in which different governments varied enormously. Many reviews identified the importance of targeted, informed, and coherent communication with and accountability to the public, as well as a system to monitor disinformation. Decision making should involve the population, non-government stakeholders and civil society, as well as market participants. The reviews also
emphasise the importance of effective coordination between different levels of government; vertical coordination between central and local government and horizontal coordination within the health sector and across sectors or HiAP as highlighted above.

**Universal Health Coverage and access to services is key**

Achieving Universal Health Coverage (UHC) and reducing barriers to service access, especially for vulnerable people are important lessons to improve health system resilience.

The reviews found that funding of health policies should be evidence-based, flexible, sufficient stable and with a crisis buffer. Many reviews emphasised that stable and sufficient funding is important for all parts of the health system. Some reviews highlighted particular health system functions that require sufficient and stable funds, such as prevention and preparedness, preventative care, public health and primary care, the health workforce, digitalisation, innovation, and long-term care.

In the context of the COVID-19 pandemic, experts found that it was important to adapt purchasing, procurement, and payment systems to meet changing needs. This often requires balancing economic incentives and ensuring that funds are transparent and flexible.

Good public financial management goes hand-in-hand with good financing decision making. Expert reviews highlighted the importance of appropriate risk management that considers a One Health approach. Other suggestions include to flag budget lines that represent investment and innovation in health system accounts.

COVID-19 exposed gaps in every healthcare system and showed their importance, with “hot-spots” of infection among vulnerable populations, among for example meat-packing workers, that caused them great harm and perpetuated the crisis. A solution is to strengthen welfare states and universal healthcare access so that healthcare systems are able to respond in crises and people are not incentivised to avoid healthcare systems or work in unsafe conditions due to financial or other access barriers.

Ensuring access needs to be paired with mechanisms to handle the disruptions of the shock, including the enormous surges of patients in some areas, absent healthcare workers due to illness or burnout, the financial disruption of stopping so much planned care right as unplanned care needs exploded, and the backlog of non-COVID-19 healthcare that is still a problem. Solutions found in the review focus on ensuring UHC before the crisis, through evidence-based coverage expansion and removal of barriers to access, and creation of mechanisms that will provide flexible, sufficient, and stable funds to healthcare systems as they absorb the challenge and try to recover. Ensuring adequate purchasing, procurement, and financial controls is important and often not done or sufficiently monitored in a crisis, and many governments circumvented their normal purchasing models to better or worse effect. Learning about effective models for crisis purchasing should be a priority to avoid the problems seen.

**The EU can promote financially sustainable universal healthcare**

The EU’s relatively small budget and entrenched principle of subsidiarity means that it cannot directly ensure UHC, but it can provide data and benchmarking exercises that show gaps in UHC that Member States can remedy outside crisis times. This could be done through existing mechanisms such as the European Semester. It can also strengthen its investment in public financial management, including anti-corruption and good government measures, in order to help maintain its own financial integrity and that of its Member States. The desire to move on from the pandemic should not mean that the vulnerabilities exposed by the pandemic are allowed to remain.

More ambitiously, the EU does have tools that could help move Member States closer to sustainable UHC (see article by Martini et al.). Cohesion funds and lending from EU institutions could take financial protection and UHC as serious goals. The EU could even go so far as to legislate a closer to sustainable UHC (see article by Martini et al.). Cohesion funds and lending from EU institutions could take financial protection and UHC as serious goals. The EU could even go so far as to legislate a
to support patients with problems that individual Member States cannot efficiently address.

EU funding instruments have facilitated much needed reforms and investments in health and health systems. However, these funding instruments are currently fragmented and often challenging for policymakers to access and navigate. Going forward, regulations and rules governing existing instruments may need to be revisited and objectives, specificities, and timelines aligned with Member States priorities. The creation of a “One Stop Shop” “EU Health Resources Hub” could help provide tailored technical support to MS and improve access to EU instruments (see article by Mauer et al.).

Resilient health systems have sufficient health workers that are well trained and supported

Workforce challenges were already severe across most of the continent, and COVID-19 precipitated a wave of burnout, retirements, and sick leave that undermined the resilience of healthcare systems while also interfering with training and education. Most of the reviews have very similar messages when it comes to the health workforce. They emphasise the importance of scaling up capacity, which requires attracting health workers to the profession and ensuring an equitable distribution among health and care workers. Reviews also recommend reskilling and repurposing existing health workers, for example by using an inter-professional approach to training. Existing health workers also need to be well supported, protected, and retained. Some reviews suggest to develop a dedicated, trained and scalable medical reserve or health emergency corps.

The EU can help build and support the European health workforce

Building and supporting the health workforce is a clear imperative. The EU can help build and support the health workforce in several ways. Among promising policy options are ones focused on better use of better data. This includes workforce data including cross-border flows that can enable EU-wide workforce forecasting and planning. It could create EU-wide professional registers, lowering the cost of mobility, and enable freer flows, and upskilling with EU-wide skill-mix standards. This would allow for greater worker mobility among Member States, although this is not an appropriate strategy to address national health worker shortages. Discussion around a revision of the professional qualifications directive could be useful, and could be paired with an EU-wide workforce strategy that could help to anchor Member State workforce strategies (see article by Wismar and Goffin).

Strengthen capacity of frontline services and transforming health service delivery

Many expert reviews suggested actions to support or transform frontline health services. However, there was some heterogeneity in which service to choose to support. There was a broad consensus on the need to strengthen delivery of essential healthcare services, especially public health and primary healthcare services. Other services to support include areas where the pandemic led to backlogs and loss of focus such as mental healthcare services, and emergency services. Reviews also suggested thematic priorities such as for post-acute infection syndrome, cancer, cardiovascular disease, chronic diseases, dental care for vulnerable groups and rare diseases.

While supporting frontline services is important, it is equally important to encourage innovation and implementing new models of care. These could include alternative or flexible care pathways, new mechanisms of health service delivery or other innovative solutions. A key innovative development is integrated digital health for healthcare, which holds the potential to bring about major improvements in the efficiency of health systems, both in terms of care provision and the administration of the system as a whole. Integrated digital health is an important development and should come hand-in-hand with standardised metrics for evaluation and minimum standards.

New models of care delivery such as flexible care pathways and use of e-health technologies are areas in which pandemic innovations could be retained and expanded. Finally, retaining surge capacity, the skills to mobilise, and flexible patient load-balancing arrangements can help improve patient pathways during crisis and normal times.

The COVID-19 pandemic also highlighted the importance of access to pharmaceuticals, consumables and technologies. Lessons learned include the importance of using a cross sector approach and ensuring scalable manufacturing capacity informed by national and European needs (In other words, the ability to rapidly expand production to respond to needs in Europe). Reviews featured the importance of considering and reinforcing the entire health supply chain, including for stockpiling. For example, this could be achieved by advanced purchase agreements and a transparent purchasing policy or by developing a pre-negotiated platform for tools and supplies, similar to the Access to COVID-19 Tools (ACT) Accelerator.

Access to pharmaceuticals, consumables and technologies was also deemed important at a global level. Reviews recommended to ensure flexibility, competition and specialisation in global value chains as well as universal access to medication, for example through technology transfer and voluntary licensing.
The EU can transform and strengthen health service delivery

The EU’s contribution in this area would be primarily knowledge development and dissemination as well as regulatory frameworks for digital health. In terms of knowledge development and dissemination, it could invest more in its existing priority areas such as cancer and neglected areas, supporting research and dissemination underpinned by comparative data. EU basic research could shape science and practice around the world.

In terms of regulatory frameworks, digital health initiatives should focus on areas that clearly support healthcare delivery, for example interoperability standards, stronger regulation of medical devices with more effective implementation, and a shared system for evaluation and approval of innovative technologies. It is easy to view these areas through the lens of innovation and industrial policy, but there are major opportunities to use policy in these areas to support healthcare delivery.

Health Technology Assessment (HTA) and Needs Assessment contribute to resilience by enabling policymakers to target resources and make the best use of funds (see article by Cleemput et al.). The EU is developing its capacity in HTA as it implements the 2021 Regulation on Health Technology Assessment, with joint HTAs scheduled to start in 2025. Shared needs assessment or technology assessment standards would be suitable for all contexts, but shared investment in technical resources and development of guidelines and good practice could enable this important element of preparedness and resilience. The basic European network model that works through creating and strengthening networks of Member State agencies can expand capacity and knowledge of good practice while improving policy and resilience.

Finally, one of the breakthroughs of the COVID-19 pandemic was the successful implementation of joint purchasing of vaccines. Many EU Member States have difficulties procuring adequate supplies of medicines in a timely way, and orphan drugs can see shortages or major price discrepancies. The recent European Commission communication on addressing medicine shortages outlines strategies, including joint procurement, that could be expanded and used outside emergencies to address these problems.  

Expert reviews suggested assessing preparedness and health system resilience, ensuring the long-term care sector is considered and included in these exercises. Further, governments could practice a crisis response by running yearly multisectoral simulation exercises or develop a collaborative approach to stress testing and mechanisms to ensure weaknesses are addressed. Some reviews also highlighted the importance of investing in learnings from past pandemics.

The EU can strengthen public health preparedness

The EU’s role in this area is already expanding due to the newly adopted Cross-Border Health Threats Regulation, the broadened mandate of ECDC and EMA and the creation of HERA (see article by Renda et al.). The post-pandemic EU preparedness and response system now needs to be implemented and also requires further development, as mandates of agencies and governance platforms are overlapping. For instance, the Civil Protection mechanism that is at the centre of the Commission’s own disaster resilience architecture and which mobilises considerable resources is sometimes omitted from discussions in the health sector. Aligning HERA, EMA, and ECDC offers quick wins in terms of preparedness and builds on their new powers, while understanding the relationship between the civil protection system and the public health systems at the EU and Member State level could prevent duplication and waste of the considerable resources being put into both. It would also make it clear where additional resources or legislative attention should go, by identifying problems in technical areas that otherwise only emerge in a crisis.

Next, the pharmaceutical legislation shows the ways in which the EU can use its competencies to leverage equitable access to medicines and enhance transparency of supply chains. Visibility into supply chains is essential to identify potential vulnerabilities in medicines production and to allow early detection of production bottlenecks. Furthermore, the recent Commission communication on addressing medicine shortages in the
EU announced the creation of an EU list of critical medicinal products for which a vulnerability assessment will be carried out. The communication also envisages the creation of a Critical Medicines Alliance, in anticipation of a Critical Medicines Act, to address these vulnerabilities and ensure a minimum EU production capacity for the most important medicines. Finally, EU trade and intellectual property policy is globally influential due to the size of its markets, industry, and institutional power in these arenas. There might be scope for rethinking the balance between industrial and health policy in this area given the impact of the old policy framework in terms of shortages, global access problems, and global vaccination policies.

The EU was long thought to have little to contribute to health and health policy, despite the obvious and enormous health impact of its environmental, agriculture, food, and market regulation policies. That era is behind us; the scale of the EU’s impact on health is clear and the question is how to best use it not just for good health but also for building resilient, healthy societies.

Using the EU’s powers will require matching policy tools with the scale of our ambition and political possibility. Options discussed by authors elsewhere in this issue of Eurohealth range from shifting priorities or guidelines within a single agency – politically relatively simple – to taking advantage of any reopening of the treaties. That means advocates of resilient health systems and resilient, healthy societies have many options that can build momentum and develop coalitions while achieving things right now. This special issue shows some of the ways forward.

Conclusion: The EU can contribute to resilience

Resilience is a necessary goal for health policy and health systems, not because of COVID-19 but because of what COVID-19 taught us: we cannot predict the future and we therefore should focus on building the health systems and societies that will be as resilient as possible in the face of the unexpected. As threats appear to multiply, from war to climate change to new infectious diseases, it becomes increasingly important to focus not on predicting individual risks and advocating for individual programmes to address them but rather on prioritising the policies that will make resilient health systems capable of confronting the unexpected. It also becomes increasingly important to prioritise the essential over the nice-to-have.

References


TACKLING THE HEALTH WORKFORCE CRISIS: TOWARDS A EUROPEAN HEALTH WORKFORCE STRATEGY

By: Matthias Wismar and Tom Goffin

Summary: Many countries in the European Union (EU) are experiencing a health workforce crisis, which is straining the performance and resilience of health systems. To support and complement the efforts of Member States to address the crisis, the EU should develop a comprehensive health workforce strategy. This strategy should include EU support for health workforce development, the alignment of the EU labour market with health system goals, and advance the review of the professional qualifications directive.

Keywords: Health Workforce, Human Resources for Health, EU-Labour Market, EU Support, Professional Qualifications Directive

A crisis with many faces and different roots

There is a health workforce (HWF) crisis in Europe with many countries reporting a shortage of healthcare workers (HCWs). These shortages are a result of: 1) COVID-19, which led to many HCWs leaving the sector; 2) Supply and demand discrepancies of which a topical example is the medical deserts appearing across the region and beyond;* 3) a lack of planning and forecasting resulting in skill-gaps. These gaps in training are noticeable across the region, for example in digital skills which are indispensable for care integration; 4) labour market and legal framework disputes where some countries have recently witnessed frictions surrounding the pay and working conditions of their HWF. While these are all general issues contributing to the HWF crisis in many countries, the extent of the crisis varies considerably between countries. There are vast differences in staffing levels between countries, while some countries make better use of HCWs thanks to primary care and integrated care models.

One of the root causes of the HWF crisis in the EU is demography. An ageing society requires more services and, therefore, more health workers. But the HWF is ageing too, and the replenishment of retirees is not a given. The cohorts of young people graduating from school and moving into training are getting smaller. In many countries, the training pipeline as it is currently will not suffice but it is not demography alone. Countries are now addressing omissions of the past: a lack of strategy development, inadequate forecasting and planning, insufficient investment in training and education, inadequate allocation of resources for needed positions, ineffective lifelong learning mechanisms, and a mismatch

* Medical deserts can be found in almost all countries, mostly in remote and rural areas, where some services cannot be provided on time or with the expected quality, because of the lack of HCWs.
between newly trained health professionals and the skills required for health system reforms and new care models.

While COVID-19 has aggravated the HWF crisis, it has also helped move the topic up on the political agenda. The WHO Regional Office for Europe launched an influential report at its Regional Committee in 2022 and followed up with a high-level conference in 2023 resulting in the Bucharest Declaration. At the global level, the WHO has focused its attention on the remedies for the HWF crisis with the 5th Global Forum on Human Resources for Health.

**An EU health workforce strategy**

A comprehensive EU health workforce strategy will need to address the twin-challenges EU Member States are confronted with. First and foremost, it must lend support to Member States currently struggling with the HWF crisis previously described. Simultaneously, the HWF strategy needs to support Member States in their efforts to transform their health systems by introducing new models of care. These innovative models of care may include care integration, digitalisation, teamwork, community involvement, healthcare delivery approaches like hospital-at-home services, to name a few. These models are designed to respond to the evolving demographic, social and environmental realities in Europe while making the best use of medical and technological innovations.

Often, it is argued that the public health mandate stipulated in article 168 of the Treaty on the Function of the European Union (TFEU) doesn’t provide much scope for EU action on the HWF let alone the development of a HWF strategy. Indeed, the public health mandate is limited and explicit with regards to the Member States’ responsibility for the organisation and delivery of health services and medical care. These limitations, however, do not preclude the EU from taking decisive action as demonstrated by the EU’s COVID-19 health system responses. Moreover, the public health article 168 is not the only source of EU-health policy. Legal instruments, budgets and strategies outside the scope of article 168 are shaping EU health policies and with it the HWF. The challenge will be the alignment of the legal and budgetary instruments impacting the HWF with health system goals.

The following sections present three elements that could make up such a European HWF strategy. This includes EU-support for health workforce development, an EU labour market for health workers that is aligned with health system goals, and finally a thorough review of the existing EU legal framework regulating health professions.

**EU support for health workforce development**

Four key areas of action can address the current HWF crisis, while also supporting the adoption of new models of care:

*Recruiting* focuses on improving the alignment between labour demands in the health system and the supply of health workers. It involves utilising foresight, forecasting, and planning to anticipate future workforce needs, investing in education and training programs, and establishing intersectoral governance to coordinate education, finance, and health initiatives effectively.

*Retaining* aims to ensure that health workers remain in the health sector, preferably within each healthcare facility. While fair salaries play a crucial role, working conditions extend beyond remuneration. This strategy encompasses measures such as providing physical protection against infectious diseases and violence and harassment, which is a prevalent and growing issue in healthcare facilities. Additionally, retention strategies include social interventions like sick-pay, as well as the provision of nurseries and kindergartens in hospitals to create family-friendly working conditions and improve work-life balance. Protecting mental health is also vital, as health workers are often affected by conditions like burnout.

*Reactivating* encompasses programs designed to facilitate the return of health workers who have taken time off, such as during their children’s early years. It also aims to reactivate and re-skill health workers who have transitioned to other sectors and professions. Furthermore, it addresses health workers from third countries whose qualifications are not fully recognised by the competent authorities, offering opportunities for their reactivation within the health sector. Reactivation is an often-neglected strategy, but is an intervention worth exploring given the magnitude of health workers active in other sectors. In Germany alone it is estimated that at least 300,000 full-time equivalents of trained health workers are working in other sectors.

*(Re-)skilling* involves adapting vocational and academic curricula, creating new roles and professions, and improving lifelong learning systems to enhance
the skills of health workers. Re-skilling initiatives can support the implementation of new care models and bridge skill gaps, including digital skills, and green skills. Very important for primary care and care integration, also with links to social care, are teamwork skills including the communication and coordination competencies.

In order to help Member States implement these tools, the EU has a large array of support tools at its disposal. These tools encompass policy development, piloting and implementation that can be used for health and health systems and the development of the HCWF (for an overview see the article by Mauer et al. in this issue).

Research and action-oriented research play a crucial role in supporting HWF developments in Member States. Initiatives led by DG Research, Erasmus+, and the European Commission’s Public Health Programme, EU4Health, are instrumental in driving these advancements. There are also important Joint Actions in the remit of DG SANTE. These projects offer valuable insights and practical implementations that contribute to the improvement of HWF planning, addressing issues such as medical deserts, skill-mix optimisation, bridging the digital and green skill-gaps, ensuring mental health protection for health workers, and implementing retention-oriented workplace interventions. These topics are of utmost importance to Member States as they strive to strengthen their health systems and ensure the availability of a skilled and sustainable HWF.

There are several important EU tools available for investing in health systems and the health workforce. One of these tools are the European Structural and Investment Funds (ESIF). They have been open since 2010 to fund health-related investments. Originally focused on large-scale investments, they now have become more accessible for targeted and focused investments. A study, focusing in particular on the European Social Fund and the European Regional Development Fund, which are part of the ESIF has reviewed the health investments during the 2014–2020 period. It identified over 7,000 projects, amounting to more than €8 billion, with an average of approximately €1.2 million per project. ESIF also emphasises lifelong learning, including initiatives aimed at improving and adapting skill-mix, human resource management, continuous professional development, reorientation of specialists to general practitioners, expanding education and training opportunities, and increasing the involvement of non-doctor health staff. Additionally, ESIF aims to enhance the attractiveness of healthcare professions, attract young people to the field, and improve working conditions to facilitate effective retention of health workers.

Another significant player in investing in the HWF is the European Investment Bank (EIB), one of the world’s biggest lenders. The Bank’s investment program includes a focus on education and training, which directly contributes to the development and enhancement of the HWF.

Furthermore, the Recovery and Resilience Facility (RRF), a temporary instrument introduced as part of the European Semester in response to the COVID-19 pandemic, offers opportunities for investing in the HWF as well. For example, Spain has utilised the RRF to invest in professional skills and reduce temporary employment of nurses and doctors to address shortages in the healthcare workforce. Estonia is also leveraging the funds to address health workforce shortages. Malta is utilising the RRF to develop and implement its health policy framework, including the strengthening of the health workforce. Romania is directing the funds towards enhancing the health workforce in community health centres, while Austria is investing in community nurses through these funds.

There are more EU tools available. But already this selection demonstrates funding opportunities within the EU provide Member States with avenues to invest in and strengthen their HWF, address shortages, improve skills, and enhance the overall effectiveness and quality of healthcare provision.

Not all tools and budgets are equally easily accessible for health systems and HWF development. Sometimes in countries focal points for specific funds are not in the health administration. A HWF strategy could help to improve the visibility of this issue and underscore the urgency.

An EU-labour market for health workers that aligns with health system goals

Health workers can choose to seek employment in any other Member State of the EU. Medical doctors, nurses, midwives, pharmacists and dentists are recognised as regulated professions and enjoy an automatic procedure stipulated in the directive on the recognition of professional qualifications (Directive 2005/36/EC). This makes cross-border mobility much easier. While the free mobility of workers is a great achievement, criticism with regards to the effects on patients, professionals and health systems have always been present. Indeed, the directive is rather indifferent to health system goals and the role of the HWF contributing to them.

In this regard, the EU-labour market for HCWs appears incomplete. While the free mobility within the EU-labour market is thriving, the minimal control mechanisms (robust monitoring of HCW movement or training pipelines) to make such a labour market sustainable are missing. Therefore, the following additions are necessary:

EU-wide electronic health professional register, including health professional cards and employment data that would allow to monitor the EU-labour market. This would remedy the problem that currently the EU-labour market is like a black-box.
We neither have timely nor accurate data on the numbers, full-time equivalents, training pipelines, leavers and cross-border HCWs.

An EU-planning and forecasting mechanism that complements forecasting and planning in Member States. This mechanism could identify/flag up early any under-production of health workers or certain specialties, e.g., primary care doctors. It would help to address imbalances and underinvestment before shortages appear.

Monitoring health workers from third countries should also be considered. EU Member States agreed to the World Health Organization (WHO) Global Code of Practice for the International Recruitment of Health Personnel. This code specifies that health workers should not be recruited from countries that suffer from severe HWF shortages. According to research most EU Member States adhere to the WHO Global Code. The monitoring of third country health professional recruitments is also necessary because of the EU Global Health Strategy. In its guiding principles it states that it should address imbalances and foster skills. It aims a strengthening international collaboration and foster mutually beneficial mobility arrangements. Currently, the data collected by Eurostat the WHO Regional Office for Europe and OECD are incomplete and come with a considerable time lag.

A thorough review of the EU legal frameworks regulating the professions

An EU HWF strategy should also advance the review of the professional qualification directive. It may steer research and the political debate on unresolved, albeit important issues. And there are plenty of issues which would need to be addressed.

Sufficient policy space is among the major concerns of policy-makers with the directive. Using the professional titles of the directive may render HWF development to some extend dependent on those definitions. Diverging HWF development may become difficult. National legislation and policy-making always interacts with EU policy and law. The question is, however, how these interactions, and sometimes conflicts can be resolved. A health workforce strategy would provide the framework to look at these issues from a health systems and health workforce point of view, acknowledging that policy-makers in countries require room for manoeuvre to develop the health workforce of the future.

Skills-standards and training curricular that make the skills of health workers, especially in cross-border healthcare better comparable are an issue for review and debate too. Today, for the regulated professions, skill-equivalents are assumed, though mostly the length of the training is basis for the recognition of professional qualifications. Bearing in mind the quickly evolving professions and their qualifications, training length may not be sufficient to ensure comparability of qualifications across Member States.

EU-wide training schemes for continuous professional development which ensures that skill-gaps can be addressed and closed in a timely manner are also a subject for review. Life-long learning is a need for most professions as technologies and organisations are changing rapidly. There are, however, no shared criteria among Member States what should be subject of the continuous professional development. In the worst case that could mean that while basic qualifications are comparable, over time the additional qualifications obtained differ widely.

Voluntary cross-border collaboration in the health workforce, with a view to specialist training should receive both attention and support. Small countries, which cannot provide all specialist training in depth could benefit from such arrangements. The Maltese Presidency in 2016 proposed these developments.

A legal framework for health workers. Given the specificity of healthcare, the role of health professionals in protecting human life and health and the key importance of health workforce policies to ensure accessibility of healthcare of high quality, a horizontal directive, dealing with a broad range of regulated professions, from accountants to medical specialists, may not be the most appropriate instrument to regulate health professionals. Furthermore, the shift needed to a more competency driven system for health professionals, may not fit with the architecture of the Directive on professional qualifications. Given these unresolved yet pressing issues, creating an EU legal framework specifically on and for health professions could prove to be of great value. This framework could have a double legal basis in the TFEU (public health and internal market) and could provide the necessary basis to regulate health professions in a flexible way.

A dedicated sectoral directive for health workers could also open up opportunities for including more health professions. While in principle all health workers are covered by the directive on the recognition of professional qualifications only the so called five regulated professions, medical doctors, nurses, midwives, dentists and pharmacists, fall under the automatic procedure. The question to discuss is whether there are additional professions that may fall under the automatic procedure.

Conclusions

An EU HWF strategy covering the proposals discussed in this article has the potential to draw attention to the pressing need for addressing the HWF crisis while also aligning it with the ongoing transformations within healthcare systems. Such a strategy could offer guidance on utilising and enhancing access to existing healthcare support tools. Moreover, it could play a crucial role in establishing a more harmonious EU labour market for health professionals by more effectively aligning to the objectives of health systems. Lastly, the EU strategy could aid in the adaptation of existing legal frameworks and budgets to meet the evolving HWF requirements of future healthcare systems.

While seemingly challenging, the creation of an EU HWF strategy is not entirely unrealistic. There is a trend aligning existing legislation to health system goals. The Patients’ Rights Directive (2011/24/EU) has clearly demonstrated that the

† As is the case with the Directive 2011/24/EU on patients’ rights in cross-border healthcare.
Box 1: Summary of proposed actions for EU-support for health workforce development

- EU-wide electronic health professional register, including health professional cards and employment data that would allow to monitor the EU-labour market.
- An EU-planning and forecasting mechanism that complements forecasting and planning in Member States.
- Monitoring health workers from third countries.
- EU-wide training schemes for continuous professional development.
- Voluntary cross-border collaboration in the health workforce, with a focus on specialist training.
- Creating an EU legal framework specifically on and for health professions.

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free movement of services can be leveraged to benefit both patients and healthcare systems. The pharmaceutical strategy, adopted in April 2023, has provided a clear path for shifting legislation from its original industrial policy focus towards aligning it with the goals of healthcare systems. An additional, significant step in this direction would be the improved alignment of the EU legal frameworks regulating the professions. Belgium’s Presidency 2010 and the Council conclusions resulting from it paved the way for the Health Workforce Action plan, which has proven to be an important step forward. The next step would be the push for an EU HWF strategy.
ENSURING AFFORDABLE ACCESS TO HEALTHCARE FOR EVERYONE IN THE EUROPEAN UNION: WHAT GAPS REMAIN AND HOW CAN THE EU SUPPORT MEMBER STATES TO OVERCOME THEM?

By: Jessica Martini, Giorgia Fleischmann, Sebastiano Sabato, Jonathan Cylus, Sarah Thomson, Nicolas Bouckaert and Carine Van de Voorde

Summary: European Union (EU) Member States have made multiple commitments to progress towards universal health coverage (UHC), so that everyone can access quality healthcare without experiencing financial hardship. Yet, significant gaps in all three dimensions of health coverage (population coverage, user charges, and benefits packages) remain. This article highlights some of these gaps, looks at how access to healthcare has been addressed through the EU’s socio-economic governance and funding instruments, and suggests ways in which the EU can further support national progress towards UHC.

Keywords: Healthcare Access, Coverage Policy, European Pillar of Social Rights, European Semester, Universal Health Coverage

Introduction

The COVID-19 pandemic highlighted the importance of affordable access to quality healthcare in ensuring economic and social resilience. Before the pandemic, European Union (EU) Member States had already agreed that everyone should have access to quality healthcare without experiencing financial hardship and committed to move towards “universal health coverage” (UHC) through the Council conclusions on common values and principles in EU health systems (2006), the Tallinn Charter on Health Systems for Health and Wealth (2008), the Sustainable Development Goals (SDGs, 2015) and the European Pillar of Social Rights (2017). Yet, many Member States still have significant gaps in health coverage, indicating a need for greater effort to make progress towards UHC.

This article explores what the EU can do to help Member States improve affordable access to healthcare. Part 1 focuses on some of the main gaps in coverage in EU countries. Part 2 looks at how access to
healthcare has been addressed through the EU’s socio-economic governance and funding instruments. The conclusion suggests proposals for more effective EU engagement with Member States.

**What are the main gaps in affordable access to healthcare in the EU?**

Many EU health systems still rely heavily on out-of-pocket payments. These undermine affordable access to healthcare (financial protection) in two ways. First, they can create a financial barrier to access, often leading to unmet need for healthcare. Second, they can cause financial hardship for people using healthcare, leading to impoverishing or catastrophic health spending (see Box 1). Analysis shows that households on low incomes consistently experience higher levels of unmet need and catastrophic health spending than richer households. This deepens poverty, erodes health and well-being, and increases social inequalities within and across EU countries.

**UHC should be monitored using quantitative and qualitative analysis**

Indicators of affordable access to healthcare – unmet need and catastrophic health spending – show that there are important gaps in health coverage in many EU countries. These indicators are helpful in identifying the types of healthcare that undermine financial protection and the types of people most in need of better protection. However, to understand what countries can do to improve affordable access to healthcare, it is also useful to consider qualitative information on coverage policy (the way in which health coverage is designed and implemented), a key determinant of the level and distribution of out-of-pocket payments (see Figure 1).

We focus on two dimensions of coverage policy: the basis for entitlement to publicly financed healthcare, which determines population coverage, and the design of user charges for covered healthcare.

Many EU health systems also have gaps in the publicly financed benefits package, especially for dental care and experience problems with the availability and quality of services. These factors contribute to timely and affordable access to healthcare, but we do not consider them further in this article.

**Gaps in population coverage occur when entitlement is linked to narrow criteria**

To achieve UHC goals, the basis for entitlement to publicly financed healthcare should encompass everyone living in a country. In practice, it almost always relies on narrower criteria such as payment of contributions to a social health insurance (SHI) scheme, or legal residence, which leaves some groups of people lacking access to some or all publicly financed healthcare.

The share of the population not covered by the SHI scheme or other forms of mandatory health insurance is relatively small in countries like Austria and Germany (under 0.1%), but much more significant in other countries, ranging from over 1% in Belgium to over 5% in Estonia, Hungary, Lithuania and Poland, and over 10% in Bulgaria and Romania. Those most likely to lack SHI coverage are people working in the informal economy or in other forms of precarious employment, as well as unemployed or self-employed people; many of these groups cannot afford to pay SHI contributions or find it difficult to pay due to administrative complexity.

To reduce population coverage gaps, the French government changed the basis for entitlement from employment and payment of contributions to residence in 2000 and gave all adults an automatic and permanent right to healthcare in 2016. France maintains an SHI scheme financed through earmarked contributions (and taxes), but all legal residents are now covered.

Concerning the criterion of legal residence, most EU countries exclude undocumented migrants from access to publicly financed non-urgent healthcare, including many countries which report to cover the whole population. Spain is one of the only EU countries that offers undocumented migrants access to the same health benefits as legal residents after they have been in the country for 90 days.

**Box 1: Out-of-pocket payments contribute to unmet need and catastrophic health spending in the EU**

Out-of-pocket payments are formal and informal payments made at the time of using any type of healthcare delivered by any healthcare provider. They include user charges for covered care and payments for non-covered care. In 2019, the out-of-pocket payment share of current spending on health ranged from 9% in France to over 25% in Bulgaria, Cyprus, Greece, Hungary, Latvia, Lithuania, Malta and Portugal. These payments can lead to unmet need for healthcare, meaning that people forego or delay healthcare due to cost, distance or waiting time. The incidence of self-reported unmet need for healthcare in 2019 ranged from 0% of the population in Malta to 15.5% in Estonia. These data come from household surveys; people are asked if there was a time in the last 12 months when they needed healthcare but did not receive it because of the cost of care, the distance involved or the presence of waiting lists.

Out-of-pocket payments can also cause impoverishing or catastrophic health spending. The latter refers to out-of-pocket payments that are greater than 40% of a household’s capacity to pay for healthcare, with capacity to pay defined as total household consumption minus a standard amount to cover basic needs (food, housing, and utilities). This indicator is calculated using data from household budget surveys. The incidence of catastrophic health spending in 2019 ranged from under 2% of households in Ireland, Spain, Slovenia and Sweden, to over 8% in Bulgaria, Greece, Hungary, Italy, Latvia, Lithuania, Poland, Portugal and Romania.
Countries with stronger financial protection tend to limit user charges

Gaps are also caused by weaknesses in the design of user charges for covered healthcare

All EU countries apply user charges to some types of healthcare, even though a large body of evidence shows that user charges are not a good instrument for directing people to use resources more efficiently and can have negative effects on equity and efficiency. User charges are most often applied to outpatient prescribed medicines, dental care, and medical products; evidence shows that these types of care are among the main drivers of catastrophic health spending.

Countries with stronger financial protection tend to limit user charges and have protection mechanisms designed to reduce their negative effects – for example, exemptions from user charges for people on low incomes and income-based monthly or annual caps on user charges. Spain’s low incidence of catastrophic health spending can be attributed to very limited use of user charges – they are only applied to outpatient prescribed medicines and medical products – and to the fact that people on low incomes and some other groups (around 16% of the population in total) are exempt from user charges for outpatient medicines. Austria has an income-based cap on user charges for outpatient prescribed medicines, while Belgium has an income-based cap on almost all user charges for covered healthcare – an approach that reduces financial uncertainty for people.

While all EU countries exempt some groups of people from certain user charges, demonstrating widespread acknowledgement of the shortcomings of such charges, only a third exempt people on low incomes, and very few have income-based caps or caps on all user charges. This suggests that there is significant scope for improving affordable access to healthcare through better design of user charges. Prioritising the reduction of out-of-pocket payments for low-income people – an approach known as progressive universalism – is essential, particularly where public resources are under pressure. This also builds resilience: if coverage policy enhances protection for the most vulnerable to unmet need and financial hardship, health systems and households can better withstand economic and health shocks.

How has the European Union addressed affordable access to healthcare?

The organisation and financing of national health systems, including coverage policy, come under the competence of Member States. Consequently, the EU’s most visible role in affordable access to healthcare is through data collection and analysis. For example, the EU supports a common approach to national data collection on unmet need for healthcare, through two household surveys: EU Statistics on Income and Living Conditions (EU-SILC), collected annually, and the European Health Interview Survey (EHIS), carried out every six years. The EU also: assesses access to healthcare in its series of “State of Health in the EU” reports on each Member State, published every two years; supports national health system performance assessment (HSPA) through the HSPA Expert Group; and, via the EU4Health programme, provides grants to enable systematic monitoring of affordable access to healthcare in EU Member States and to analyse the redistributive impact of health coverage.

In addition, the EU has played an influential but less visible role in shaping national healthcare reforms, and thus coverage policy, through its socio-economic governance – notably the European Semester – and funding instruments.
UHC is monitored through the European Semester

Launched in 2011 to enhance the monitoring and coordination of economic and fiscal policies, the European Semester provides guidance to Member States at different stages of the policy process (see Figure 2). It assesses the situation and outlines the EU’s economic and social priorities; evaluates national programmes and provides Country-Specific Recommendations (CSRs) for national reforms and budgets; and monitors their implementation. Healthcare has always been part of the Semester but, in the aftermath of the European sovereign debt crisis, the focus shifted heavily toward fiscal sustainability, with insufficient consideration for potential adverse effects on healthcare access and other social protection measures. This imbalance contributed to increased inequalities and reduced access to healthcare for people in vulnerable situations.

Access to healthcare gained traction in the second half of the 2010s, following the European Commission’s decision to add the Social Scoreboard (in 2018) and the SDG indicator set (in 2020) to the European Semester to monitor progress towards implementation of the European Pillar of Social Rights (hereafter the “Pillar”) and the SDGs. Framed as a tool to ensure fair employment and social outcomes, and to promote “upward social convergence” in the EU, the Pillar includes UHC through principle 16 on the right to timely access to affordable, preventive, and curative healthcare of good quality.

The Social Scoreboard uses self-reported unmet need for medical care as a headline indicator to monitor implementation of principle 16, supported by two secondary indicators: public spending on healthcare as a share of gross domestic product, and out-of-pocket payments as a share of current spending on health. Unmet need is also part of the SDG indicator set used by Eurostat to monitor progress on SDG 3.8 on UHC.

The effectiveness of these monitoring tools is limited, however. First, because the Pillar and the SDG indicators are non-binding instruments, their impact is limited. Second, the Social Scoreboard’s headline indicator is self-reported unmet need for medical care, which may not accurately reflect the true burden of unmet need or access to health services. The Weighted Medical Needs Index, which measures the financial risk patients and households face from healthcare costs, could provide a more comprehensive measure of the burden of unmet need. Furthermore, the Social Scoreboard does not fully capture the impact of healthcare spending on employment and social outcomes, which are central to the Pillar’s aims of promoting upward social convergence.

* Since its revision in 2021, the Social Scoreboard includes 17 headline indicators, which are used to monitor 18 of the 20 Pillar principles and to support analyses in key Semester documents, such as the Joint Employment Report. The secondary indicators aim to achieve broader coverage of the Pillar principles.
may be limited in an area like access to healthcare, in which the EU has no direct power and there is no legislative initiative at European level. Second, the indicators used in the Social Scoreboard and the SDG indicator set do not provide a comprehensive understanding of healthcare affordability. Unmet need for healthcare is a useful but only partial measure of affordable access, since it does not capture the financial hardship caused by out-of-pocket payments. Similarly, the health spending indicators are only proxy measures of healthcare affordability, which is better captured by indicators of financial hardship, such as impoverishing and catastrophic health spending. Finally, the monitoring tools lack qualitative analysis of the different dimensions of coverage policy (population coverage, the benefits package and user charges) in Member States; this analysis helps to identify the types of changes Member States can make to improve affordable access to healthcare.

Country-Specific Recommendations target access to healthcare

CSRs define the areas in which Member States are monitored in the subsequent Semester cycle. The number of healthcare-related CSRs has increased since the Semester was launched, but it was only in 2020 that all Member States received a CSR on healthcare reforms. In response to the COVID-19 pandemic, the recommendation urged them to strengthen the resilience of their health systems, and investment in healthcare was facilitated by increased fiscal flexibility, enabling Member States to depart temporarily from EU budgetary requirements.

The 2020 CSRs focused on access to healthcare in 12 countries (see Table 1). These access-related recommendations most often targeted service availability (e.g., workforce shortages) and focused on the affordability of services (user charges or the benefits package) in three countries. Attention to healthcare reforms did not last long, however. Healthcare-related CSRs dropped to eight in 2022, and six in 2023, with only four explicitly targeting access to healthcare (see Table 1). This drop may reflect the recovery from the pandemic, a renewed emphasis on macroeconomic and fiscal stability, and the Commission’s decision to focus the CSRs on issues not already covered by funding instruments such as the Recovery and Resilience Facility.

EU funding instruments support access-related healthcare reforms

Various funding instruments support national reforms and investments in health, including access to healthcare. In 2021, the Commission introduced the Recovery and Resilience Facility (RRF) in response to the pandemic. This temporary funding instrument aims, among other things, to increase crisis preparedness and the response capacity of Member States, including by improving the accessibility and capacity of health and care systems. As a result, all national Recovery and Resilience plans contain healthcare measures, including reforms to improve access to healthcare. For instance, Hungary has planned measures to eliminate informal payments, while Ireland has focused on improving the accessibility of primary healthcare. These plans are monitored through various tools, including the Semester’s Country Reports and a new RRF Scoreboard. In relation to “health, and economic, social and institutional resilience”, the RRF Scoreboard monitors the yearly capacity of healthcare facilities, reflecting the maximum number of patients

Table 1: CSRs addressing access to healthcare with a focus on affordability, 2020, 2022 and 2023

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<thead>
<tr>
<th>Country</th>
<th>Access to healthcare</th>
<th>Population coverage</th>
<th>User charges</th>
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Source: Authors' own

† Technical support is also provided, as described by Mauer et al. in this publication.
that can be treated annually, and measures the number of individuals who use new and enhanced public digital services, products, and processes. A third monitoring tool, the methodology for reporting social expenditure, includes “health and long-term care” as one of four broad social categories used to classify Member States’ RRF spending. These tools focus on healthcare capacity, digitalisation, and expenditure; however, they do not provide much information on affordable access to healthcare.

Under the EU Cohesion Policy 2021–2027, the European Social Fund Plus and the European Regional Development Fund support healthcare reforms in almost all Member States, including with a view to improving access. In relation to affordability for example, these reforms address concerns regarding population coverage in Czechia and Romania, and user charges in Latvia. The Recovery assistance for cohesion and the territories of Europe (ReactEU) completes these instruments by providing funds for cohesion and regional development. As the European Court of Auditors has noted, the systems used to monitor the Cohesion Policy and the RRF are not yet sufficiently harmonised, limiting the potential for international comparison.

**Proposals for more effective EU engagement: How can the EU improve its support for affordable access to healthcare?**

EU and Member State commitments to UHC are encouraging, but limitations remain. Many national policies still create gaps in health coverage, increasing inequalities both within and between Member States. This undermines the implementation of principle 16 of the Pillar and of SDG 3.8 on UHC, as well as the Pillar’s overall objective of promoting upward social convergence in the EU, leaving no one behind. In addition, EU action on healthcare reforms has been characterised by ambiguity and contradiction. Over the years, the European Semester has developed a stronger social dimension, paying greater attention to healthcare; fairness is also one of the four dimensions that now guide the EU’s recovery. Nevertheless, the Semester continues to focus disproportionately on economic and fiscal priorities. Further action is needed to enhance the social dimension of the Semester and achieve the stated objective of the Commission’s proposal for a reformed EU economic governance: strengthening public debt sustainability while promoting sustainable and inclusive growth through reforms and investment, including for the implementation of the Pillar.

We propose two complementary approaches to improving EU support to Member States. First, EU policy coordination and data collection should be strengthened, to make the Semester’s analyses and recommendations on access to healthcare more consistent, transparent, and effective. Second, implementation of principle 16 of the Pillar must be explicitly recognised as a key priority for the EU agenda in the years to come. An important step in this direction would be the adoption of a specific initiative such as a Council recommendation on moving towards UHC. This could use the Council Recommendations on access to social protection and on childcare as examples. Its aim would not be convergence towards a single health system “model”, but rather the introduction of context-specific measures needed to progress towards UHC. **Box 2** provides concrete examples of how both approaches could be further developed.

**Box 2: Summary of proposals for more effective EU engagement**

1. Strengthen EU policy coordination and data collection to make the Semester’s analyses and recommendations on access to healthcare more consistent, transparent, and effective.

Examples of actions in this direction:

- Expand the quality and availability of data collected in a standardised way.
- Support the quantitative indicators of unmet need for healthcare with indicators of financial hardship caused by out-of-pocket payments (derived from analysis of household budget survey data) and analysis of the role of health coverage in reducing poverty.
- Require Member States to carry out household budget surveys more regularly and make the microdata easily available to researchers.
- Make more use of qualitative information on coverage policy in Member States, not only to interpret quantitative indicators but also to identify the specific policy changes needed to improve access to healthcare in each country.
- Use WHO/Europe’s new monitoring tool, UHC watch, to inform CSRs in the European Semester as well as EU and national health system performance assessments.

2. Explicitly recognise implementation of principle 16 of the Pillar as a key priority for the EU agenda in the years to come, by adopting a specific initiative such as a Council recommendation on moving towards UHC.

Examples of content and scope of a recommendation on UHC:

- Flag the key principles underpinning affordable access to healthcare.
- Identify a minimum share of EU and national resources needed to support progress towards UHC.
- Highlight examples of good practice and indicate reforms to be included in national health plans.
- Enable Member States to introduce the context-specific measures they need to progress towards UHC.
- Set a timeline for implementation.
Stronger EU support for affordable access to healthcare will provide Member States with a clearer policy framework, improve the coordination and effectiveness of EU instruments, and ensure a more efficient use of EU funds.

References

A RENEWED CALL TO ACTION: HOW CAN THE EUROPEAN UNION SCALE-UP ACTION ON NON-COMMUNICABLE DISEASE PREVENTION?

By: Judith Lambert, Ann Marie Borg, Gauden Galea, Kremlin Wickramasinghe and Caroline Costongs

Summary: Primary prevention is an effective strategy to maintain and improve population health and to achieve resilience in the face of crises. This article aims to highlight the progress of legal initiatives aimed at prevention of Non-communicable diseases (NCDs) risk factors and wider health determinants under the European Commission’s Europe’s Beating Cancer Plan. We also explore how the European Union (EU) can use its policy levers to strengthen prevention and tackle NCDs. Future potential actions for the next Commission, including addressing the impact of commercial determinants on the establishment of policies, are also suggested.

Keywords: Non-communicable Diseases, Commercial Determinants of Health, Europe’s Beating Cancer Plan, Regulation, European Commission

Introduction
Non-communicable diseases (NCDs) account for almost 90% of all mortality in the World Health Organization (WHO) European Region. A significant proportion of this burden of disease is preventable and is largely dependent on risk factors such as tobacco use, harmful use of alcohol, unhealthy diets, physical inactivity, air pollution, and exposure to carcinogenic agents and radiation. Improved promotion of healthy lifestyles coupled with prevention measures to tackle key NCD risk factors have the potential to reduce the prevalence of NCDs by as much as 70%. Hence, addressing these risk factors through prevention and health promotion as well as addressing the underlying socio-economic determinants of NCDs, should continue to be prioritised in public health policies in Europe.

NCDs not only place a heavy burden on the general health and well-being of the population, they also negatively affect our economies, the workload of our health workforce and place a disproportionate burden on health systems, which in many European countries are notably understaffed and lack sufficient investment. Moreover, as we have seen during the COVID-19 pandemic, people suffering from NCDs are also more heavily
affected during public health crises. They are more vulnerable to contracting communicable diseases and experience weakened immune responses, including a higher risk of becoming severely ill from communicable diseases such as COVID-19.

Thus, the investment case to address NCD risk factors is clear: not only do NCDs account for high healthcare and pharmaceutical costs across countries, they also result in significant societal expenses such as loss of productivity. Additionally, with ageing populations in Europe, healthcare costs are set to increase. The return of investment of prevention is well-known, yet, the share of investment in prevention as opposed to overall healthcare expenditures remains considerably low, accounting for only 3% of total health spending in the EU.

The European Commission has developed a number of strategies and initiatives to help Member States tackle NCDs. This includes the European Commission’s Healthier together – EU Non-Communicable Diseases Initiative (EU NCD Initiative), which offers structured support to Member States for further action on NCDs including tackling health determinants, health promotion and disease prevention. In this article, we consider another initiative – the Europe’s Beating Cancer Plan (EBCP) – as a useful entry point to reflect on how the EU is making use of its policy instruments to fight NCDs. The EBCP stands out as an all-encompassing strategy with prevention as one of its pillars (see Box 1). It also covers different risk factors and wider health determinants of cancer and other common NCDs.

The EBCP should also be seen in synergy with other EU strategies such as the European Green Deal and its related Farm to Fork strategy, and the Zero Pollution Action Plan. In fact, several actions listed in the EBCP are stemming from objectives in the food or environment policy areas and are brought together in the EBCP in a Health in All Policies approach.

In addition to several non-legislative measures aimed at strengthening primary prevention, the EBCP sets out an ambitious legislative agenda to tackle health determinants including nutrition, and alcohol and tobacco use. These foreseen proposals are aligned with Article 168 (5) of the Treaty of the Functioning of the European Union (TFEU) with regard to measures to protect and improve human health including “the protection of public health regarding tobacco and the abuse of alcohol”. In this article, we will explore the current state of play of these legal initiatives under the EBCP, and review the progress made under the current Commission. As a next step, we will consider potential future directions for health policy in the EU to reduce the burden of NCDs and improve health for all.

Progress made in advancing the legislative agenda foreseen in the EBCP

Table 1 outlines the progress made across several legally binding initiatives referred to in the EBCP in relation to tobacco, alcohol, and nutrition.

What can we learn from this overview? The extensive list of initiatives listed in the table alone demonstrates the Commission’s strong commitment and ambition to tackle key NCD risk factors. However, the table also indicates that the foreseen legal measures pertaining to tobacco (no. 1–3), alcohol (no. 4–7), and nutrition (no. 8, 9) have not progressed according to the initial timelines indicated in the Plan and remain behind schedule. Thus, to date, the progress indicators set out in the EBCP’s implementation roadmap for these files have not been met.

Although the intentions of alcohol-related initiatives are promising, including legislation for mandatory ingredient information and health warnings on alcoholic beverage products. However, the ambition of these initiatives has met considerable opposition. Nonetheless, an example has been set by Ireland, whereby mandatory health warnings will be introduced on alcoholic beverage labels by 2026. Will the Commission follow suit and propose harmonised health warnings to alcohol labelling requirements across the Union?

Foreseen initiatives in the area of tobacco also face significant delays. While first steps have been taken to review current pieces of legislations, it is unclear whether proposals revising the existing legislation to strengthen measures will be published in the near future. These delays appear to be inconsistent with the European Commission’s overarching vision under the EBCP of creating a “tobacco free generation”. In its report on the EBCP, the European Parliament has also urged the Commission to take appropriate measures and bring forward these legislative proposals.

In the area of nutrition and healthy diets, due to strong opposition of a mandatory EU-wide front-of-pack nutrition labelling (FOPNL) scheme, the long due foreseen revision of the Food Information to Consumers Regulation (EU) No. 1169/2011 seems to be stalled. Thus, in this vacuum, several Member States have started to implement national FOPNL schemes.

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* The initiative proposes the undertaking of concrete actions until 2027 to support Member States and stakeholders address major causes of mortality and morbidity in Europe, such as cardiovascular disease as well as tackle health determinants, with the overarching aim of helping countries reach the Sustainable Development Goals and WHO 2025 targets on NCDs.
enable consumers to make more informed healthy and sustainable food choices. Will this serve as an impetus for the Commission to take action and propose an EU harmonized approach to front-of-pack nutrition labelling?

Whilst there are several reasons behind these delays, it can be noted that in certain policy areas, non-legislative measures are more easily accepted and adopted. Conversely, legal actions to tackle health determinants that are often contentious and face opposing views and interests among stakeholders or Member States are blocked or, once proposed, are heavily watered down during the negotiation process. The agri-food sector, in particular, witnessed that in addition to industry influence, political sensitivities contributed significantly to delays. Moreover, legal initiatives for more sustainable food systems envisaged for the current Commission term, risk being replaced by softer measures such as “strategic dialogues”.

It is also worth comparing the progress made regarding different legislative proposals across health, food or environment policy areas. Some environmental legal initiatives referred to in the EBCP for example on tackling carcinogenic substances, pollutants in water, or revising asbestos limits, have made swifter progress.

Delays may also point at a rather lengthy EU legislative-making process whereby proposals for new legislation or revisions to current legislation undergo public and/or targeted stakeholder consultations and comprehensive impact assessments. Although imperative to assess the necessity and added value of legislation, the process hampers concerted timely action. Therefore, if we wish to turn the tide on NCDs, the significant current delays in the publication and adoption of EU legal measures directly impacting the reduction of NCD risk factors, is not acceptable. We also have to bear in mind that even after negotiations and an agreement by the Council of the EU and the European Parliament, the lengthy implementation of adoption of legal measures nationally, especially in view of long transition periods, implies that it could take several years before we can see any desired impact.

<table>
<thead>
<tr>
<th>Legal initiative</th>
<th>Commission proposal foreseen for publication in*</th>
<th>Actions taken</th>
<th>Status (as of September 2023)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Review legal framework on cross-border purchases of tobacco by private individuals</td>
<td>2022</td>
<td>Public consultation carried out in 2021 [15]</td>
<td>Delayed</td>
</tr>
<tr>
<td>4 Review of EU legislation on taxation of alcohol</td>
<td>2022</td>
<td>Public consultation carried out in 2022 [15]</td>
<td>Delayed</td>
</tr>
<tr>
<td>5 Review legal framework on cross-border purchases of alcohol by private individuals</td>
<td>2022</td>
<td>Call for evidence/public consultation carried out in 2022 [15]</td>
<td>Delayed</td>
</tr>
<tr>
<td>6 Proposal for mandatory labelling of the list of ingredients and nutrition declaration on alcoholic beverage products (as part of the revision of the Food Information to Consumers Regulation)</td>
<td>2022</td>
<td>Public consultation completed in 2022 [15]</td>
<td>Delayed</td>
</tr>
<tr>
<td>7 Proposal for health warnings on alcoholic beverage products</td>
<td>2023</td>
<td>Evidence gathering phase</td>
<td>Delayed</td>
</tr>
<tr>
<td>8 Revision of EU school fruit, vegetables and milk scheme</td>
<td>2023</td>
<td>Public consultation completed in 2022 [15]</td>
<td>Delayed</td>
</tr>
<tr>
<td>9 Propose mandatory front-of-pack nutrition labelling (as part of the revision of the Food Information to Consumers Regulation)</td>
<td>2022</td>
<td>Public consultation completed in 2022 [15]</td>
<td>Delayed</td>
</tr>
</tbody>
</table>

* Timeline for foreseen publication based on Commission proposal and communication.

Source: Authors’ compilation/assessment based on the initial timelines presented in the EBCP and its implementation roadmap as updated in January 2022 and other activities undertaken since the publication of the EBCP [23]
and resistance to legislative proposals from policymakers or stakeholders which has the power to derail foreseen timelines set by the European Commission, we recognise that there are several challenges which need to be addressed for better and swifter regulation in the area of NCDs.

**What is the way forward to accelerate the implementation of prevention initiatives under the EBCP?**

As we approach the end of the current European Commission’s term, we must ensure that the foreseen legal actions stay on the political and policy agenda. In fact, this delayed or ‘unfinished’ EBCP agenda on alcohol, tobacco, and nutrition, should serve as an opportunity for us to reflect on how to bring forward this agenda more effectively in the next Commission mandate. How can the EU bolster stronger action on fighting NCDs? Are we able to make the next Commission a game changer in tackling health determinants and prevent NCDs? We have to remain ambitious yet be more grounded in reality if we want to see concrete action being undertaken.

Firstly, due to the cross-cutting nature of policy measures addressing health determinants and risk factors such as alcohol, tobacco and nutrition, we must reiterate that multisectoral collaboration and coordination is key. While efforts to fulfil the EBCP actions are undertaken by the European Commission’s Directorate General for Health and Food Safety (DG SANTE), the involvement and close engagement of other DGs such as DG Trade is imperative for a successful outcome. EU legislation in the area of health must also respect current EU internal market rules as set out in Article 114 TFEU. Since safeguarding public health and trade within the EU’s single market are often not compatible, we could even consider this to be one of the root causes of the high burden of NCDs that would need to be addressed.

Secondly, understanding and unravelling the complex role commercial determinants play in health policy is crucial. This also involves considering how political and economic systems and norms influence policy, as well as its implementation practices. By doing so, it also becomes easier to anticipate and address any attempts by commercial actors to influence policy and possibly even diffuse independent evidence-based findings to downplay the impact of behavioural, and thus modifiable risk factors, on the burden of NCDs. Recent analyses published by the *Lancet* and *Eurohealth* reveal the impact of these practices. For example, the narrative spread by the alcohol industry that an occasional glass of wine is beneficial for your health is supported by weak empirical research with the aim to diffuse the evidence-base on the harmful effects of alcohol. While many of these tactics were first identified by the tobacco industry, they are now also being used in other sectors. Treating these sectors separately would only be to their benefit as it also creates a division where we see one as less harmful than the other.

Therefore, the time is ripe to have an open and honest conversation among legislators on commercial determinants and the prevention of NCDs, bringing together Ministries of Economy, Trade, Agriculture, Transport and others, in the spirit of Health in All policies and a whole-of-government approach.

**Proposals for more effective EU engagement to tackle NCDs**

First, we invite the new European Commission to maintain the planned actions outlined in the EBCP on its political and policy agenda, with a particular emphasis on regulatory measures aimed at primary prevention and health promotion. Both the Member States and the Commission should continue to closely monitor the progress made in this area to ensure that the level of ambition is retained. The absence of foreseen legislative EU action on reducing the harmful use of tobacco and alcohol and empowering consumers to make healthier and more sustainable food choices, continue to undermine efforts to address some key factors which exacerbate the burden of NCDs. We thus strongly recommend that evidence-based actions under the EBCP are adopted in order to achieve their projected public health impact without further delay. Self-regulation is unsatisfactory in order to achieve the desired results. The WHO guidance, and especially the policy actions recommended as “best buys”, should be used as a starting point in this regard.

Second, we recommend addressing the cross-sectoral nature of actions against NCDs through the appointment of a European Commission Vice-President for a Well-being Economy, in addition to a Commissioner for Health and Food. These broader mandates of European Commissioners will put equal emphasis on health, well-being and human capital alongside social, natural and economic capital. Putting the health and well-being of people and the planet at the centre of policymaking, balances multiple interests and would even facilitate new EU legislation in the area of NCD prevention, mitigating cross-border effects.

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**Box 2: Summary of proposals for more effective EU engagement on to tackle NCDs**

- Ensure that the planned actions outlined in the EBCP are taken forward and adopted without further delay, with a particular emphasis on regulatory measures aimed at primary prevention and health promotion.
- Explore a stronger and broader mandate for the Health Commissioner, appoint a Vice-President for a Well-being Economy and consider additional legal initiatives to further strengthen the fight against NCDs.
- Consider more explicitly the commercial determinants in cancer and NCD prevention policies and integrate transparency at all stages of policy development.
- Allow for the participation of international organisations, civil society organisations and Member States in EU NCD policies through a dedicated high-level platform on NCDs prevention.
In addition to health promotion measures referred to in the EBCP and proposed by the Joint Action BestReMap, this may include regulating digital marketing and advertisements of unhealthy food and drinks, and implementing tax measures on sugary drinks and ultra-processed foods.

Third, we invite EU decision-makers to look at NCD prevention policies through a commercial determinants lens. This would give a more comprehensive approach to the legislative process and demonstrate the need to act on the systems, practices and pathways through which commercial actors mislead health and impact on equity. Managing the impact of industry influence could be achieved through transparency at all stages of policy development related to NCD prevention. Article 5.3 of the WHO Framework Convention on Tobacco Control (FCTC) could set the tone for ensuring transparency in the interaction between policy makers and the industry and may also act as a vital step in gaining public trust for more successful implementation of public health policies. To achieve greater transparency, a Council recommendation on the roles for engagement with the commercial players in the field of NCDs could also be considered.

Finally, we encourage the Commission to consider the establishment of a high-level platform to engage across sectors to understand trade-offs and facilitate meaningful collaboration with Member States, international organisations and civil society organisations in an open dialogue on NCD prevention.

References


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IDENTIFYING DISEASE-SPECIFIC PATIENT AND SOCIETAL NEEDS TO FOSTER NEEDS-DRIVEN HEALTHCARE AND INNOVATION POLICIES IN THE EU

By: Irina Cleemput, Charline Maertens de Noordhout and Wim Goettsch

Summary: Healthcare policy decisions in the European Union are largely supply-driven. To move towards needs-driven healthcare innovation and policy, patient and societal needs should be defined upfront and subsequently guide decisions of researchers, research funders, regulators and health technology assessment bodies. Evidence-based needs-driven policy assumes the availability of scientific evidence on disease-specific needs in a large range of diseases. Collaborative efforts at EU level are necessary to establish a needs assessment and appraisal framework, gather evidence, and incorporate these into assessment and decision-making processes. The EU pharmaceutical regulation, EU HTA regulation and EU research funding programmes can stimulate this effort.

Keywords: Needs Assessment, Biomedical Research, Pricing and Reimbursement, Regulatory Approval

Introduction

In a patient-centred healthcare system, research and development (R&D) should focus on addressing high-priority patient and societal needs. However, private investments in R&D often fail to target the highest priority needs due to the absence of commercial interest. Current intellectual property frameworks for innovation and supply of health technologies are failing to stimulate and deliver solutions for priority healthcare needs, such as prevention of multimorbidity, mental health, antimicrobial resistance and treatment of neglected diseases.

Industry tends to prioritise innovation that promises significant long-term revenue. In Germany, for example, an empirical study found that pharmaceutical innovation is more closely related to market size than disease burden. A Dutch study found that for about 30% out of 33 selected high need conditions, there was no or little pharmaceutical development (including, among others, stroke, hearing disorders,
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Figure 1: Conceptual framework for a needs-based decision approach

Requirements for a life-cycle approach to needs-based policy in healthcare

1. Patient and societal needs framework:
   - criteria to be assessed
   - type of evidence
   - evidence sources

2. Assessment:
   - Collecting evidence on the criteria for various health issues
   - Input in an evidence database

Evidence database of health-related needs criteria

3. Appraisal:
   - Ranking or classification of health-related needs
   - Scoring/Deliberating on relative level of health-related needs

4. Use of needs categories

Scientific work
Tool
Evidence-based decision making

Weighing the criteria in the light of the evidence

R&D programmes, research funding, marketing authorisations, innovation incentives, pricing and reimbursement decisions …


Oesophageal cancer, brain cancer, contact eczema, arthrosis. Yet, for other conditions, such as diabetes mellitus, HIV and breast cancer, continuous development has been observed in the pharmaceutical sector over the past 15 years. As a consequence, important amounts of public resources are being invested to bridge these gaps, through research funding, pharmaceutical incentives, early (conditional) access and temporary reimbursement schemes.

However, there is little discussion about priorities across diseases between different types of decision-makers. Decisions are often made following ad hoc requests for one specific product or related to one specific disease. For example, incentives for R&D are provided following a request of developers (e.g., a pharmaceutical company), rather than granted on the basis of previously defined and prioritised patient and societal needs. Moreover, the focus of decision-makers is commonly on the assessment of single technologies instead of having a broader agenda addressing the health needs of the whole society.

This article describes a possible approach to move towards needs-driven healthcare innovation and policy, including a framework for identifying disease-specific societal and patient needs, and proposes ways to implement these principles at the EU and national level.

Steering innovation towards areas with high needs

Moving towards needs-driven healthcare policy requires the consideration of health-related patient and societal needs’ before, during and after the development of any new healthcare intervention. Therefore, the patient and societal health-related needs under the current standard of care must be identified in an evidence-based manner. Based on this scientific evidence for a large range of diseases, priorities for innovation can be identified and be used in research and innovation policy decisions.

Once interventions for high need diseases are being developed, regulatory and reimbursement assessment processes should take the information about the basic underlying needs that the interventions aim to address into account to allow for a suitable judgment about their value. This life-cycle approach to the use of patient and societal needs evidence is at the core of the statement of the Global Policy Forum of HTA International (HTAi – the global health technology assessment society) saying that the value of a technology at various points in time should drive the focus of resources to areas where they are most needed.

An example of a national initiative in this direction includes the Future Affordable and Sustainable Therapies (FAST) initiative in the Netherlands. FAST aims to ensure the affordability of therapeutic innovations targeting healthcare needs of chronically ill patients by allocating public resources for innovation in a less fragmented manner.

* Health-related needs are the specific needs related to a particular health condition, which encompasses the needs of individuals affected by the condition and possible broader societal needs that involve the consequences of the condition which impact segments of society not directly afflicted by the condition (externalities).
It is important to consider all types of health interventions when steering innovation towards areas with high needs, as defined needs could potentially be addressed by different types of interventions. Health-related needs are independent of the disease-specific interventions in the pipeline. Besides medicinal products, also medical devices, surgery, (supportive) care, preventive interventions or organisational changes could be efficient solutions to specific patient or societal needs.

We prefer to use the term “health-related needs”, rather than “unmet medical needs”, as the latter term is often used in relation to pharmaceutical products or in relation to access to healthcare services. The different terminology also avoids confusion with the mainly individual patient needs-driven interpretation of the term ‘unmet medical needs’. Moreover, it is important to emphasise that health-related needs should be defined ‘given the current standard of care’, irrespective of whether this standard of care involves a pharmaceutical product, a medical device or another type of treatment, care or disease management approach.

Distinguishing individual patient needs from societal needs is challenging. However, it is important to acknowledge that needs can be defined from both an individual patient’s point of view (health issues representing a high individual burden of disease, despite current diagnostic, preventive or therapeutic options available) and from the societal point of view (health issues representing a high burden on population health, a high impact on the sustainability of the healthcare system, or with ethically unacceptable consequences). Patient needs may relate, for instance, to increased life expectancy or quality of life. While societal needs may relate, for instance, to the availability of an affordable treatment option or of a preventive treatment for a contagious condition.

**How can EU policy contribute to a needs-driven approach to healthcare innovation and policy making?**

Evidence-based, needs-driven innovation and policy making requires a scientific evidence base on patient and societal needs in various diseases. Whilst there is no consensus among stakeholders, both on a national and European level, regarding the definition of (unmet) health-related needs, there is agreement among stakeholders that specific criteria can and should be defined for the assessment of health-related patient and societal needs. This is a prerequisite for the use of evidence about health-related needs in decision-making processes at all geographical levels. Therefore, a framework must first be developed with transparent criteria on which evidence must be collected and a database with evidence on each of these criteria for a variety of diseases must be established (“assessment” in Figure 1). This framework should be endorsed at EU level to ensure efficient use of resources for research on disease-specific patient and societal needs.

Secondly, stakeholders at different levels (EU, national, regional) should agree to use this evidence to make an appraisal of the disease-specific patient and societal needs, i.e., the determination of the relative importance (or level) of the health-related needs in different disease areas (“appraisal” in Figure 1). How the evidence is used for the appraisal may vary between decision-makers. For decisions at EU level (e.g. regarding research funding programmes, incentives for innovation), Member States should agree on the ranking of patient and societal needs. However, for national decisions (e.g., reimbursement of health interventions, national research funding programmes), the ranking may differ between Member States. A classification in categories representing the level of need (high, medium, low or none) or, alternatively, a complete ranking of needs (“ranking” in Figure 1) could be pursued.

Finally, there should be agreement to use the classification or ranking for concrete decisions. At the EU level, the high priority needs can be used to inform or define EU research funding programmes. EU regulators (e.g., the European Medicines Agency, EMA) can use them to inform decisions regarding regulatory incentives for the development of health interventions for major health-related needs (e.g., PRIME†, data protection and conditional marketing authorisation for pharmaceuticals). Similar types of possible uses exist at lower geographical levels.

Based on the appraisal of the relative importance of health-related patient and societal needs in different health conditions, like-minded countries could indicate to healthcare technology developers who have an intervention (e.g., medical product, new medical procedure) in the pipeline, where it is worthwhile to pursue efforts and where investments are less likely to offer sufficient returns because of the expected willingness to pay for the intervention. In the context of HTA, health-related need categories or rankings may assist HTA bodies and payers, both in national HTAs and joint clinical assessments on the EU level, to assess whether new treatments respond to the real needs of patients and society.

**Patient and societal needs framework**

A framework for identifying, measuring and assessing health-related patient and societal needs should be developed with input from stakeholders, including citizens, patients, healthcare providers, policy makers and industry. Because the societal and patient needs perspectives are difficult to merge into one framework, we propose the development of two separate frameworks, one for societal needs and one for patient needs. As a consequence, health-related needs can be appraised as being ‘high’ because either the patient needs or the societal needs are high, or both are high. This approach also allows

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† PRIME is a scheme run by EMA to enhance support for the development of medicines that target health-related needs. This voluntary scheme is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation so these medicines can reach patients earlier. See https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines.
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the consideration of specific health objectives, if these have been defined. For example, if reducing inequity in health is a defined health objective, diseases with high inequity between patients will get higher weight in the societal needs appraisal. Societal needs could also include future needs, such as the need to protect future generations.

A combined framework for patient or societal needs should start with defining the relevant dimensions and then criteria to operationalise the needs for each dimension. Table 1 provides some examples.

### Table 1: Possible dimensions and criteria for societal and patient needs

<table>
<thead>
<tr>
<th>Societal needs dimensions</th>
<th>Possible criteria</th>
</tr>
</thead>
</table>
| **Impact on population health** | - Frequency of the health issue  
- Duration of the condition  
- Mortality  
- Transmissibility  
- Antimicrobial resistance  
- Burden on informal caregivers  
- Value for money of standard of care  
- Affordability of current management options |
| **Impact on healthcare** | - Productivity losses  
- Environmental impact of standard of care |
| **Social impact** | - Future burden of disease  
- Future economic burden |
| **Future impact** | - Financial accessibility  
- Burden of health issue in vulnerable groups (e.g., children, pregnant women) |
| **Equity** | - Financial accessibility  
- Burden of health issue in vulnerable groups (e.g., children, pregnant women) |

<table>
<thead>
<tr>
<th>Patient needs dimensions</th>
<th>Possible criteria</th>
</tr>
</thead>
</table>
| **Health** | - Mortality  
- Quality of life before vs. after onset of disease/experienced burden of the disease |
| **Healthcare** | - Availability of treatment  
- Experienced burden of treatment  
- Experience with healthcare organisation  
- Accessibility of care (financial, geographical, waiting times)  
- Timely diagnosis |
| **Social** | - Social support needs  
- Impact on work  
- Financial consequences |


After establishing and agreeing on such a framework the next step is to establish a deliberative process that could help to weigh the different criteria to identify the most pressing patient and societal needs.

### A research infrastructure to inform EU research funding priorities

While most healthcare related policy matters fall within national competencies, healthcare research has a significant European dimension. Several large scientific funding programmes, such as Horizon Europe, the Innovative Health Initiative, the Innovative Medicines Initiative, and EU4Health have been established to promote healthcare research in the EU.

However, funding is often fragmented, and priorities determined in different ways. For a more coherent prioritisation of topics for health-related needs research, the establishment of a research infrastructure at EU level is needed. This research infrastructure should be responsible for the organisation, coordination and quality assurance of scientific research on health-related patient and societal needs and should create a needs evidence database to support priority setting for research funding programmes.
Scientific work has been performed at EU level regarding possible research infrastructures that would better address the objective of needs-driven R&D in the EU. This research concluded that a public European biomedicines infrastructure should be created to tackle market failures and ensure a proper return on investment, while addressing the pricing of medicines and intellectual property rights. The idea was presented to the European Parliament by the European Parliament’s Panel for the Future of Science and Technology (STOA) in 2022: “Such an initiative could answer the identified issues of shortages and high costs and prices of pharmaceuticals, lack of transparency, and unmet therapeutic needs, by taking back public ownership rights to innovations that are exclusively in the public interest. It would also centralise public investment in public interest areas of low economic return, such as rare medicines and antimicrobials.”

Another study highlights that due to the lack of coordination of EU-funded research, there is no coherent investment and long-term strategy that would benefit Europe’s competitiveness and leadership in biomedical innovation. Both studies propose the creation of an independent EU research agency to coordinate EU Health Research and Innovation and address structural weaknesses in the current R&D system.

There is a clear link between our proposed approach and these proposed initiatives. Issues such as shortages, and high costs and prices of pharmaceuticals relate to the societal need of wanting to address respectively sufficient product availability and affordable treatments, while unmet therapeutic needs refer to patient needs. Both types of needs can be addressed through a European research infrastructure. Furthermore, a prioritisation based on available capacity is foreseen. The issues at stake for an EU research infrastructure focusing on the establishment of an evidence database for patient and societal needs, are similar to the ones described for the biomedicines infrastructure (i.e., available resources, prioritisation, diversification of the agenda: bottom-up approach versus product-driven approach or a combination).

**Adaptation of approval and reimbursement processes**

The implementation of the needs-driven approach both in regulatory processes and at the HTA/reimbursement decision level is crucial to achieve improved healthcare for European citizens based on their needs. Regulatory incentives for innovation in specific disease areas, as for instance provided for in the EU pharmaceutical legislation, should consider the identified disease-specific needs of patients and society, as included in the evidence database created by an independent research infrastructure. The evidence will highlight which specific needs must be met to reduce the burden of the disease to patients and/or society, which helps to direct incentives towards interventions that are most likely to meet these needs (e.g., pharmaceutical, devices or other).

Although the organisation and funding of healthcare still primarily fall under the responsibility of individual Member States, new EU legislation like the EU HTA Regulation can offer incentives to support this approach. Within this regulation, activities on horizon-scanning, joint scientific consultation, joint clinical assessment and post-license evidence generation are organised in subgroups under the Coordination Group. We propose that all these activities incorporate evidence-based needs in their methodological guidelines, to promote the development of health technologies that address the predefined patient and societal needs. Including evidence on patient and societal needs in horizon scanning, helps to identify upcoming (potentially) high impact interventions. This has a signalling effect to policy makers to take or prepare action (e.g., on reimbursement), and will, in the long run, stimulate developers to invest in such potentially high impact interventions to benefit from such actions. Needs evidence can inform joint scientific consultations and joint clinical assessments by highlighting the criteria on which an appraisal of the relative importance of the disease-specific health-related needs, (4) the creation of smart and predictable incentives towards health intervention developers and researchers to steer R&D activities towards the highest needs, and (5) approval and reimbursement processes that take the performance of new health interventions on these needs into account.

A strong collaboration at the EU level is required.

We therefore call on the European Commission to draft an EU strategic plan that helps both the EU and the Member States to implement a needs-driven ecosystem in healthcare, taking into account all types of health interventions as possible solutions for (unmet) health-related needs, and aiming at the coordination of public support and incentive mechanisms for R&D in order to adequately and effectively respond to the most pressing patient and societal needs.

The development of a general approach to define, assess, appraise and use evidence on patient and societal health-related needs should be initiated, including a common framework with needs criteria, to support
Box 1: Summary of proposals for more effective EU engagement

- Initiate the development of a general approach and common framework with criteria for identifying health-related patient and societal needs.
- Draft an EU strategic plan towards responding to the most pressing patient and societal needs.
- Support health-related needs research in the EU and establish a Needs Evidence Database.
- Establish at the EU level a Needs Appraisal Committee for the purpose of ranking patient and societal needs.
- Commit to addressing the most pressing patient and societal needs through policies and programmes, bringing together stakeholders.
- Implement a life-cycle approach in regulation and reimbursement at the European level.

The reflection at EU level on the various factors that contribute to health-related patient and societal needs should continue and the EU should commit to addressing these needs through policies and programmes, for instance through the EU Health Policy Forum, which brings together stakeholders across the healthcare sector. A life-cycle approach should be implemented in all activities on regulation and reimbursement at the European level, using existing structures such as EMA and the joint work under the EU HTA framework with criteria for identifying health-related patient and societal needs.

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REVAMPING THE EU’S HEALTH SECURITY FRAMEWORK TO MANAGE FUTURE HEALTH CRISSES

By: Andrea Renda, Timothy Yeung, Hien Vu, Jane Arroyo, Amy Kokalari and Panka Rékasy

Summary: After the COVID-19 pandemic, the European Union (EU) introduced several reforms to improve its crisis response capabilities. However, doubts remain as to the complexity of current governance arrangements. We review recent reforms and propose 19 recommendations. These include clarifying the relationship between the institutions involved in crisis management; streamlining scientific advice; coordinating IT platforms on medical countermeasures used by the European Medicines Agency (EMA) and the Health Emergency Preparedness and Response Authority (HERA); streamlining and expanding funding sources for R&D; improving data flows; and strengthening the EU’s ability to communicate with the general public. All these measures can be adopted without EU Treaty reforms.

Keywords: Health Emergencies, EU Treaties, Coordination, Countermeasures

Introduction

Almost four years after its emergence, the COVID-19 pandemic has massively impacted society and the economy at the global level. In Europe, the pandemic has caused more than 275 million infections and over 2 million reported deaths as of August 2023, and 36 million cases of long COVID between 2020 and 2022. Many of these deaths could have been avoided had the European Union (EU) and its Member States been better prepared and thus able to respond more effectively.

Numerous problems emerged, including the weakness of health systems at the national and local levels despite the obligations stemming from the 2005 International Health Regulations, the difficulty to put in place evidence-informed policies and effectively communicating them to citizens while fighting misinformation; the delays and transparency issues in the procurement of COVID-19 vaccines and the lack of coordination of national border closure measures.

Importantly, problems also emerged in the EU because its approach to crisis management was not yet fully comprehensive. The pandemic exposed inadequate cohesion and coordination among Member States, as evidenced by early attempts to limit the circulation of medical countermeasures (MCMs) within
the Single Market. While on the surface legal constraints stood in the way of EU institutions’ ability to manage the crisis due to the wordings of Article 168 of the Treaty on the Functioning of the European Union (TFEU),

* the bigger problem was political. Since 2016, some of the legal limitations have been overcome by a rather extensive use of Article 122 TFEU, which provides more powers to the Council in the event of exceptional occurrences (including health emergencies). However, such measures lead to significantly more Member State-driven processes, which leave little space for EU-level coordination (e.g., by the European Commission), and do not involve the European Parliament in the decision-making process.

The limited competences held by the EU on health translated into an incomplete institutional framework for pandemic preparedness and response. Existing agencies, such as the European Centre for Disease Prevention and Control (ECDC), were overwhelmed by the scale of the threat. Member States called for urgent guidance while needing to take immediate action in the early days of the pandemic, leading to the adoption of disjointed measures across and within EU countries. Partly due to the weak influence of existing institutional bodies where Member States coordinate their actions, the European Commission struggled to defend the integrity of the Single Market and orchestrate actions taken by Member States.

The Commission indeed began responding to the threat in January 2020, as reflected in the Health Security Committee (HSC) meetings. Yet, due to the absence of an existing response framework, public health measures at Union level arrived relatively late (compared to economic support measures, where the experience of the financial crisis provided a clearer division of responsibilities*), and had to be speedily adopted. Joint procurement of vaccines at Union level was new to the EU and at the end sacrificed transparency in some circumstances. Eventually, the European Commission managed to address many of the coordination issues, and successfully paved the way for a coordinated approach in key aspects of crisis response, such as the negotiation of vaccine procurement and the development of a common COVID-19 certificate, which was also widely adopted beyond EU borders.

This article illustrates and analyses the reforms introduced in the area of health emergency response. Readers should be aware that at the time of writing, the two important regulations in this domain – Regulation (EU) 2022/2371 and Council Regulation (EU) 2022/2372 have been enacted for less than a year. The Commission and other institutional bodies are still working on implementing regulations – e.g., another being Regulation (EU) 2023/1808 on prevention, preparedness and response planning, which was adopted on 21 September 2023. The authors recognise that the process is still ongoing. That said, this paper aims to provide an interim evaluation and offer recommendations that the Union may consider in future evaluations and reviews of relevant regulations.

In addition, the article focuses on the response framework in the area of MCMs, and Public Health and Social Measures (PHSMs) to a lesser extent. The main reason is that the recent reforms in the EU, such as the establishment of the Health Emergency Preparedness and Response Authority (HERA) and the Council Regulation (EU) 2022/2372, have predominantly focused on MCMs. Decisions over PHSMs remain largely in the hands of national governments, with some enhanced communication and coordination mechanisms at Union level.

Recent steps towards a more cohesive governance of health emergencies

The past three years have seen several steps towards greater EU integration and cohesion. These include, among other things, the launch of the European Health Union, and in particular the adoption of Regulation (EU) 2022/2371 on serious cross-border health threats and Council Regulation (EU) 2022/2371 on the Emergency Framework of measures for MCMs; the strengthening of the mandate of existing agencies (ECDC and EMA); the announcement of a new Commission service in charge of health emergency preparedness and response for MCMs (HERA); and most recently the Commission’s Communication on actions to address critical shortages of medicines and strengthen security of supply in the EU. Other major reforms include prevention, preparedness and response planning at national and Union level, the establishment of an EU reference laboratory network, and enhanced epidemiological surveillance and risk assessment. The EU has also strengthened its use of the One Health approach to preventing, preparing for and responding to health emergencies. Its public health measures also aim to address broader categories of cross-border threats to health, covering threats of biological, chemical, radiological and nuclear origin.

Given the magnitude of the threat posed by COVID-19, momentum for a possible Treaty change to enable stronger EU competences in public health started to emerge. The latter was also broadly endorsed by the working group on health at the Conference on the Future of Europe (CoFoE). However, this momentum gradually waned. Meanwhile when the establishment of HERA was announced, many expected it to become an independent agency. Yet the policy

† Among its four proposals in the health area, the CoFoE’s recommendation to i) ensure equal and universal access to healthcare for all EU citizens (through a supranational healthcare system), and ii) enable health and healthcare to be a shared competence between the EU and Member States, would require Treaty changes (by amending Article 4 TFEU). The CoFoE’s proposals led to a vote in the European Parliament to call for establishing a constitutional convention to reopen the EU treaties. Indeed, these forward steps show signs of hope that the EU will be more prepared for another major health emergency.
process that could have led to this outcome was set aside, and HERA was launched as an internal service of the Commission – in part due to the need of speedy actions with competences and resources that may warrant a new intervention in the future.\footnote{We sometimes mention the two regulations together without explicitly stating the difference between a Regulation and a Council Regulation for brevity.}

Key provisions, in this season of reforms, include two consecutive regulations: Regulation (EU) 2022/2371 on serious cross-border health threats, and Council Regulation (EU) 2022/2372 introducing a framework to ensure the supply of crisis-relevant MCMs in the event of a public health emergency at EU level. Both entered into force on 26 December 2022.\footnote{These regulations define a governance framework for future responses to health crises, with a key role entrusted to a newly created Health Crisis Board (HCB); and to a strengthened Health Security Committee (HSC).}

Handling future health crises in the EU: who does what?

Good crisis management requires good situational awareness (e.g., through the Early Warning and Response System as is the case for the EU); the ability to anticipate a wide variety of potential threats; clearly defined responsibilities; streamlined decision-making processes; and the ability to couple transparent and legitimate decision-making with agility and speed. It also requires that actions are taken at the appropriate level of government.

In the past two decades, events such as 9/11, the 2005 Madrid terrorist attacks and the 2004 Fukushima Daiichi nuclear disaster led to the creation of an integrated system for crisis response at the EU level. Since 2013, with the launch of the Integrated Political Crisis Response (IPCR) mechanism, the Union Civil Protection Mechanism (UCPM) has become the overarching coordination mechanism for crisis management. As of 2016, with the peak of the refugee crisis, the EU started relying more on Article 122 TFEU to handle emergency situations through direct decisions adopted by the Council. Since the onset of the COVID-19 pandemic, and also due to new and unforeseen events such as the war in Ukraine, a deep reflection had been launched on the need for a more integrated crisis management system in the Union. The European Commission set out new Disaster Resilience Goals, which feature a ‘response component’, mostly revolving around the role of the UCPM. A stronger Emergency Response Coordination Centre (ERCC) will operate as a central hub in a network that links all crisis management actors across the EU, respecting existing competencies. In June 2023, the Council of the EU reiterated the need for ‘whole-of-society resilience in the context of civil protection, including chemical, biological, radiological and nuclear (CBRN) preparedness’.

Who is in the driver’s seat?

Regulations 2022/2371 (on system preparedness and response to cross-border health threats) and Council Regulation 2022/2372 (on MCMs) have laid down the roadmap from identification of a threat to the activation of an emergency framework. Upon the recognition of a public health emergency and a proposal by the Commission, the Council decides whether to activate the emergency framework for the provision of MCMs, as well as the activation of the HCB. Note that the HCB’s mandate, together with HERA’s, is restricted to the area of MCMs. Managing an emergency requires coordination at both the political and technical levels. In the case of health emergencies, it is likely that both PHSMs (e.g., social distancing, lockdowns) and MCMs will have to be adopted quickly and coherently.

In this context:

- EU-level political coordination takes place in the IPCR, led by the presiding Member State of the Council. Closely with the IPCR, the Employment, Social Policy, Health and Consumer Affairs (EPSCO) configuration of the Council gathers higher ministerial-level representatives from Member States to discuss and attempt to agree on a common EU approach.

- Health-specific coordination of MCMs falls within the remit of the HCB. The HCB forms part of the Emergency Framework under Council Regulation 2022/2372, the legal basis of which is in Article 122 TFEU, and as such mostly in the hands of the Council and Member States.

- HERA shifts into emergency mode\footnote{HERA feeds into the work of the HCB, i.e. by providing preparedness and response plans and managing and monitoring the joint procurement of MCMs.} under the coordination of the HCB, following the decisions made by Member States. HERA feeds into the work of the HCB, i.e. by providing preparedness and response plans and managing and monitoring the joint procurement of MCMs.

- The HSC is the highest body in the EU for health security, issuing opinions and guidance, ensuring the exchange of sensitive information and enhancing cooperation among Member States.
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The HSC is in charge of ‘prevention, preparedness and response planning for serious cross-border threats to health’.

- The Commission, in cooperation with Member States and relevant agencies and bodies, shall establish a ‘Union prevention, preparedness and response plan,’ as stated in Article 5 of Regulation 2022/2371. The plan shall ensure timely cooperation between the Commission, the Council, the Member States, the HSC and other relevant agencies and bodies. Meanwhile, Article 8 states that the ECDC shall assess the Member States’ national plans and their relationship with the Union plan. Most recently, the Implementing Regulation (EU) 2023/1808 of 21 September 2023 sets out the template for the provision of information on prevention, preparedness and response planning. DG SANTE oversees the implementation of the Regulation (EU) 2022/2371, ensuring and supporting Member States’ prevention, preparedness and responses to the emergency.

Against this background, there seems to be room for clarification and improvement of the current governance framework. Figure 1 shows the possible information and decision-making flows between institutions, agencies and bodies at different levels of government in the case of an EU health emergency. The complexity of the diagram may suggest several needs, including clear leadership; predetermined plans; agreed procedures; a good division of labour; and clear-cut communication to the public to avoid frictions and transaction costs that are likely to emerge in moments of emergency.

In particular, we recommend the following actions.

R1. At the higher political coordination level, it would be useful to clarify what relationship exists between the IPCR mechanism, the HCB and (when appropriate) the EPSCO Council configuration. The HCB can perform its role within the governance framework only if Member States share the same expectation of its functions and powers, and as such assign high-level officials to it, where they make swift decisions about MCMs. Member States, through the Council, maintain most of the power while the Commission keeps the leadership of how measures are implemented. A clear definition of responsibilities would help avoid misunderstandings and transaction costs during emergency times.
R2. The relationship between the HSC and the HCB with regard to MCMs should be better defined, as both seem to have coordinating roles in the case of an emergency, despite the fact that the HCB will solely be working in the area of MCMs. Regulation 2372 specifies that the HCB and the HSC should coordinate, but the division of labour between them is still unknown, and the European Commission is now working on the details of the coordination. The difference in the mission and modus operandi of the HCB and the HSC might challenge their interaction and collaboration.

R3. It is necessary to clarify whether HERA, as a Commission service and in crisis mode, would set up a ‘crisis board’. The Commission Decision that established HERA does not mention a crisis board. However, the authors of this report have received conflicting information concerning the establishment of a HERA crisis board. Based on one source, HERA will transform its HERA Board into a HERA Crisis Board once the Council activates the emergency framework under Council Regulation (EU) 2022/2372. This means that HERA’s crisis mode is automatically activated alongside the emergency framework, yet there is no explicit mention of this mechanism in the law. Meanwhile, Regulation 2372 states that the HCB must coordinate with the HERA Board, implicitly assuming the HCB and the HERA Board will be two distinct and co-existing bodies.

R4. MCMs and PHSMs, and with them the activities of the HERA Board (in peace mode)/the HCB (in crisis mode) and the HSC, should be coordinated. Separating activities related to MCMs and PHSMs may be tricky, given the many overlaps between these fields. For example, for social distancing measures Member States have almost exclusive competence, with the ECDC providing only non-binding guidance (which was pro-actively requested and welcomed particularly by smaller Member States during the COVID-19 pandemic). Border closures, however, are subject to the Schengen Borders Code, and as such to a deeper coordination at the EU level. EU institutions should consider leveraging existing mechanisms to avoid fragmentation of measures across Member States in future public health emergencies.

R5. It would be important to provide a single point of contact for Member States wishing to raise an issue during an emergency. Member States can raise a health-related issue to the ECDC, the HSC, the EPSCO and even the IPCR if activated. The absence of a single point of contact may lead to additional complexity, with Member States wishing to raise an issue having to try parallel avenues with different existing platforms, bodies and forums until receiving sufficient attention.

Who advises on the measures to be adopted?

Scientific advice is an essential input in situations that require multidisciplinary thinking, technical knowledge and the ability to convert evidence and foresight into well-designed and communicated decision-making. The lack of rapid, effective advice emerged in many countries during the early stages of COVID-19. In the EU, the Advisory Committee on public health emergencies was first introduced in Regulation 2022/2371 and officially established under the Commission Decision C(2023)6017 of 11 September 2023. The Advisory Committee is tasked, if called upon, with advising the Commission and the HSC on the recognition and termination of a public health emergency at Union level and specific response measures. The Advisory Committee is expected to include experts from various disciplines, including epidemiology, social sciences and communication.

The Advisory Committee is not the only advisory entity that is operational during emergency times to provide advice. On the one hand, Article 5 of the Council Regulation 2022/2372 specifies that the HCB can appoint an ad hoc expert group to decide on specific issues (e.g., on the use of resources and measures to respond to a public health emergency). On the other hand, the ECDC (or other Union agencies depending on the public health threat) is tasked with carrying out a risk assessment of the potential severity of the threat to public health and possible public health measures. Scientific advice is also provided by the EMA in the form of health technology assessments, or benefit-risk assessments of newly authorised products. Finally, the ECDC can mobilise experts in the forthcoming EU Health Task Force (EUHTF).

While these advisory mechanisms have rather different mandates and scope of activities, there is no clear indication as to how they would interact in case their scientific opinion diverges. In the area of public health, there are advisory bodies at various levels, from the World Health Organization (WHO), ECDC, to national authorities and independent researchers and institutions. Chances that multiple, perhaps conflicting, opinions and recommendations on the same matter are circulating at the same time should not be dismissed.

At the same time, for key decisions to be adopted during emergencies – such as how to address key trade-offs (e.g., economic impacts versus health impacts in case of possible PHSMs) – it remains unclear which entity will process all information and recommendations and advise EU decision-makers. Possibly, this role would require a procedure to set up an ad hoc working group in the HCB (for MCMs only); the engagement of the HSC for PHSMs, or the involvement of crisis management structures with broader mandates such as the IPCR and the (strengthened) ERCC.

Possible improvements to the status quo may entail the following actions.

R6. Clarify the functions of different advisory bodies and ad hoc groups to avoid conflicting messages and recommendations during an emergency.
R7. Ensure adequate resources to the EMA, beyond what is provided for by Regulation (EU) 2022/123, for it to be able to sustain the proper functioning of the Emergency Task Force during emergencies, as well as to conduct adequate health technology assessments (HTAs) for crisis-relevant health technologies such as medicinal products, medical equipment or treatment methods. Regulation (EU) 2021/2282 has established a Coordination Group on HTA; yet such a group has no specific mandate in a public health emergency.

R8. Ensure that the ECDC has the ability to mobilise sufficient key experts for the EU Health Task Force to cope with large-scale public health emergencies, in a relatively short timeframe.

Who coordinates the monitoring of medical countermeasures?

The sourcing, distribution and delivery of MCMs are key activities during a public health emergency, and a lot of attention has been devoted to this domain over the past three years. At the EU level, two different bodies (EMA and the Commission/HERA) are in charge of related activities. More specifically, EMA is responsible for building a list of critical medicines and medical devices and mapping their potential shortages, whereas HERA (when in crisis mode) is tasked with gathering additional information on MCMs not already collected by EMA, and reporting monitoring results to the European Parliament, the Council and the HCB.

The joint operation of two institutions is, of course, not a problem per se. HERA informed the authors that the two bodies are in constant communication. However, two issues are worth mentioning.

First, both bodies are currently developing an IT platform to carry out their tasks. EMA is building the European Shortages Monitoring platform (to be delivered in 2025), and HERA’s Medical Countermeasures Intelligence Platform (to be set up in 2023). The two platforms are in the making, and it is of utmost importance that they are developed in a way that ensures interoperability.

Second, the activities of EMA and HERA depend on Member States’ willingness and ability to provide an overview of national stocks; as well as pharmaceutical companies’ willingness to share information on the stock, supply, demand, and potential supply chain bottlenecks of relevant MCMs and raw materials – during both preparedness and emergency phase. Data collection is proven difficult. Both Member States’ position during the meeting of the HERA Advisory Forum on 13 April 2023 and claims by the private sector that relevant data are protected by trade secret make it difficult for the EU to exercise its right to obtain these data, introduced by Regulation 2022/123 (and by the proposed pharmaceutical legislation).

In the future, the EU may have to sharpen its tools in this respect, along the lines of what other countries (e.g., the U.S. and Australia) have done.

The below actions will be needed.

R9. Ensure the effective implementation of the working agreement between HERA and EMA, maintaining regular communication between the two bodies, avoiding potential duplications in their data collection and ensuring the interoperability between their IT platforms.

R10. Ensure that Member States and pharmaceutical companies provide data on MCMs during both preparedness and emergency times, by leveraging Regulation 2022/123 (Articles 3 to 14 and 21 to 30 thereof), the forthcoming pharmaceutical legislation (Articles 116 to 126, Chapter X) and the Data Act (Chapter V).

Who funds and procures innovative medical countermeasures?

A public health emergency response must be accompanied by an effort to boost research and development (R&D) efforts on new countermeasures, as well as actions to secure existing ones. The COVID-19 pandemic was a revealing moment in this respect. The EU took many initiatives, including two emergency calls on Coronavirus research, the HERA incubator call for urgent research into coronavirus variants, and the launch of two European trial networks to ensure the development of MCMs to fight the COVID-19 pandemic. The procurement of COVID-19 vaccines started later than countries such as the U.S. and the United Kingdom, and this affected the scale and speed of vaccination in the first half of 2021. The Commission eventually managed to provide funding for innovative technologies such as mRNA, and strengthened its ability to jointly procure vaccines – although partly at the expense of transparency.

What would happen in the case of a future health emergency? In our opinion, there is still some uncertainty as to where R&D funding would come from. While Regulation 2022/2372 and HERA’s Work Plan for 2022 state that the EU’s health emergency activities should rely on the Emergency Support Instrument, the latter has so far been used mostly for non-research activities (e.g., procurement of vaccines and therapeutics, management of the Vaccine Steering Board, and detection and categorisation of COVID-19 variants). Instead, during the COVID-19 pandemic funds for vaccines development mostly came from the 2020 InnovFin Infectious Disease Finance Facility—which, whereas the funding of preparedness-related R&D activities is managed under Horizon Europe (€389 million for HERA’s 2023 R&D budget) and EU4Health (€86 million for the same). Horizon Europe and EU4Health also include funding opportunities for procurement of MCMs in emergencies. Complexity increases if HERA must coordinate with the bodies managing its funding programmes, such as

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3 Information relating to the preliminary negotiation process of the biggest COVID-19 vaccine contract signed by the Commission as of 2023 (with Pfizer/BioNTech) has not been made available to the European Court of Auditors as requested. Critical information of public interest such as unit prices, liability, and the amount of public funding support during the development phase has not been made available to the public either; raising concerns from, among others, the European Ombudsman.

4 For example, the EIB provided BioNTech with up to €100 million in debt financing for COVID-19 vaccine development and manufacturing; and the European Commission and EIB provided CureVac with a €75 million financing for vaccine development and expansion of manufacturing.
DG SANTE and DG RTD. The recent launch of the funding stream for HERA (HERA INVEST), while potentially improving HERA’s budgetary autonomy, features the European Investment Bank (EIB) as implementing entity under the InvestEU programme.

Additional sources of uncertainty are found in the procedures for joint procurement of MCMs, EU Regulation 2022/2371, while specifying the procedure at Article 12, is less explicit on the measures to be adopted to ensure transparency in the EU’s negotiation with pharmaceutical companies. In this respect, it bears recalling another measure adopted in the aftermath of COVID-19, i.e. the possibility of activating a network of warm production facilities for vaccines and therapeutics manufacturing (EU FAB). However, it must be recalled that the EU FAB is not a suitable solution for the next health emergency since it only lasts for eight years and (for now) applies only to vaccine production.

Finally, as a general comment, the menu of instruments available to EU institutions to mobilise R&D investment and secure the availability of resources in times of health emergency seems rather limited compared to other countries.

In summary, the following recommendations can be identified.

R11. The EU could rely on ‘at-risk’ investment, providing funds to support the development and production of MCMs even before they have been granted marketing authorisation (as in the U.S.’s Operation Warp Speed model).

R12. As suggested by the Chair of the European Parliament’s COVI Committee, the EU should consider introducing an emergency clause in its budgetary rules, mandating that different funding streams contribute to one single budget line (i.e. the Emergency Support Instrument) in times of emergency.

R13. The EU could also draw inspiration from the U.S.’s use of priority-rated contracts, i.e., measures aimed at re-shoring the production of critical inputs (e.g., active pharmaceutical ingredients, bioreactor bags, filters and tubes) through supporting innovative manufacturing technologies, as well as subsidies along critical supply chains and investment to scale up manufacturing capacity.

R14. The EU should consider reinforcing HERA’s budgetary autonomy and empower it to promote forward-looking support for R&D, facilitating the blending and sequencing of different funding programmes, including different levels of technological readiness.

R15. More specific rules and guidelines should be introduced to ensure transparency in the decision-making process of the joint procurement of crisis-relevant MCMs.

R16. The EU should work on an improved structure of the current EU FAB going beyond its current term of eight years, and on extending the categories of MCMs covered by the FAB beyond vaccines, for example including antivirals, antibiotics, personal protective equipment, and medical devices.

Who communicates policy decisions and fights misinformation?

Clear efforts were made to communicate to the public during the COVID-19 pandemic. Among other initiatives, the Commission established an ad hoc advisory panel in April 2020 and appointed a special advisor to the President of the European Commission as of May 2020. The ECDC also published remarkable amount of data, information, reports, infographics and videos about the virus and relevant MCMs and PHSMs.

Importantly, the pandemic also precipitated the circulation of misinformation and disinformation about the virus and vaccines, which widely spread across Europe through social media platforms and messaging applications. Several EU measures to control misinformation (such as the Code of Practice on Disinformation in 2018 and its modified version in 2022) proved insufficiently effective, mostly due to their voluntary nature and a lack of precise information at the Member State level. Mis- and disinformation led Europe (and the world) into an ‘infodemic’, which posed a comparable level of danger to the virus itself. In this respect, in the future the ECDC should be given more resources and play a more important role in disseminating scientific evidence and proposing measures to dismantle misinformation adapted to epidemiological circumstances.

Related actions include the following.

R17. The next European Commission and governments, through the implementation of Regulation (EU) 2022/2371, will have to seriously tackle the issue of scientific advice, foresight and communication, a key role to nurture in the age of poly-crisis. Otherwise, the public’s temptation to adhere to conspiracy theories and populist discourse will further distance the Union from its citizens, weakening the effectiveness of crisis response, among other things.

R18. A first step that the EU could take is to develop an all-round strategy against disinformation that includes a global dimension (e.g., through developing joint anti-disinformation plans or facilitating innovative technologies to identify misinformation) and a bottom-up channel (e.g., through boosting literacy and awareness in areas such as new media technologies and health, or supporting bottom-up dialogues).
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Conclusions

Ensuring that the EU can effectively respond to emergencies is a necessity. At the same time, no governance framework for health emergencies can be effective without adequate efforts to ensure its proper implementation. This will require adequate investment in preparedness and simulations aimed at testing the effectiveness of response plans under a variety of alternative scenarios, based on a comprehensive assessment of human, animal and environmental health trends (following a One Health approach). This is even more necessary as future public health emergencies may take different forms, and emerge from different threats. In addition, the human factor is crucial for the proper implementation of Regulation 2022/2371 and relevant EU legislation in the field: even the most comprehensive and effective institutional framework cannot achieve its intended effects in the absence of competent leaders, skilled personnel and a trusted relationship between all involved entities and stakeholders.

Since the pandemic, we have witnessed positive initiatives and reforms by the EU in the area of public health emergency prevention, preparedness and response. Understandably, given the novelty of most instruments and mechanisms, in our research we have found several areas where clarifications are necessary. Importantly, the 19 recommendations

Box 1: Summary of proposals of engagement for the European Union

- Clarify the relationship between the Integrated Political Crisis Response mechanism, the Health Crisis Board and (when appropriate) the Employment, Social Policy, Health and Consumer Affairs (EPSCO) configuration of the Council.
- Better define the relationship between the Health Security Committee and the Health Crisis Board with regard to medical countermeasures (MCMs), as both seem to have coordinating roles in cases of emergency.
- Explain whether Health Emergency Preparedness and Response Authority (HERA), as a Commission service, in crisis mode, would set up a dedicated ‘crisis board’.
- Coordinate the planning and delivery of MCMs as well as public health and social measures (PHSMs), to assess cumulative and interactive effects, and better integrate the activities of the Health Security Committee and the HERA Board (in peace mode)/the Health Crisis Board (in crisis mode).
- Provide a single point of contact for Member States wishing to raise an issue during an emergency.
- Clarify the functions of different advisory bodies and ad hoc groups.
- Ensure adequate resources for the European Medicines Agency (EMA) to sustain the proper functioning of the Emergency Task Force and perform rapid, effective benefit-risk assessments.
- Enhance the ability of the European Centre for Disease Prevention and Control (ECDC) to mobilise experts for the EU Health Task Force to cope with large-scale public health emergencies.
- Ensure the effective implementation of the working agreement between HERA and EMA, maintaining regular communication between the two bodies, avoiding potential duplications in their data collection and ensuring the interoperability between their IT platforms.
- Ensure that Member States and pharmaceutical companies provide data on MCMs by leveraging Regulation 2022/123, the forthcoming pharmaceutical legislation, and the Data Act.
- Rely on ‘at-risk’ investment, providing funds to support the development and production of MCMs even before they have been granted marketing authorisation.
- Introduce an emergency clause mandating that different funding streams contribute to one single EU budget line (i.e. the Emergency Support Instrument) in times of emergency.
- Consider introducing priority-rated contracts, i.e. measures aimed at re-shoring the production of critical inputs through supporting innovative manufacturing technologies, as well as subsidies along critical supply chains and investment to scale up manufacturing capacity.
- Consider reinforcing HERA’s budgetary autonomy and empower it to promote a forward-looking support to R&D, thereby facilitating the blending and sequencing of different funding programmes.
- Introduce specific rules and guidelines to ensure transparency in the decision-making processes of the joint procurement of crisis-relevant MCMs.
- Work on an improved structure of the current EU FAB, and on extending the categories of MCMs covered by the EU FAB beyond vaccines.
- Tackle the issues of scientific advice, foresight, and communication through the implementation of Regulation (EU) 2022/2371.
- Develop an all-round strategy against disinformation that includes a global dimension.
- As the EU works on its preparedness and response plan, it is important that the plan is put to the test in ad hoc exercises to ensure it can effectively be implemented when the emergency does occur.
presented in this article do not require a Treaty change. Nevertheless, we encourage the forthcoming Belgian presidency of the Council to consider relaunching the debate on a possible Treaty reform. This, if properly undertaken, could bring more coherence and a stronger multilevel governance in the domain of health, and enable a stronger legal basis for the implementation of response plans. For example, Council Regulation 2022/2372 is based on Article 122 TFEU, which empowers the Council to adopt emergency measures, yet does not involve the European Parliament in the decision-making process. This is a measure originally conceived for exceptional situations; however, as crises become more frequent and intertwined, such an emergency mechanism cannot become a routine modus operandi.

R19. As the European Commission works on the Union preparedness and response plan as required by Regulation 2022/2371, it is important that the plan is tested through ad hoc exercises to ensure it can be successfully implemented when an emergency occurs. These exercises are particularly necessary to measure coherence between the Union and the national preparedness and response plans (Regulation 2022/2371 requires that Member States seek coherence with the Union plan ‘to the largest extent possible’). They can be supported by the EU4Health Programme, and should involve local, regional and high-level decision-makers.

References

BUILDING CAPACITY AND IDENTIFYING APPROPRIATE SUPPORT: HOW CAN THE EU CONTRIBUTE TO SECURING RESOURCES FOR HEALTH SYSTEMS?

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Summary: European health systems face increasing challenges and demands, while striving to provide high-quality care. The European Union (EU) offers support to complement national efforts, but accessing and utilising it can be challenging for Member States. Austria, Belgium, and Slovenia are collaborating on a multi-country project supported by the EU’s Technical Support Instrument, to create an EU Health Resources Hub. This advisory service aims to help Member States access EU funding instruments for their health needs. This article discusses the project’s goals and early learnings, offering insights that could inform future health funding opportunities and policies in Europe.

Keywords: Investment, Health System Strengthening, Capacity Building, Technical Support Instrument, EU Funding

Introduction

European health systems may be different, but they share common values, challenges, and priorities for transforming their health systems including strengthening the health workforce, greening the health sector, advancing digitalisation, and better integrating healthcare. In this context, adequate funding is key to ensure sustainable, innovative, and resilient health systems. While health systems are primarily a competence of the Member States, the European Union (EU) can provide support for strengthening health systems and complement national activities in the area of health policy. Specifically, funding beyond what is available at country level, including EU instruments, can facilitate much needed reforms and investments in health and health systems. However, as previous European Observatory on Health Systems and Policies (Observatory) publications highlight, when it comes to health, most EU funding instruments are presently fragmented and challenging for policymakers to access and navigate.
The Observatory conducted a mapping exercise to identify relevant EU instruments that match the reform priorities that Austria, Belgium, and Slovenia chose for this project and developed a hands-on manual for each country. The three Member States have chosen pilot projects (see next section) where the realisation is crucial for current reform efforts on the one hand, and which will serve as an exercise to gauge how the EU can best support its Member States when they seek funding opportunities for health on the other. These pilots will inform the process of conceptualising the “One Stop Shop” for EU funding for health, a “EU Health Resources Hub”, to supply these services. In the process of building this EU Health Resources Hub, tailor-made approaches are developed through technical assistance and capacity building, targeting: 1) Project Inception and Scoping, by supporting Member States in developing concepts based on first ideas on the health policies to be implemented; and 2) Project Development and Financing, by supporting the selection of the EU funds to apply for, and by advising on strategic blending of different funding mechanisms.

**Box 1: What is the Technical Support Instrument?**

Through the Technical Support Instrument (TSI), DG REFORM helps EU countries design and implement reforms that support job creation and sustainable growth. The technical support offered is tailor-made and can take the form of, for example, strategic and legal advice, studies, training, and expert visits. The application process runs on a yearly basis and is very simple, requiring submission of a short request on behalf of interested Member States. Key assessment criteria (as defined by the TSI regulation) include the urgency and scope of the challenges listed in a request and how the support requested matches the priorities, as well as the institutional and administrative capacities of the Member State involved. The added value of the TSI consists in accompanying, on the ground, the authorities undertaking reforms throughout the reform lifecycle: from working closely with them in designing the reform, through its preparation and all the way to implementation. In doing so, it offers tailor-made support to the Member States and promotes the implementation of reforms with measurable impacts at national level. There is no requirement of co-financing.

Health has become a more prominent Commission priority following the COVID-19 pandemic and thus DG REFORM will continue to focus support to Member States carrying out reforms of their health systems. DG REFORM currently supports over 40 health reforms in 21 Member States.

**Member State pilot projects: Reaching EU funding for greener, more integrated, and needs-driven healthcare**

The Austrian pilot “Greening Health Care Facilities” focuses on reducing the environmental impact of the healthcare sector, particularly in the area of hospital infrastructure. With a share of 7% of the national CO2 footprint, the Austrian healthcare sector generates significant emissions and is thus an important target for achieving the federal government’s goal of climate neutrality by 2040 and fulfilling international commitments to reduce greenhouse gas emissions. Substantial investments are needed to increase the environmental sustainability of healthcare facilities. Therefore, the objective of the project is to identify suitable funding opportunities on the EU level for climate projects (such as implementing energy efficiency measures) in selected hospitals. The pilot project further foresees the formulation of recommendations for the potential combination of different funding mechanisms as well as support for hospitals during the application process. Participating hospitals can apply in two phases – in autumn 2023 for already well-defined projects and in spring 2024, benefitting from the knowledge obtained in the first phase of the pilot.
The Belgian pilot, “Building a digital dashboard to support the implementation of Population Health Management (PHM) at locoregional level”, has been drawn up in the context of an inter-federal plan on integrated care to be implemented from 2024 onwards. PHM is crucial for improving integrated care and a data-driven population needs-based approach has the potential to strengthen prevention, provide tailored care and thereby improve health outcomes. This innovative approach requires both investments to build capacity in different areas as well as developing the necessary data and IT infrastructure to support its implementation. The European Health Data Space will serve as an essential framework in this regard. The pilot is thus composed of two stages. The first is centred around capacity-building and bringing together key actors and expertise to facilitate learning from existing examples of databases and dashboard development, including their application for PHM. This preparatory stage is conducive to the success of the subsequent dashboard design and implementation. The second stage focuses on creating the digital infrastructure to integrate health, social and other data sets from different sources into a single dashboard.

Primary healthcare has a central role in the Slovenian healthcare system. The increase in demand for primary care services has exacerbated since the pandemic and is compounded by a lack of healthcare professionals, in particular family medicine specialists. Given the current situation, the Slovenian pilot on “improving access to primary care” aims to achieve this by broadening the scope of the existing national call centre to include telephone triage and advice. A more general standardisation of triage guidelines is also needed, in particular related to non-urgent conditions relevant to primary care. Hence, the project also foresees the establishment of a training programme for a large number of primary care nurses. Furthermore, the pilot project will explore the possibility of establishing a centre for coordination and development of primary healthcare. The main purpose of such a centre would be to streamline the implementation of organisational, technological, and professional innovations in primary care with a nationally coordinated approach. All the elements of the pilot are set to fit the digitalisation and primary care strengthening agendas supported by the Ministry of Health.

Mapping the range of EU instruments
Overall, there is a wide range of EU instruments with the potential to support the chosen pilot cases, which have different thematic priorities, but all broadly seek to leverage investments for different types of infrastructure, digital solutions, and training opportunities. Notably, the mapping identified several instruments of different (budgetary) size and potential to support projects in the areas of Research & Training, Infrastructure & Climate, and Digital (see Figure 1). These instruments are all subject to different types of management, timing, application, and eligibility criteria. The EU instrument landscape is composed of a mix of funds that are programme-based, like EU4Health, Digital Europe or Erasmus+;

![Figure 1: Comparative overview of relevant EU funding mechanisms by budgetary size and type of support provided](image)

Note: This figure does not seek to provide a comprehensive mapping of all available EU funding and only includes those instruments which have been identified as being relevant for the three chosen pilot cases. Funds are allocated according to the area of intervention they are more likely to support within the three given pilots. They may however also be relevant for other interventions (e.g., EU4Health could be relevant for Digital, given that it provides funding for the development of the European Health Data Space).

Source: Authors’ own
Operational programme-based, like the Cohesion Policy Funds; or demand-driven investment instruments, like InvestEU or the support provided by the European Investment Bank (EIB). Some of them primarily fund multi-country projects like Horizon Europe and EU4Health, while others are focused at promoting country-level initiatives, like the Recovery and Resilience Facility and the Cohesion Policy Funds.

"Blending various European and national funds is usually required"

Generally, a single EU funding programme will not have the remit (or the capacity) to fund complex health system projects in their entirety, hence blending various European and national funds is usually required. Thus, when planning a project, it is crucial for Member States to have an understanding of different EU funding instruments’ scopes and deadlines and how they can be aligned. The TSI project on the EU Health Resources Hub also explores avenues for policymakers to make the case for and leverage health investment at national level (see Box 2).

**Box 2: Making the case for public investment in health**

The first strand of work in the TSI project aims to strengthen the capacity of Member States to make the case for public investment in health at the national and EU level and demonstrate clear evidence of the socioeconomic benefits of already undertaken or planned strategic public investments in health. The Observatory conducted an exercise to identify relevant analytical approaches and tools to promote greater alignment between health and financial objectives, and thus better make the case for public investment in health. These tools typically fall under five cross-cutting arguments that address common public financial management concerns and objectives:

1. Health systems investments address health needs and improve health; and without adequate funding, there will be consequences to population health outcomes and wellbeing.
2. Health system investments further societal goals and have co-benefits beyond the health sector (e.g., education, employment, economic, equity, and social cohesion benefits).
3. Health system financing can (or will be) sustainable following additional investment.
4. The health system has the capacity to use additional resources effectively and efficiently.
5. The public (particularly voters), non-governmental organisations (NGOs), and civil society groups care about health and health system-related issues, and think more funding is needed.

Data and evidence can guide and steer decision-makers towards informed investment choices, but political will, engagement, cooperation, communication, transparency, accountability, and trust are essential in driving the budget case for health forward successfully. For more information, please refer to the full report.1

**Box 3: Designing EU advisory services to support implementation**

Over the years, the EU has established different types of advisory services for its Member States. The aim of this TSI project is to fill this gap, given that no identified advisory services are specifically dedicated to health and that they do not necessarily align/match the needs, priorities, and timing of projects with the application scopes and objectives of specific EU calls/funding instruments. This is in line with the Council Conclusions (2021/C 512 I/02) which invited the Commission to “strengthen the coordination across the EU programmes and policies to support more effectively the implementation of national health systems reforms with all available EU mechanisms” and “explore the provision of an advisory service” to that effect.

Yet, among the available advisory services, none are specifically dedicated to health systems and most target large loans or infrastructural projects (e.g., the InvestEU Advisory Hub). These findings confirm a gap in the current EU advisory service landscape and highlight the need for an EU Health Resource Hub dedicated to health reforms, which would aim to avoid duplications and ensure synergies while considering existing structures and services offering technical and financial support to Member States in strengthening their health systems (see Box 3).

The results of the mapping exercise for relevant EU support instruments are informing the pilot phases in Austria, Belgium, and Slovenia. Where suitable funding opportunities can be identified
within the given time frames in the TSI project, the emerging Health Resource Hub (carried within the project by Expertise France) will support the Member States with developing their applications for funding. Despite the diverse EU funds that theoretically match the selected thematic priorities identified in the mapping, only a limited range of instruments could be potentially relevant to the participating Member States’ specific pilot projects. The probability of accessing available funding is further dependent upon the current framework conditions under which these instruments operate, including tight application windows and lengthy processes, which can intensify the administrative burden already placed on the competent national authorities as well as the expected budget of the project. While the activities performed under this TSI project do not guarantee Member States access to EU funding, they aim to build crucial hands-on experience which will contribute to capacity building, as well as guide the design and delivery of a sustainable advisory hub for health systems’ transformations in Europe beyond the project’s end.

Outlook on future health priorities

While this TSI project focuses on the three participating Member States, it aspires to pave the way for others who face similar, shared challenges to access the EU funding opportunities they need. Raising sufficient funding for health systems will depend on making a convincing case at the national level but also at the EU level to secure complementary funding to address these challenges. A good knowledge of the funding landscape, including specific timelines and opportunities, is at present essential to navigate this process successfully and pool available resources to maximise health outcomes. In the future, support can be provided by an EU Health Resource Hub that is based on the experiences gathered in the project.

While the range of EU instruments is broad and their potential to address different health system priorities seems high in theory, the work conducted as part of this TSI project has also uncovered some important gaps. To date, the scope, as well as the eligibility criteria, timing and rules underpinning some of these instruments have been difficult to reconcile with the capacities, objectives, specificities, and timelines of Member States – for their chosen pilot projects in particular. Beyond the scope of this TSI project, these findings raise potential questions for the mandate of future EU Commissions concerning the suitability of the current EU funding landscape to fund health projects in Member States, to address those major challenges like prevention, digitalisation, and health workforce training, and to improve access to available instruments in the future. A summary of implications for future health priorities are highlighted in Box 4.

As the European elections draw closer and the new Commission takes charge of defining funding priorities for the next Multiannual Financial Framework, these findings shine a light on the progress made with leveraging EU support for health systems. At the same time, the challenges encountered reinforce the call for an EU Health Resources Hub that would enable Member States to use existing instruments more easily, while the framework conditions governing existing instruments may merit closer examination against Member States’ specific needs to ensure access to the required support can be bolstered and health can play a central role in Europe’s future policy and funding frameworks.

References


Box 4: Summary of implications for future health priorities

- The ongoing TSI project on the development of an EU Health Resource Hub is collecting valuable experiences towards creating a one-stop-shop that helps Member States access EU support instruments to strengthen their health systems
- In addition, future EU Commissions could consider whether current EU support instruments are sufficiently tailored to address health system needs.

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EU JOINT ACTIONS 2.0: A BOOSTER FOR HEALTH IN THE EU?

By Laurence Ballieux, Silke Baumann and Guy Dargent

Summary: Since 2008, the Joint Action (JA) mechanism in the EU Health Programme has been promoting collaboration among Member States. This article assesses whether it is well-equipped to strengthen European collaboration in the post-COVID world and suggest ways in which the Commission can further improve this instrument. They can have a significant impact on health policies in the EU, yet challenges remain related to sustainability, administrative burden, and co-financing structure. In order to contribute to the EU Health Union, we believe they need to become more politically driven, outcome-focused, and contribute to a comprehensive long-term vision regarding the role of health in the EU.

Keywords: Joint Action, EU Health Programme, Collaboration, EU4Health, EU financing

Introduction

European Union (EU) Member States share similar national challenges to enhance public health and strengthen health systems performance including strengthening crisis preparedness, the health workforce, and digital health, and tackling non-communicable diseases among many others. Member States could gain significant benefits by identifying those challenges that could be addressed better by joining forces and developing collaboration to tackle these challenges together.

Throughout the years, the Commission and Member States have already developed various instruments to facilitate collaboration in health policy. One of these was the creation of the Joint Action (JA) mechanism in 2008 within the EU Health Programme (see Box 1).

This article will first discuss JAs as a funding mechanism by explaining how the policy priorities are identified, and their goals and expectations established. Next, the benefits and challenges of JAs are analysed. In preparation, group discussions were held with representatives from selected Member States (National Focal Points or EU4Health Steering Group Members), with representatives from Belgian institutions active in one or several JAs, as well as an interview with experts at HaDEA (Health and Digital Executive Agency). The article concludes with proposals for more effective EU engagement.

The authors would like to emphasise that while the analysis is not exhaustive, it is based on their long-standing experience with the JA mechanism. The objective of this article is to put the issues on the table to start a constructive discussion between the Commission and the Member States...
JAs can have different objectives, such as addressing pressing issues like mental health, health workforce and crisis preparedness, collaborating on joint projects such as Health Technology Assessments (HTA), or providing support in policy preparation (European Health Data Space) and implementation (EU Beating Cancer Plan).

They have an impressive track record* for bringing Member States together around common objectives. The COVID-19 pandemic drastically increased the need for collaboration on public health in Europe. Concurrently, the EU Health Programme's budget was increased by almost 12 times, from €449 million in the 2014–20 programme to €5.3 billion in the current 2021–27 Multiannual Financial Framework. As a result, the Commission can now provide more budget for each JA. Previously, a typical JA was co-funded for €2–3 million. In 2022, the Commission proposed a JA on non-communicable diseases and cancer with a maximum co-funding contribution of €75 million and in 2023, the maximum co-funding for one JA reached €90 million.

What are the goals and expectations of Joint Actions?

This increased budget presents significant opportunities, but it also comes with high expectations, notably from the Member States. The objective is to have a tangible impact at the national level that benefits European citizens. This impact at national level is important as public money is involved, and should be used appropriately and efficiently.

However, is the JA mechanism up to this job? The next part of this article will assess whether the JA mechanism is well-equipped to strengthen European collaboration in the post-COVID world and suggest ways in which the EU can adapt this instrument to meet these new challenges.

The technical nature of the mechanism

JAs are inherently voluntary, and hence they can only have an impact if there is a high level of political leadership and clear objectives that drive the initiative. The choice of a JA topic is political, linked to the objectives identified in EU4Health. The Commission initiates them with a clear societal objective in mind. The priorities in the annual work programmes are of a political nature, whereas the implementation of the JA focuses more on technical aspects. There is a risk of gaps between political and technical levels. It is therefore important to keep the health administrations informed and ensure political support in all stages of the JA process.

Before the beginning of the Joint Action (preparatory phase)

Scope of the Joint Action/Preparation of the annual Work Programme – Once a JA topic is determined and published in the Annual Work Programme, the administrative preparation starts. It’s worth noting that the application preparation falls under the responsibility of participating Member States, while the objective and scope of the JAs are only defined at a very general level. The way the information is provided is often not conducive to convince policymakers to invest in this collaboration, and neither does it help in determining who should be involved.

Application process – It falls under the consortium of participating Member States to set up the concrete design of a JA (work package content, etc). However, according to the National Focal Points, the Member States, comprising the leader and participating countries, typically also only have three to four months to prepare their application. This limited timeframe is deemed insufficient for setting up the JA appropriately, often resulting in a compromised quality of the proposal.

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* For instance, during the 3rd Health Programme, there were 33 countries participating in JAs (each country was involved on average in 10 different JAs).
We believe that JAs would benefit from more comprehensive preparations (even before the Member States have to make decision about their participation) leading to proposals that can persuade ministers and high-level policymakers to become active in this European collaboration, including providing the necessary co-funding and resources.

During the Joint Action

Budget – We already indicated that the EU4Health budget has been significantly increased in response to the pandemic. As a result, each JA – in general – now receives a higher budget. While this may positively influence the impact of these actions, this also puts a greater financial burden on Member States to provide the necessary co-funding. Currently, Member States are required to co-fund either 20% or 40% of the total budget, depending on certain criteria. However, doing this several times may stretch the budget of the ministry of health/competent authority and its affiliated entities.

Administration – Preparing and participating in JAs involves a lot of administrative work for the beneficiaries. Although the authors recognise that this is necessary for transparency and accountability, it has become a significant burden. The detailed time sheets were frequently mentioned as an example. It seems that Member States often choose not to participate in JAs because of the administrative burden involved. An administrative system that emphasises both transparency (project progress, etc.) and cost-effectiveness/efficiency would be beneficial in this matter.

Furthermore, the quantity of JAs significantly affects the administrative workload. Managing the participation of the health administration within the Member States for an increasing number of JAs with increased budgets for many of them makes a significant difference, not only for smaller countries.

Lastly, we have seen that it has become more difficult to find an authority which is willing to act as the coordinator in the large JAs. Given that a larger budget is at stake, which means more activities during the JA, the role of coordinator is becoming increasingly difficult for some Member States. This function should be made more attractive with greater support provided by HADEA.

After the end of the Joint Action

Sustainability – After three years, the project comes to a conclusion. At this point, much expertise has been accumulated, and the outcomes are disseminated through reports, websites and conferences.

Unfortunately, there is not always a sustainable long-term platform for these initiatives (not all actions request however a follow-up), the substantial investments made by the Commission and Member States in these fields often disappear.

Europe has, however, shown that there are alternative ways to approach this challenge. For instance, the European Centre for Disease Prevention and Control (ECDC) was created through a collaboration of various European networks and projects that aimed to address communicable diseases. Additionally, the HTA regulation was developed through multiple JAs and was established as a legal framework for Europe. What’s more, the HTA JAs brought together numerous Member States and key European stakeholders, enabling wider dissemination to the target audience.

Proposals for more effective EU engagement

JAs already have a significant impact on health policies in the EU. However, if we want them to contribute also to the development and strengthening of the EU Health Union in the future, we believe they need to become more politically driven (as public money is involved), outcome-focused, and contribute to a comprehensive long-term vision regarding the role of health in the EU. The upcoming section will suggest structural changes to the JA mechanism that align with this perspective. Please note that these suggestions are interconnected and should be read in their entirety.

1. Create political ownership, clear objectives, impact assessment process, and monitoring for each Joint Action

Member States who opt to participate in a JA receive significant financial support from the Union in return, thanks to the increased budget in the EU Health Programme. At the same time, they commit to contribute for a three-to-four-year period to the joint work and to provide co-financing. The significant amount of funding as well as the effort and workload spent in JAs demands a sustainable impact and clear objectives with a stronger political commitment.

Although Member States are involved in the development of the annual work programmes as described above, the subjects and goals of JAs are designed by the Commission according to its political agenda and do not necessarily mirror Member States’ political preferences. We feel that closer involvement of Member States in the decision making and topic setting for the annual work programme could encourage stronger political support from the health ministries for the JAs and drive to make active changes in national policies.

It is important to know what has been accomplished by the JAs, especially when compared to their ambitious political goals. A regular reporting on this within the EU4Health Steering Group could be a first step in this direction.

HADEA and the Commission will initiate a mid-term evaluation of the EU Health Programmes. This should include an analysis of gaps and could be an opportunity for all the Member States to reflect with the Commission around the results of these projects.
2. Invest in the preparatory phase

Many challenges with the set-up of a JA originate in the preparatory phase. To address these challenges, it is essential to improve and better support this preparatory phase. By doing so, Member States can prepare a project proposal with great care and diligence, which will attract high levels of political attention.

Funding the preparatory phase to help the Member States building the JAs would be essential even if the payment would be retroactively given after the signing of the grant agreement.

Thorough preparation within national institutions (ministries and other entities) is also essential to create ownership and interest inside the ministry with all the responsible divisions and divisional leads. This could facilitate the process at national level (determining national objectives for participation in the JA, determining the resources to be put in place, having discussion with policy makers and at the political level to convince them, having discussion with national stakeholders even though they will not be part of the JA, etc). It could contribute to a more streamlined process and better implementation at national level.

3. Simplifying administration

To improve JAs, reducing the administrative burden is crucial. This can be done by shifting the accountability and evaluation framework towards focusing on the achievement of predefined objectives instead of monitoring the inputs.

More technical and co-coordinative support could be given by HaDEA (or an external body) to the coordinators and participants of the JAs. It could also take over coordination tasks and thus reduce the burden of the coordinators and harmonise the administrative framework of the different JAs.

4. Budget

It is crucial to restructure the budget framework to establish a more efficient and viable system. First, the current co-financing structure has reached its limitations due to the budget increase in the EU Health Programme. Member States are facing constraints in their involvement in JAs as they are often unable to provide the required resources. Transitioning towards up to 100% EU-funded JA mechanism (for the next Multiannual Financial Framework) would allow Member States interested in participating to do so. However, despite this change in funding, it is important that EU Member States retain ownership and responsibility for the progress, results and impact of the JA at EU and national level.

Second, another way to streamline the process would be to implement a new payment mechanism (for example a lump sum). This system of lump sum payments (which are already in place for certain Horizon Europe projects (see Funding & tenders) involves creating a grant agreement that outlines the specific ways in which the grant must be spent, and what progress ought to be expected as a result. The beneficiary submits a report at the end of an agreed period where they give an overview of their spending and their outputs, and as long as this is according to the grant agreement, the lump sum is paid in full.

Working with a reduced administrative mechanism (for example a lump sum) and putting the focus on the achieved outputs instead of the process could be beneficial for the Member States. This approach provides greater flexibility for the beneficiaries while focusing on achieving the set outputs. This would also alleviate the administrative burden.

References


Box 2: Summary of proposals for more effective EU engagement

- More political ownership through closer involvement of the Member States in decision making and topic setting. More engagement to achieve tangible results at EU or national level.
- Clear process for impact assessment of the Joint Actions
- Deepen and extend the preparatory phase (also at national level) and to fund it
- Simplify administrative tasks (e.g. more administrative support, use of another budget mechanism like a lump sum)
- Up to 100% financing from the EU.
State of Health in the EU Country
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