TOWARDS A EUROPEAN HEALTH UNION: NEW INSTRUMENTS FOR STRONGER AND MORE RESILIENT HEALTH SYSTEMS

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Summary: The pandemic has underlined that many of today’s challenges to health systems are shared, prompting the European Commission to put forward proposals for a stronger European Health Union. While the primary objective is to strengthen the European Union’s health security framework in response to cross-border threats, this is accompanied by a renewed and wider political commitment to improve European health systems and invest in their sustainability and resilience. This momentum has started to take shape in the instruments under the new Multiannual Financial Framework and raises questions on how EU health action may unfold and evolve in the coming years.

Keywords: European Health Union, Preparedness and Response, Health Security Framework, Health Systems, COVID-19

Introduction

Since the inception of the European project, the planning and delivery of health care has primarily been a Member State competence. In recent years, diverse cross-border challenges, including rising antimicrobial resistance and new infectious threats like COVID-19, have started to impact on the capacity of national governments to respond, jeopardising the provision of health care in Europe. While the ongoing COVID-19 pandemic is not the first shared challenge, it is the most devastating to date, with a death toll of over one million in Europe alone. In the early stages of the pandemic, governments’ responses were often uncoordinated and marked by a wave of border closures and supply chain challenges. Among shortages of medical countermeasures and the exhaustion of hospitals and intensive care units, most European Union (EU) Member States reverted to nationwide lockdowns over several weeks and months. The resulting social and economic devastation has underscored the collective need for better monitoring, testing and contact tracing capacities, as well as more flexible, stable, and rapid supplies of medicines and protective equipment.

Although European solidarity and cooperation has been progressively reinstated, the pandemic has brought...
attention to the shortcomings of existing preparedness and response frameworks at both national and EU levels. While the sovereignty of Member States and the principle of subsidiarity as anchored in article 168 of the Treaty on the Functioning of the European Union (TFEU) remain uncontested, the pandemic has underlined that many of today’s challenges to health systems can no longer be overcome by national states alone and adds to calls for a stronger role of the EU in health.

A European Health Union on preparedness and response?

Six months into the pandemic, on occasion of her yearly State of the Union address, the President of the European Commission, Ursula von der Leyen, called for the creation of a European Health Union with a focus on expanding the Union’s preparedness and response capacities. The commitment to strengthening EU mechanisms to better protect citizens in the event of future health adversities took shape in the European Commission’s Communication on “Building a European Health Union” in November 2020. This document delineates a first proposed action plan envisioning a better coordination of preparedness and response mechanisms at EU level.

The Communication draws on the lessons learnt from the EU’s pandemic response, putting forward four main proposals in line with current EU treaty provisions (see Box 1). These include a new Regulation on serious cross-border health threats, upgrading the current legal provisions made under Decision 1082/2013/EU, the expansion of mandates for two of the EU’s existing agencies (the European Medicines Agency, EMA and the European Centre for Disease Prevention and Control, ECDC) and finally, the creation of a new Health Emergency Preparedness and Response Authority (HERA). These are discussed in the corresponding sections, below.

A series of consultations were held in late 2020 and the first half of 2021 to gather public and stakeholder feedback on the European Health Union proposals.

This was followed by the initiation of negotiations with the European Parliament and the Council. On 28 October 2021, the Council and European Parliament reached a political agreement on a new mandate for the EMA, with its formal adoption expected by the end of February 2022. This was closely followed by a political agreement on a second Health Union pillar, the broadening of the ECDC’s mandate, on 29 November 2021. Negotiations to find a consensus on the Regulation on serious cross-border threats to health are still ongoing.

Civil society actions welcoming the Commission’s efforts to strengthen EU action on health have started to emerge in parallel. The proposals are wide ranging, with some praising a strengthened health security framework and calling for the development of a common Global Health policy, over ten years after the EU’s Global Health strategy was first defined and last updated. Others like the European Health Union initiative go one step further, proposing a juridical basis for the EU to protect and secure European citizens’ health, which may require the revision of European treaties to enhance EU legal competence on health policy. While supporting the proposals of the European Commission to create mechanisms for concerted action on cross-border health threats and better prepare for the next pandemic, the initiative’s Manifesto (see Box 2) advocates for an ambitious longer-term vision beyond a European

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**Box 1: Commission Communication on Building a European Health Union**

Commission Communication on “Building a European Health Union: Reinforcing the EU’s resilience for cross-border health threats” proposes to:

- Adopt a Regulation on serious cross-border threats to health, repealing and upgrading Decision 1082/2013/EU
- Extend the mandate of the European Medicines Agency (EMA)
- Extend the mandate of the European Centre for Disease Prevention and Control (ECDC)
- Establish a new Health Emergency Preparedness and Response Authority (HERA).

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**Box 2: Manifesto of the European Health Union initiative**

The Manifesto, which has received more than 1,270 signatures to date, is a document endorsed by experts and relevant organisations calling on the political leaders of Europe to commit to creating a European Health Union, which should not be exclusively framed as a response to the pandemic. The Manifesto points to some of the weaknesses within existing mechanisms for collaboration between Member States and with the European institutions and sets out a vision of a European Union, which protects the lives and health of all. Its main goals are to:

- Strive for health and wellbeing of all Europeans, with no one left behind;
- Strengthen solidarity within and among Member States with particular attention to the needs of disadvantaged populations;
- Ensure environmental sustainability by adopting the European Green Deal;
- Provide security for all Europeans, protecting them from major threats to health;
- Enable everyone’s voice to be heard, so that policies affecting their health are created with them and not for them.
Health Union framed as a reaction to the shocks of COVID-19, placing a strong emphasis on the rights of individual states to shape such a union. Accordingly, it envisages a European Health Union which champions national, European, and global solidarity, strives for the promotion of healthy living and working standards, as well as wellbeing and equality, and fashions people-centred policies that prevent disease and protect health for all.

many challenges to health systems can no longer be overcome by national states alone

Building a solid European Health Security Framework

Decision 1082/2013/EU is the EU’s current legal framework for serious cross-border threats. Among other things, it forms the basis for Joint Procurement Agreements for medical countermeasures, which have allowed Member States to procure medicines, personal protective and medical equipment in past outbreaks and the current pandemic.\footnote{Within the scope of Decision 1082, Member States are required to present their preparedness and response plans for review by the European Commission in 3-year intervals. However, at the start of the pandemic, many of the national plans were inadequate and poorly updated, leaving Member States grappling with overwhelmed health systems, while also highlighting gaps within the Decision framework and the lack of legal instruments at the disposal of the Commission to ensure Member State compliance. It was the deficiencies unveiled by the pandemic that spurred plans for a new Regulation, which foresees a stronger and more comprehensive legal framework for the Union to prepare and respond to serious cross border threats and public health emergencies. This includes strengthened preparedness planning at EU level, rules for a flexible and more integrated EU-level surveillance system, increased capacity of the EU and its Member States for risk assessments and targeted action. Finally, the proposal envisions the development of a binding EU pandemic preparedness plan, allowing the Commission to recognise and declare a future health emergency at EU level and thereby trigger the adoption of common measures and specific response mechanisms. The proposed Regulation supports actions eligible for funding under the EU4Health programme (described in further detail below). Its legal basis, TFEU Article 168, and focus on biological, chemical, environmental, and unknown threats, remain unchanged.}

Strengthening EU agencies: EMA and ECDC

As part of the Commission’s proposals for a mandate expansion, the EMA will oversee the coordination of clinical trials and studies on vaccine safety and effectiveness within the EU, as well as the issuance of scientific advice on pharmaceuticals. Its role will also extend to monitoring and mitigating medicine shortages in the future.\footnote{During the ongoing COVID-19 pandemic, the ECDC has been hampered by lack of access to data and a limited capacity to respond adequately to large-scale disease outbreaks. To remedy this, the mandate of ECDC will be extended to monitor Member States’ health systems capacity and assess preparedness gaps, to develop and review frameworks for preparedness plans, as well as to establish an improved Early Warning and Response System and monitor the level of vaccination coverage against major communicable diseases across Member States. Among its newly gained responsibilities are also the issuance of concrete recommendations to coordinate Member States’ responses, the establishment of a reference laboratory network for crisis-relevant advice on new pathogens and an EU Health Task Force to assist Member States in response to outbreaks of communicable diseases.}

Creating a new authority to coordinate preparedness and response mechanisms

The Health Emergency Preparedness and Response Authority (HERA) is planned to fulfil a broad set of tasks to facilitate the coordination of preparedness and response mechanisms at EU level. Specifically, its functions will range from identifying promising new medicines and technologies, to supporting their development and expanding EU manufacturing capacity. It will address supply chain weaknesses and ensure raw material availability. In order to rapidly activate response mechanisms, it will continuously monitor emerging biomedical issues (e.g., new or re-emerging pathogens), as well as coordinate emergency procurement and the rapid deployment of medical countermeasures. Finally, it will complement the Commission’s current efforts to establish medical reserves through the RescEU stockpile, an integral part of the European Civil Protection Mechanism, and ensure EU-wide access to such reserves.\footnote{As part of the HERA package, the Commission submitted a proposal for a Council Regulation on a “framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level” in September 2021. This includes the monitoring, procurement, purchasing and manufacturing of crisis relevant medical countermeasures, as well as the activation of flexible manufacturing facilities and emergency research and innovation plans. The proposal also envisions establishing an inventory for crisis-relevant medical countermeasure production facilities and the facilitation of emergency funding. A political agreement was reached in December 2021.}

Beyond pandemic preparedness: Strengthening health systems in the European Union

The new Multiannual Financial Framework (MFF), which determines the allocation of EU funds to the various EU programmes and projects over a seven-year financial period, was launched earlier this year and is heavily influenced by the consequences of the pandemic. It has
reserved substantial sums for the economic and social recovery of Member States through the Recovery and Resilience Facility (RRF) and the Cohesion Policy Funds, as well as specifically for health through the new €5 billion Health Programme (EU4Health), the Research Programme (Horizon Europe) and the EU’s existing emergency response mechanisms, such as RescEU for medical stockpiling.

The heightened consensus for joint health action at EU level has also pervaded areas other than pandemic preparedness and response, with the European Commission currently in the midst of implementing an ambitious plan to fight cancer, the €4 billion Europe’s Beating Cancer Plan (actions funded through the EU4Health, Horizon Europe and Digital Europe programmes), and concrete plans for the modernisation of the EU’s pharmaceutical framework to enhance the resilience of medicine provisions and markets in Europe, as well as to better address unmet therapeutic needs for patients. These and other actions are receiving funding from EU4Health, which focuses on four main priorities. Beyond crisis preparedness, it will concentrate on disease prevention, health systems and the healthcare workforce, and digital health, with a transversal focus on cancer. The EU4Health 2021 work programme supports a wide range of actions of relevance for national health systems along each of these priorities: from grants to strengthen infectious disease surveillance capacities and mitigate medicine shortages to the prevention of non-communicable diseases, including actions dedicated to mental health, primary care and the promotion of healthy lifestyles. For cancer, the programme aims to improve the screening, diagnosis and testing of different types of cancers and to enhance access to human papillomavirus vaccination across Europe. A new executive agency, the Health and Digital Executive agency (HaDEA), has been established to manage and implement EU4Health, as well as health-related actions within Horizon Europe (Cluster 1 on Health), the Connecting Europe Facility’s Digital portfolio and a new complementary instrument, the Digital Europe programme. This novel constellation with a substantial budget dedicated to health may contribute towards the targeted identification and investment in transversal health priorities, as well as the effective steering of synergies across the various programmes included in HaDEA’s portfolio. For instance, health research with a focus on innovating health systems may be funded through Horizon Europe and be complemented by the development of new digital infrastructure through Digital Europe, which focuses on innovative technologies such as artificial intelligence, and the digital interoperability mechanisms developed within the scope of the Connecting Europe Facility. The funds are closely interlinked with the European Semester and will be used to address some of the reforms suggested in the country-specific recommendations produced by the Commission as part of the yearly cycle. In 2020, all Member States received recommendations for the implementation of health system reforms, with a focus on strengthening the health workforce, securing the supply of critical medical products, improving access to primary health care and eHealth tools. The Recovery and Resilience Facility can also be complemented by the technical support provided through the European Commission’s Technical Support Instrument (TSI). The TSI is a tool designed to assist Member States in tailoring and implementing national

Box 3: Recovery and Resilience Facility: Potential for Strengthening Health Systems

Several Member States have decided to prioritise health systems in their National Recovery and Resilience Plans, with some pledging several billion euros to fund initiatives, for example, in the areas of:

- **Primary Health Care and Prevention**
  - Austria: €100 million reserved for its Primary Health Care Reform with a focus on building new primary care units and enhancing the digital and environmental sustainability of existing infrastructure.
  - Greece: €254 million to improve Universal Health Coverage and set up national screening programmes, as well as promote psychosocial care integration and strengthen palliative care.

- **Digital Transition, Hospitals and Infrastructure**
  - France: €2.5 billion reserved for renovating hospitals and health care facilities, modernising existing infrastructure and equipment.
  - Germany: €3 billion pledged to modernise hospitals and invest in digital infrastructures including telemedicine, robotics, IT and cybersecurity.
  - Italy: €15.6 billion to invest in new technologies for hospitals, telemedicine for home health care services and territorial medicine.
reforms upon request, including those identified in the European Semester, and is available to help Member States prepare, implement and revise the National Recovery and Resilience Plans required to dispense the Recovery and Resilience Facility funds. Several Member States have opted to include health system reforms among their priorities and implemented different approaches to tackle health system gaps in their national plans (see Box 3).

Ministers from the Member States met at the EPSCO (Employment, Social Policy, Health and Consumer Affairs) Council on 7 December 2021 to discuss and approve the Council conclusions on “Strengthening the European Health Union”, which feature four main priorities: developing and deploying innovative solutions for resilient health systems, enhancing the accessibility and availability of medicinal products and medical devices, beating cancer and strengthening the role of the EU in Global Health. The document reflects the lessons learnt from the pandemic and underscores that strengthening resilience and building a European Health Union have become a priority for the EU and its Member States.

Shaping EU health policy in the future

Limited competence in the area of health has resulted in EU health policy having been shaped primarily by other fields for which the EU has a legal mandate over many years, such as agriculture and the internal market. This is also reflected in the variety of EU tools, which are scattered across different policy areas and are oftentimes difficult for Member States to navigate, but which are nonetheless relevant for strengthening health systems (also see the article by Mauer et al. in this issue on EU health system support tools). This has resulted in fragmentation and has reduced the added value which the EU could have for Member States in the area of health. The pandemic has highlighted the need to enhance the EU dimension in health security, while also reminding us of the global nature of health and the need to strengthen other health system pillars to ensure their sustainability and resilience to future shocks. This prompts further discussion into how European leaders may best strengthen solidarity and shape EU action on health in the upcoming years.

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