



MONITORING COORDINATION  
PREVENTING HEALTH EMERGENCIES  
COORDINATION **ADDED VALUE**  
MONITORING AND MITIGATION OF RISK  
EFFORTS AGAINST  
CROSS-BORDER HEALTH  
SUPPORT THREATS  
FUNDING AND CRISES

**HERA Civil  
Society Forum**

**RESPONSIBILITIES**  
NEED FOR A MORE HOLISTIC VIEW OF HEALTH  
**DEVELOPMENT SUPPORT**  
MAKING CONNECTIONS **MONITORING**

The Future Of The Health Emergency Preparedness  
And Response Authority (HERA)  
Working group 1 discussion paper

## Disclaimer

This paper is prepared by the HERA Civil Society Forum set up by the European Commission. The Forum is a sub-group of the HERA Advisory Forum that constitutes a mechanism of exchanging information on preparedness and response in the area of medical countermeasures and the pooling of knowledge. The members of the HERA Civil Society Forum are European organisations with a specific focus on patients', consumers and healthcare professionals' interests.

The views reflected in this paper are the views of the assenting members of the Civil Society Forum only<sup>1</sup>. They neither constitute the views of the European Commission or its services, nor provide an indication to the policy approach that the European Commission may take in its future work.

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# The future of the Health Emergency Preparedness and Response Authority (HERA)

## HERA Civil Society Forum working group 1 discussion paper

### Introduction

*The COVID-19 pandemic has demonstrated that health emergencies do not stop at borders and require a coordinated response across a breadth of fields. With other potential health threats that could emerge on the horizon, including pathogens with high pandemic potential, antimicrobial resistance, and the risk of chemical, biological, radiological and nuclear (CBRN) threats, the EU has adopted new legislation and initiatives to strengthen its preparedness and response for possible future health threats, and deepen the EU Health Union through increased capacity at Member State level, and better coordination at EU level.*

*An important part of the EU-level coordination on preparedness and response towards cross-border threats to health has been allocated to a new European Commission service, the Health Emergency Preparedness and Response Authority (HERA), established almost two years ago. Now is the moment to take stock of the role of HERA, its achievements and limitations, and how it can continue strengthening the EU's capacity to address health threats.*

*The HERA Civil Society Forum (CSF) has served as a bridge of information and exchange between the Commission Services and European-level civil society in the health field. Involvement of civil society organisations is essential, as they represent key interest groups including healthcare professionals and citizens, who play a fundamental role in both the preparedness and response phases. The Civil Society Forum brings together a broad variety of these organisations and is instrumental in scoping health threats and guiding optimal operational responses to health threats.*

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<sup>1</sup> This document has been endorsed by all members of the HERA Civil Society Forum except AMGROS and HOPE.

*Working group 1 has reflected on the strategy and upcoming review of HERA, and this document should be seen as a discussion paper that is not individually endorsed by each organisation. The group of stakeholders includes: patients' organisations, consumer organisations, health-related foundations, research organisations, healthcare professional organisations and other health-related stakeholders (see composition of the Civil Society Forum at the end of this document). This exercise is part of the broader mid-term review of HERA and will feed into this process.*

**1. In your view, to what extent does HERA's mandate, as laid down in COM Decision C (2021) 6712, provide HERA with an effective set of tools to strengthen the EU's health emergency preparedness and response capabilities? Where do you see the added value created by HERA up until now? Are there any gaps within HERA's mandate that should be addressed?**

Adopted in the midst of a global pandemic and generalised lockdown, the European Commission set up the new service, to face a severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) infection, generalised as COVID-19, and other potential future health threats. The European Commission Decision (2021) 6712 establishing HERA defines broad responsibilities for HERA, to support EU Member State action through coordination of efforts against cross-border health threats and crises.

#### Added value

The added value of creating HERA is in having a body or Commission service that has a truly European focus and overlook. The COVID-19 pandemic showed the need for EU coordination initiatives that promote a fair and equitable allocation of medical countermeasures and the need for rapid data provision to inform member states' national health strategies. HERA can enhance preparedness for possible cross-border threats to health for EU citizens and beyond, and coordinate the emergency response through various means, including by rapidly improving the availability and equitable access to medical countermeasures across the EU, strategic stockpiling for a broad range of threats, and boosting European health research and development (R&D). While it has only just begun its operations, HERA has already created added value on several fronts. For example, by identifying a priority list of health threats (which includes e.g. antimicrobial resistance), mapping priority medical countermeasures, identifying potential incentives for the development of new antimicrobials, supporting stockpiling, procuring mpox vaccines, forging strategic alliances with global actors (e.g. WHO, CEPI, BARDA), and most recently setting up HERA invest which shows potential to support R&D related to serious cross-border health threats. In the coming years, we will hopefully see the full added value that HERA can provide and how it will live up to its ambitious objectives.

#### Coordination

The system of preparedness and response at the EU level is complex, and there is a need for better cooperation with other institutions that have a role in health threat preparedness and response. In addition, a clear strategy on how these institutions will respond to health threats in a coordinated manner is yet to be developed. We welcome the establishment of working arrangements between HERA, ECDC, and EMA, under the overall coordination of DG SANTE, but these working arrangements merely state broad intentions and are yet to be put to the test. HERA's efforts should be complimentary to those of EMA and ECDC, and we should avoid a duplication of efforts. In addition, more clarity is needed on collaboration between HERA and member states in times of crisis and on HERA's effective ability to

coordinate EU actions in the face of potential unilateral national measures. In the preparedness phase, it is important to leverage synergies between HERA and member states' activities and avoid duplication.

Likewise, global cooperation should remain at the forefront of HERA's role in enhancing the global health emergency preparedness and response architecture. By contributing to the guiding principles of the EU global health strategy (e.g., strengthening global health capacities and engagement with key global health stakeholders), HERA could further support the EU's role as a key global health actor.

## Mandate

HERA's competencies, tasks, resources and overall mandate should thus be further defined and specified. It would also be helpful to further clarify specific goals and responsibilities in the inter-pandemic period (preparedness) and during the emergence of a new health threat (response). The tools are not the same, and this is a major gap in the description of HERA's mandate. Likewise, the chain of decision-making is different for preparedness and response.

**In the case of pathogens with pandemic potential and AMR**, preparedness and response are closely linked with the EU's capacity to influence and contribute to global health. However, DG SANTE and DG INTPA are responsible for the delivery of the EU Global Health Strategy but it is unclear to what extent and in what capacity and HERA is involved in these discussions. We recommend clarifying and, if necessary, expanding the mandate of HERA within the broader Commission services, especially during the preparedness phase.

In the case of Chemical, biological, radiological and nuclear defence (CBRN), which are mostly addressed by DG ECHO, DG HERA might also be relevant. However, HERA's current mandate does not specify which Commission services should interact with HERA nor in what form.

Member States should therefore seek to strengthen the HERA's structure and to expand its scope.

## Preventing health emergencies: the monitoring and mitigation of risk

Health emergency preparedness and response must include activities to prevent health emergencies from occurring where possible. To this end, the role of HERA in developing standardised tools to monitor health threats and supporting early and effective remedial responses, together with other responsible EU entities, must be considered critical to the authority's success.

Identified threats and mitigating actions should be continually and regularly reviewed and we encourage HERA to take a broad approach. An example in this respect, is evidence of growing healthcare professional shortages including in many areas of critical importance during health emergencies, such as pathology and nursing. Such issues have, as yet, received very limited attention from HERA. Despite recognising subsidiarity issues and the lack of EU competencies in this area, ways to address this issue in the future should be considered. During the COVID-19 pandemic, hospitals not only faced medicine and product shortages but also personnel shortages.

Contingency planning connected to such identified threats should include support for both public and targeted communication e.g. to known impacted communities. In the case of a future pandemic, chronic disease communities, including patients and healthcare professional organisations, should be consulted to identify, measure, and mitigate potential impacts on existing patients as a result of the emergency response. During the COVID pandemic, healthcare services suffered severe disruptions due to the influx of COVID-19 patients. Patients with chronic diseases faced difficulties in accessing healthcare and

experienced unacceptable delays in detection and treatment. The emergency response should take into account the need to minimise these disruptions and maintain continuity of care for these populations, including prevention, detection, treatment and follow-up interventions. Mistakes from the COVID-19 pandemic should not be repeated. While this issue relates to the broader resilience of healthcare systems, which is not part of HERA's mandate, preparedness and response activities should include continuity planning for the healthcare delivery system as this is key to the response to any health threat.

## Funding

In addition, the current structure of HERA and the fact that it was established after the adoption of the current Multiannual Financial Framework (MFF) limit its capacity to manage more directly and in sufficient quantity the resources that are needed to fulfil its goals and expectations. A strong and more flexible budget under the next MFF is necessary to give HERA the right tools to fulfil its mandate. Looking forward and building on lessons from the COVID-19 pandemic, HERA could also contribute to the large-scale production of medical countermeasures, so they are widely available at affordable prices during health emergencies. This can be achieved by attaching conditions to R&D funding related to transparency, IP sharing and price caps.

- 2. In how far do the legal tools available to HERA (Emergency Framework Regulation; Serious Cross-Border Threats to Health Regulation) provide HERA with effective tools to address health emergency preparedness and response? Should, in your view, the EU's competencies in the fight against serious cross-border health threats be expanded? Where in practice would you see the chance for HERA to create more EU-added value?**

In order to be able to rapidly and effectively prepare for and respond to emerging health threats, HERA needs to have sufficient tools at its disposal and a clearly defined mandate and responsibilities. Currently, the place of HERA is not mentioned in the Serious Cross-Border Threats to Health Regulation which creates the unclarity of HERA's mandate in the EU health emergency preparedness and response framework. The extent of EU competencies should be consistent with the impact of the seriousness of cross-border threats to health.

## Need for a more holistic view of health

The restriction to the current definition of "medical countermeasures" is a major limitation for HERA to accomplish its mission and tasks. The definition prioritises medicinal products and medical devices, while other measures can be equally important in preventing and managing health emergencies. Indeed, threats are very likely to need a comprehensive public health approach. The wording "public health countermeasures" would be more appropriate than "medical countermeasures". This would allow for a holistic approach to health threats that includes recommendations on human resources for health, workforce distribution, training, shortages, capacity planning, supporting national capacity building for emergency preparedness, resource planning, joint procurement and above all protecting the most vulnerable. At the same time, HERA should anticipate relevant developments in our health systems and see where its work could be of added value to address pressing health issues, for instance in relation to medicine and medical device shortages which affect European patients across Europe, and which have the potential to become even more widespread in the near future. In these areas, HERA should work in coordination with other relevant EU agencies and entities including the European Medicines Agency.

In addition, the experience so far including with the COVID-19 Pandemic has demonstrated that there is an interlinkage between underlying chronic health conditions and comorbidities and the impact of emerging health threats on people's health. HERA activities should take this into account and look at health from a broader and interlinked perspective instead of looking at (potential) health threats in isolation. In order to be prepared for the next European or global health crisis, the EU needs to bring chronic diseases to the table, as a direct contributor to death in the event of a health crisis (and other crises impacting health). Some considerations for a more holistic health preparedness and response at EU level are:

- **HERA should move beyond the availability of medical countermeasures and address the efficient and equitable deployment of medical countermeasures in healthcare systems.** HERA should propose optimal and diverse ways to deliver health countermeasures within healthcare systems to promote healthcare system flexibility and resilience in the event of a crisis. It should promote exchanges of best practices and support Member States in distributing not only medical countermeasures but also human resources and staff, to minimise the impact on routine healthcare services. In addition, considering that the health workforce is key to any health threat response, HERA should look into recommendations and support for workforce planning, distribution, training and upskilling. In any health emergency, the resilience and preparedness of Europe's health workforce is vital.
- **In the future, HERA should explore broadening the health threats priority list** to cover issues like climate change hazards with effects on health such as wildfires and heatwaves (demonstrated increased mortality among chronic disease patients and vulnerable groups) seasonal allergies and floods (an increase on respiratory pathologies due to mould and infectious disease due to stagnant water) and therefore propose adaptation strategies addressed to protect health and reduce disease in the event of a climate-driven catastrophe.

### Making connections

The COVID-19 pandemic and the monkeypox outbreak showed also how interconnected the EU information market is – in a pandemic, member states and the public are closely looking at what neighbouring countries are doing. COVID-19 and monkeypox also showed the difficulty to ensure the public has easy access to scientifically validated information and to win public trust. HERA could bring added value by setting a high standard of information and harmonise communications by integrating the following considerations:

- **Support the development of** educational and training materials to address health threats, addressing healthcare professionals, patients and consumer organisations, and the media. HERA could also raise awareness on European and global scientific consensus on how to best address the health threat.
- **Support harmonised and coordinated communication among EU member states,** to ensure consistent messaging and enhance public trust.
- **Prepare the population and promote a sense of EU responsibility and solidarity** through the development of an EU-level strategy, recommendations and materials for public information to prepare and equip citizens to address health threats, especially tailored to vulnerable populations including those living with chronic diseases. HERA could help prepare unbranded materials ready to use by all interested actors. In addition, HERA could leverage existing work being done including



through the promotion of public projects for citizen information provision to enhance emergency preparedness.

- We should support the development of a **European strategy on preparedness for health threats**, to make sure the efforts of different actors that have a role in this field are aligned, and accountability well established, including through the use of relevant targets e.g. in reduction of medicine shortage, workforce shortage etc. The strategy, and associated targets, should be subject to public and targeted consultation.

### HERA as a R&D Coordinator

HERA could also create more EU-added value, strategic independence and resilience by becoming an 'R&D coordinator' for the development of medical countermeasures in the fields of:

- **Novel antimicrobials**, where HERA should exercise strong stewardship throughout the R&D chain by deploying in a coordinated way pull- and push- incentives with clear conditions to maximise product availability and affordability. As a next step, HERA should develop a comprehensive plan for the development and access to priority antimicrobials ('end to end approach'), as well as their recommended use.
- Promote research and production of precision personal protection materials used in situations related to **Chemical, biological, radiological and nuclear defence (CBRN)**, to allow it to be more effective, efficient and widely available. This includes for example digital screeners for chemicals and radiological threats or specific face masks.
- A system should be in place to ensure that HERA can easily mobilise adequate funding to support the **development of new medical countermeasures** in the face of a new threat, based on strict transparency, accountability, and stewardship principles.

### 3. To what extent can HERA deliver more effectively as COM Service or as an independent legal entity? Pros and cons

There are pros and cons to HERA operating as a Commission Service or as an independent legal entity. In both scenarios, it is essential that HERA has a strong dedicated and flexible budget, and gets the necessary tools and authority to act as a true coordination hub for the European response to cross-border health threats, making sure efforts at both Member State and EU level (e.g. of EMA, ECDC, European Commission etc.) are aligned and key stakeholders are involved.

Considering the urgency of health threat responses, a rapid response is key. A careful assessment is needed to identify which scenario would enable faster decision-making and faster translation of decisions to operational actions, in order to identify whether HERA would benefit from more rapid decision making as an Agency. It should be noted that any decision or attempt at changing HERA's status should not turn into a bureaucratic exercise that would impede HERA's ongoing work – at the end of the day, what matters is HERA's ability to fulfil its missions in an effective way.

### Current situation: HERA operates as a Commission Service

In the current situation, HERA operates as a DG within the Commission service. In this situation, HERA has the potential to become a 'total crisis hub' by being at the centre of EU decision making and benefit from the resources and connections of the Commission. It would however need a strong budget under the new MFF and sufficient resources and power to allow it to effectively respond to health threats.

Setting up HERA, as a European Commission service separate from DG SANTE, was a good compromise to advance and protect human health within the current EU institutions. This brings health to the core of EU decision-making and contributes towards realising the ambition to establish a European Health Union. In order to mirror the societal importance of health in the EU's political ecosystem, HERA must be further elevated politically, and health and health emergency response must continue to be a top priority for the upcoming Commission.

### Possible scenario: HERA becomes an independent legal entity

Preparing or responding to an emerging health threat requires autonomy and independence in decision-making. HERA should not be limited to providing advice or non-binding statements/decisions, but it should have the necessary authority and resources to act efficiently and effectively. While HERA could achieve some of this as a Commission Service, it would have more autonomy and standing as an Agency. HERA should aim to reduce heterogeneity in Member States' decisions when faced with cross-border health threats.

There is a need for full transparency in HERA processes, decisions and actions and a need for full accountability to European citizens to make sure its mission and tasks are eventually achieved. The negotiation on the COVID-19 vaccines has led to debates about the role of the Commission in procurement, conditions, liabilities, prices and contracts. Externalizing this groundwork to an independent agency might contribute to a higher degree of independence. In addition, a strong involvement of stakeholders including patients, healthcare professionals, industry, payers and other health organisations is essential to ensure an evidence-based and patient-centred response to health threats.

A strong and stable funding stream, separate from existing health (research) funding instruments, and that does not divert funding from existing programmes, would provide HERA with the tools it needs. This could facilitate the implementation of an 'end to end' approach to medicines and other health technologies along the entire translational value chain (i.e., from basic research and conception to their distribution and use).

However, there are also risks associated with HERA becoming an independent agency. It would be a lengthy and complicated process, it is not yet clear in what location the agency would be established and the agency would lose some of the connections and political power that it currently benefits from while operating within the Commission.

In 2025, the Commission should forward a concrete proposal on how to reinforce HERA, incorporating lessons learned from its first years of existence and developed in public consultation with all stakeholders.



## **Member organisations HERA CSF WG 1**

**Biomedical Alliance in Europe (BioMed Alliance)**

**Cittadinanzattiva**

**Deutsche Stiftung Weltbevölkerung (DSW)**

**European Federation of Nurses Associations (EFN)**

**European Forum for Primary Care (EFPC)**

**European Blood Alliance (EBA)**

**European Consumer Organisation (BEUC)**

**European Patients Forum (EPF)**

**European Federation of Allergy and Airways Diseases Patients' Associations (EFA)**

**European Liver Patient Association (ELPA)**

**European Public Health Alliance (EPHA)**

**European Public Health Association (EUPHA)**

**European Sepsis Alliance (ESA)**

**Standing Committee of European Doctors (CPME)**

**European Society of Intensive Care Medicine (ESICM)**

**European Respiratory Society (ERS)**