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HERA – ONE YEAR IN

Assessing the State of EU Health Preparedness against Future Fire Drills

Maria Rosaria Della Porta, Eleonora Mazzoni

The coronavirus outbreak has exposed the EU's weaknesses in emergency preparedness, planning and response, as well as its lack of adequate funding. Coordination and cooperation between EU Member States during health emergency was often difficult, and took time start functioning in a structured way. In this context, in September 2021, the European Commission established Health Emergency Preparedness and Response Authority (HERA) – a key pillar of the European Health Union – with aim to enable the EU and its Member States to strengthen preparedness and rapidly deploy the most advanced medical and other counter-measures in the event of a health emergency. HERA is expected to strengthen EU health security coordination, shorten crisis response times, and strengthen the overall health emergency preparedness and response architecture in the EU and globally.

- After the first wave of COVID-19 in Europe, the European Commission committed to undertaking bold actions to preventing and managing similar threats in the future. Consequently, the EC proposed to create a new agency for a well organised stockpiling of preparedness and response tools as countermeasures - the European Health Emergency Preparedness and Response Authority (HERA).
- HERA was established in September 2021 to replace ad hoc approaches to pandemic management by a permanent structure with adequate tools and resources to better plan EU actions in case of health emergencies. A core goal of HERA is to ensure the development, manufacturing, procurement, and equitable distribution of key medical counter-measures whenever there is a need.
- HERA is a key pillar of the European Health Union and it will work closely with the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) and complement their work both in preparedness and crisis times.
- HERA establishes in the work plan 2023 a list of specific causes of cross-border health threats and related medical defections at the EU level and develops a training and support plan to enhance Member States' knowledge of medical countermeasures preparedness and response.
- HERA, through the involvement of strategic partners, will continue strengthening cooperation and cohesion on global health security, ensuring availability and access to medical countermeasures for all.

1. INTRODUCTION: WHAT WILL BE THE MAIN HEALTH CHALLENGES FACING THE EU IN THE COMING YEARS?

The COVID-19 pandemic had massive consequences for societies and health systems across the world and showed how vulnerabilities in health systems can have profound implications for health, economic progress, trust in governments, and social cohesion¹. Moreover, the recent health crisis has threatened to set back hard-won global health progress achieved over the past two decades - in fighting infectious diseases, for example, and improving maternal and child health², and has highlighted the poor resilience of health systems.

Therefore, today, a coordinated effort is fundamental, involving the global health sector, policy-makers, international agencies and communities to help countries strengthen their preparedness for future pandemics and other health challenges³.

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As well, European health systems have to deal with major health challenges, especially the shortage of medicines, antimicrobial resistance and the spread of some infectious diseases such as hepatitis.

Between 2000 and 2018, medicine shortages in the EU increased 20-fold and, according to a note by the European Commission, are rising for widely used essential products. More than 50% of medicines to treat cancer, infections and nervous system disorders (e.g., epilepsy, Parkinson's) account for more than half of those in short supply. The reasons are complex, ranging from manufacturing problems, industry quotas, legal parallel trade and unexpected peaks in demand following epidemics or natural disasters to pricing, which is decided at national level. Moreover, the EU has become increasingly dependent on non-EU countries - mainly India and China - when it comes to the production of active pharmaceutical ingredients, chemical raw materials and medicines.

¹ <https://www.oecd.org/health/covid-19.htm>

² <https://www.who.int/news-room/spotlight/10-global-health-issues-to-track-in-2021>

³ <https://www.weforum.org/agenda/2020/02/who-healthcare-challenges-2020s-climate-conflict-epidemics/>

Decreased production, logistical problems, export bans and stockpiling due to the health crisis have further increased the risk of bottlenecks.

However, the European Union is seeking to put in place legislative and non-legislative actions to address this problem. For example, the EU health programme EU4Health aims to make medicines and medical equipment more available and calls for boosting pharmaceutical production in Europe and setting minimum quality standards for healthcare⁴.

Moreover, the EU Commission in its Pharmaceutical Strategy for Europe includes some actions to enhance crisis preparedness and response mechanisms, diversified and secure supply chains, and address medicines shortages⁵.

Another major challenge facing European and non-European healthcare systems is antimicrobial resistance (AMR).

According to the recent WHO report, “Antimicrobial resistance surveillance in Europe”⁶, antimicrobial resistance remains a major public health concern in the WHO European Region, with estimates from the European Union/European Economic Area (EU/EEA) alone showing that each year more than 670,000 infections are due to bacteria resistant to antibiotics, and approximately 33,000 people die as a direct consequence. The WHO’s report underlines that public health action to tackle AMR remains insufficient, despite the increased awareness of AMR as a threat to public health and the availability of evidence-based guidance for IPC, antimicrobial stewardship and adequate microbiological capacity. Therefore, further investment in public health intervention is needed urgently to tackle AMR. This would have a significant positive impact on population health and future health-care expenditure in the EU/EEA. It has been estimated that a mixed intervention package that included antibiotic stewardship programs, enhanced hygiene, mass media campaigns and the use of rapid diagnostic tests would have the potential to prevent approximately 27,000 deaths each year in the EU/EEA. In addition to saving lives, such a public health package could pay for itself within just one year and save around €1.4 billion per year in the EU/EEA⁷.

Infectious diseases continue to kill millions of people and also affect European countries. According to the European Centre for Disease Prevention and Control, as of 24 November 2022, 572 cases of acute hepatitis of unknown etiology have been reported by 22 European countries, including Austria, Belgium, Denmark, France,

⁴ <https://www.europarl.europa.eu/news/en/headlines/society/20200709STO83006/medicine-shortages-in-the-eu-causes-and-solutions>

⁵ https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en

⁶ <https://www.ecdc.europa.eu/en/publications-data/antimicrobial-resistance-surveillance-europe-2022-2020-data#:~:text=Antimicrobial%20resistance%20%28AMR%29%20remains%20a%20major%20public%20health,33%2000%20people%20die%20as%20a%20direct%20consequence.>

⁷ Ibidem

Greece, Ireland, Italy, the Netherlands, Portugal, Spain and the United Kingdom⁸. To reduce infectious diseases, more funding and political will are needed to develop immunisation programs, share data on epidemics and reduce the effects of drug resistance.

2. HOW THE EU PREPARES FOR AND RESPONDS TO HEALTH EMERGENCIES: THE ROLE OF THE HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY (HERA)

After the first wave of COVID-19 in Europe, the European Commission committed to undertaking bold actions to preventing and managing similar threats in the future. The EC recognised that there was a lack of capability in the EU regarding the demand-to-supply dimension of devices, commodities and products essential for preparedness and response. Consequently, the EC proposed to create a new agency for a well organised stockpiling of preparedness and response tools as countermeasures - the European Health Emergency Preparedness and Response Authority (HERA)⁹.

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HERA was established in September 2021 to replace ad hoc approaches to pandemic management by a permanent structure with adequate tools and resources to better plan EU actions in case of health emergencies. A core goal of HERA¹⁰ is to ensure the development, manufacturing, procurement, and equitable distribution of key medical counter-measures whenever there is a need¹¹.

HERA's core missions are¹²:

- to improve EU health security coordination before and during crises;
- to bring together the EU Member States, industry and relevant stakeholders;

⁸ <https://www.ecdc.europa.eu/en/increase-severe-acute-hepatitis-cases-unknown-aetiology-children>

⁹ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)01107-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01107-7/fulltext)

¹⁰ https://health.ec.europa.eu/system/files/2022-11/hera_shp-report-2022_en_0.pdf

¹¹ https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7154

¹² https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview_en

- to develop, produce, procure, stockpile and equitably distribute medical countermeasures
- to reinforce the global health emergency response architecture.

HERA is similar to the US authority, the Biomedical Advanced Research and Development Authority (BARDA), founded under the 2006 Pandemic and All Hazards Preparedness Act Bill. The act established a new post of an Assistant Secretary for Preparedness and Response within the federal administration, and a programme – BARDA – to provide an integrated and systematic approach to the development of the necessary counter-measures for public health medical emergencies¹³.

A core goal of HERA is to ensure the development, manufacturing, procurement, and equitable distribution of key medical counter-measures whenever there is a need

HERA has the particularity of having two operating modes¹⁴. During the preparedness phase it will work closely with Member States to analyse, identify and prioritise possible health threats. This is the basis for a strategic coordination in developing medical counter-measures, and the industrial capacity to produce and supply those counter measures.

The key actions in the preparedness phase are:

- threat assessments and intelligence gathering;
- advanced R&D for medical counter-measures;
- boosting industrial capacity;
- procuring and distributing medical counter-measures;
- increasing stockpiling capacity;
- strengthening knowledge and skills.

During the crisis phase, HERA will rely on its anticipatory overall management system and deploy it in the context of an emergency framework activated by the Council on a Commission proposal appropriate to the economic situation.

The key actions in the crisis phase are:

- ensuring the availability, supply and deployment of medical counter-measures;
- acting as a central purchasing body;
- monitoring medical counter-measures;

¹³ European Parliament, HERA, the EU's new Health Emergency Preparedness and Response Authority, 2022

¹⁴ https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/operating-modes_en

- activating emergency measures for research, EU FAB manufacturing surge capacity and emergency funding.

Moreover, in close collaboration with global partners, HERA will:

- address international supply chain bottlenecks and expand global production capacity;
- reinforce global surveillance;
- in case of a health emergency, facilitate international cooperation and support for medical counter-measures;
- support low- and middle-income countries to build expertise and develop manufacturing and distribution capacities;
- support access to EU-funded medical counter-measures.

HERA is a key pillar of the European Health Union (Fig. 1), and will be assigned several activities, such as intelligence gathering on health threats, procurement and R&D funding. As well, it will map EU infrastructures and set up specific facilities to secure speedy production in an emergency, and emergency activities such as the coordination of counter-measures. Some of these activities would, however, require strong and seamless coordination within the European Commission (e.g., with DG SANTE on joint procurement and international actions) and with other institutions (e.g., with EMA's emergency task force and monitoring/management of shortages, and with ECDC's epidemiological surveillance)¹⁵.

HERA will work closely with the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) and complement their work both in preparedness and crisis times. The ECDC has a specific mandate in the area of communicable disease threats but no mandate in the area of other health threats, nor on the procurement, development or production of medical counter-measures. HERA will have a stronger anticipatory, forward-looking and response-focused dimension in terms of threat assessments and foresight. On the other hand, EMA's scientific advice on the safety, effectiveness and high-quality of medical products will be a key input to the work of HERA's much broader work on development and production capacities, stockpiling and deployment mechanisms for vaccines, therapeutics and diagnostics.¹⁶ However, the division of tasks between HERA and other EU health agencies and programmes is not yet clear, and potential overlaps between their mandates are likely to emerge (Fig.2). The lack of a proper coordination between HERA and other EU institutions

¹⁵ CEPS, *IMPROVING THE MISSION, GOVERNANCE AND OPERATIONS OF THE EU HERA*, 2023

¹⁶ https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/governance_en

and programmes may easily lead to ineffectiveness (non-harmonised responses across the EU) and inefficiency (duplication of effort).¹⁷

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Fig.1: The European Health Union’s main institutional landscape

Source: CEPS, IMPROVING THE MISSION, GOVERNANCE AND OPERATIONS OF THE EU HERA, 2023

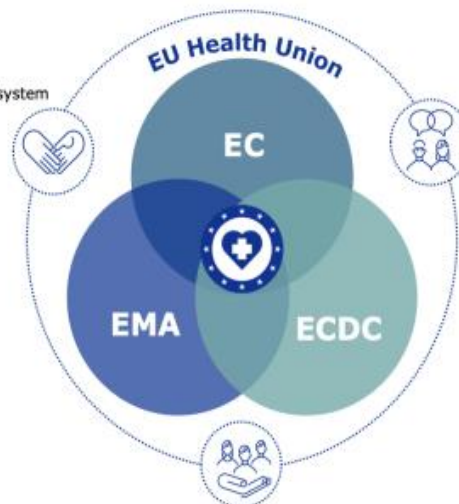
EUROPEAN COMMISSION (EC)

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY (DG SANTE)

- Policy context, pharmaceutical strategy
- Regulatory framework & authorisation
- Surveillance of communicable diseases & alert system
- Coordination of risk management in Health Security Committee (HSC)
- Cross border health threats
- Joint procurement
- International dialogue

HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY (DG HERA)

- Intelligence gathering on health threats
- Coordinated countermeasures
- Industrial capacity support
- Emergency funding
- Procurement
- Mapping EU infrastructure
- Surge manufacturing facilities



EUROPEAN MEDICINES AGENCY (EMA)

- Emergency Task Force (ETF)
- Scientific advice
- Monitoring/management of shortages
- Groups’ membership for patients/HCPs
- Vaccines safety and effectiveness monitoring
- Medical device expert panels

EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL (ECDC)

- Real-time epidemiological surveillance
- Preparedness and response planning
- Risk management advice
- EU Health Task Force
- Network of EU reference laboratories
- Network for substances of human origin



The lack of a proper coordination between HERA and other EU institutions and programmes may easily lead to ineffectiveness (non-harmonised responses across the EU) and inefficiency (duplication of effort)

¹⁷ CEPS, IMPROVING THE MISSION, GOVERNANCE AND OPERATIONS OF THE EU HERA, 2023

Fig. 2: Potential overlaps and areas for coordination – HERA, ECDC and EMA

Source: CEPS, IMPROVING THE MISSION, GOVERNANCE AND OPERATIONS OF THE EU HERA, 2023

Areas	HERA activities	ECDC activities	EMA activities
R&D and intelligence gathering and analysis	Public health-threat anticipation and prioritisation	Epidemiological intelligence and analysis and epidemiological surveillance ²⁵	–
	Training to strengthen in-house expertise on medicines and medical devices	–	Medical device expert panels
	IT platform to gather intelligence on the production and availability of MCMs, threat assessment and mapping of MCMs	The European Surveillance system (TESSy/EpiPulse) – surveillance data on infectious diseases and associated health issues	The European shortages monitoring platform – an IT platform on monitoring shortages of critical medicinal products during health emergencies
	Monitoring of crisis-relevant MCMs	–	Monitoring/mitigating the risk of shortages of critical medicines and medical devices
	Provision of non-binding recommendations on MCMs	–	Recommendations on most advanced MCMs
	Clinical trials as part of the pandemic preparedness research and innovation partnership	–	Scientific advice and coordination of clinical trials
Pandemic preparedness & response planning	Pandemic preparedness and response planning with a focus on MCMs	EU pandemic preparedness and response plan	–
Production capacities	Cooperation mechanism with EU industry	–	Sub-networks of single points of contact from marketing authorisation holders, medical device manufacturers
Training and capacity building	Capacity-building forum	Training for healthcare staff on pandemic preparedness and response planning	–
International engagement	Cooperation on availability and deployment of crisis-relevant MCMs and raw materials	–	Liaise with counterparts to mitigate shortages of critical medicines and medical devices

3. ONE YEAR ON OF HERA'S ACTIVITIES AND INITIATIVES

The first HERA Work Plan¹⁸ was published on 10 February 2022 and includes all of the HERA activities foreseen throughout the year 2022.

The Work Plan 2022 is structured around six tasks (Fig. 3) and includes a number of deliverables. Some of these actions involve the mobilisation of EU money through procurement or grants. Specifically, a total contribution of € 1.3 bn from the EU budget was allocated to HERA in 2022 for preparedness activities. Moreover, the budget of HERA for 2022 foresaw contributions from EU4Health (€ 275 m), Horizon Europe (€ 395 m) and UCPM/resceEU (€ 630 m).

HERA's main initiatives and activities concluded in September 2022¹⁹, one year after its establishment, entailed²⁰:

- setting up partnerships and collaboration with Member States, representatives of industry and civil society. The HERA Board, the Civil Society Forum and the Joint Industrial Cooperation Forum met at least once during 2022;
- launching a call for a framework contract related to EU FAB on 27 April 2022, which aims to ensure sufficient, agile, and ready-to-activate manufacturing capacities for different vaccine types;

¹⁸ https://health.ec.europa.eu/system/files/2022-02/hera_work-plan_2022_en_0.pdf

¹⁹ To learn more see: CEPS, *IMPROVING THE MISSION, GOVERNANCE AND OPERATIONS OF THE EU HERA*, 2023, pagg. 30-34

²⁰ CEPS, *IMPROVING THE MISSION, GOVERNANCE AND OPERATIONS OF THE EU HERA*, 2023

- finalising advance purchase agreements and joint procurement contracts for COVID-19 vaccines and therapeutics, taking over the tasks from DG SANTE (and contrary to what is depicted in Figure 1 above). HERA also purchased monkeypox vaccines on behalf of the Member States in 2022. A revision of the framework for an EU Joint Procurement Agreement is ongoing, meanwhile, rules about joint procurement were included in the cross-border threats regulation. Even so, the latter are insufficient, as they allow individual Member States to negotiate parallel deals while the EU negotiates on behalf of all Member States. This problem emerged also in the case of monkeypox, with Member States like France buying more than three times the amount bought at the pan-European level;
- contributing to building stockpiles to cope with chemical, biological, radiological and nuclear threats, as in the case of potassium iodide tablets to protect from radiation;
- holding discussions with international counterparts and European institutions and agencies for establishing memoranda of understanding that would clearly define HERA’s role in relation to actors with similar mandates.

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Fig. 3: HERA’s key tasks for 2022

Source: HERA WORK PLAN 2022

Task 1. Threat assessments and intelligence gathering	EUR 139.5 million
Task 2. Promoting advanced R&D of medical countermeasures and related technologies	EUR 306.08 million
Task 3. Addressing market challenges and failures and boosting the Union’s open strategic autonomy	EUR 165.3 million
Task 4. Ensuring the provision of medical countermeasures	EUR 666.5 million
Task 5. Strengthening knowledge and skills	EUR 5 million
Task 6. International dimension	EUR 2 million (+101 million under Task 2)
Total for preparedness phase in 2022	EUR 1 284.38 million

4. MAIN OBJECTIVES FOR HERA IN 2023

For 2023, HERA is committed to providing, through relevant instruments and, where appropriate, in cooperation with other Commission services, further support to Member State preparedness for pandemics and other large-scale health crises, with a focus on availability and accessibility of medical counter-measures (MCM).

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Summing up, the Work Plan 2023²¹ includes five flagship initiatives:

- the establishment of a state-of-art IT system for intelligence gathering, threat assessment, mapping medical counter-measures, supply chain risk management and management systems for stockpiling (HERA MCM platform);
- ensuring the further development of medical counter-measures for epidemic and pandemic preparedness, such as innovative vaccines, therapeutics and diagnostics, including for COVID-19 - the vaccine 2.0 strategy, aiming for investments worth at least € 80 million -, and access to innovative medical counter-measures against antimicrobial resistance (AMR);
- reservation of manufacturing capabilities for vaccines in case of a new public health emergency (EU FAB);
- establishment of a financing mechanism referred to as the “HERA INVEST” for an amount of € 100 million, to leverage private investment for the development and production, where relevant, of a wide range of medical counter-measures;
- development of a strategy on EU-level stockpiling of medical counter-measures, including stockpiling of chemical, biological, radiological and nuclear (CBRN) relevant medical counter-measures and other medical items.

²¹ To learn more see: https://health.ec.europa.eu/system/files/2022-11/hera_2003_wp_en.pdf

Moreover, in 2022, HERA identified three preliminary threat categories:

- pathogens with high pandemic potential;
- CBRN threats;
- antimicrobial resistance (AMR).

On this basis, HERA will establish in 2023 a list of specific causes of cross-border health threats and related medical counter-measure gaps in the EU.

Finally, in 2023, HERA will develop a training strategy to strengthen Member State knowledge and skills in preparedness and response related to medical counter-measures²².

5. CONCLUSION: HOW TO IMPROVE HERA'S MISSION, GOVERNANCE AND OPERATIONS IN THE FUTURE?

One year after the establishment of HERA some questions still remain open. Firstly, we focus on what will be the role of HERA in the future, especially in terms of governance, and how the relationship with the Commission and other authorities should be managed so as to not create the duplication of roles and inefficiencies.

To avoid the latter it would be desirable that, in HERA's operations, the Commission ensures it achieves a more orderly and effective coordination with DG SANTE and other agencies (notably ECDC and EMA). The need to exploit synergies and avoid costly duplication, as well as to effectively coordinate actions at the EU and international level call for a transparent and meaningful division of work.

The emerging EU Health Data Space also calls for a precise role for HERA in: (i) coordinating different health data platforms in the EU; (ii) stress-testing data governance for future emergencies; and (iii) possibly adopting standardised data use and reciprocal support agreements, trusted exchange frameworks, and core data-interopability standards. In addition, the transparency of HERA's relations with private operators must be strengthened.

On governance, HERA could gradually be given more flexible instruments for promoting R&D in academia and industry, such as transparent mechanisms for contracting with a focus on generating partnerships for innovation. It's essential that HERA invests in EU companies to try to seize innovation and facilitate innovation in Europe.

Moreover, it is crucial that HERA is able to adapt to future needs and that it has its own budget so that it can cope quickly with certain situations. It is also important that it is based on a model of cooperation with the institutions and all stakeholders.

²² https://ec.europa.eu/commission/presscorner/detail/en/fs_22_7124

Secondly, another issue is the potential absence of a One Health approach in HERA's mission that risks translating into a lack of competence and instruments, which, in turn, could defeat the mission of HERA. Therefore, a clearer public health mission needs to be defined, with adoption of the One Health approach and clearer indications for global health.

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Finally, it is important to clarify the role of HERA in international negotiations, including on the proposed pandemic treaty and reform of international health regulations. That is the only way to ensure the specific mission given to HERA to contribute to reinforcing the global health-emergency preparedness and response architecture is accompanied by appropriate competences and tasks²³.

²³ CEPS, *IMPROVING THE MISSION, GOVERNANCE AND OPERATIONS OF THE EU HERA*, 2023