



EU Health Preparedness: A strong mandate for HERA

EUCOPE's recommendations for the future of HERA

*A position paper prepared by
EUCOPE's Health Crisis
Management & Preparedness
Steering Group*



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European Confederation of
Pharmaceutical Entrepreneurs AISBL

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Introduction

In her Political Guidelines¹ for the new European Commission mandate 2024-2029, President Ursula von der Leyen outlined plans to revamp the EU's crisis preparedness capacities. Building on the current work of the Health Emergency Preparedness and Response Authority (DG HERA), Commissioner for Preparedness and Crisis Management Hadja Lahbib presented the **EU Preparedness Union Strategy**², and announced an **EU Stockpiling Strategy** and a **Strategy to support medical countermeasures (MCMs) against public health threats**. Along with the **HERA Work Plan 2025**, these initiatives are part of a common approach to better prepare and respond to health threats, alongside other initiatives³⁴⁵⁶. In this context, crisis preparedness is envisioned as a central pillar of the new Commission's mandate and is expected to be reflected in the next **EU Multiannual Financial Framework (MFF)** budget in 2027.

In a key moment for the EU's health security ambitions, HERA's operational framework as a standalone DG has received a positive evaluation in a European Commission report⁷ assessing its work. Yet, several challenges still hinder HERA's ability to fully deliver on its mission, including the absence of a sustainable budget, overlaps and duplication of responsibilities among different European Commission departments, and limited internal staffing. To effectively pursue its objectives of strengthening health preparedness, **HERA must be equipped with a clear, well-defined, and ambitious mandate, as well as adequate human and financial resources**.

EUCOPE's recommendations: a reinforced mandate for HERA

In the context of increased threats to health security due to an unstable geopolitical scenario, **EUCOPE supports a renewed and strong HERA mandate**, building on its position as the central entity for EU-level action to prevent and respond to public health crises by leading coordination efforts and enhancing synergies between EU and Member States. For that, HERA **should be backed by a budget large enough to combat/respond to priority threats effectively**. Importantly, it should maintain steady communication with all stakeholders, improving alignment between industry capacities and EU and national level strategies. To achieve these objectives, **we call on the Commission to adopt a reinforced, clear and comprehensive HERA mandate**, ensuring the EU and its Member States are fully equipped with policies and instruments to protect citizens amid growing crisis risks.

¹ Ursula von der Leyen – "[Europe's Choice – Political Guidelines for the Next European Commission 2024-2029](#)", July 2024.

² "[EU Preparedness Union Strategy to prevent and react to emerging threats and crises](#)", March 2025.

³ For instance, reinforcing RescEU programme, strengthening of Emergency Response Coordination Centre, and developing a European Civil Protection Mechanism.

⁴ "[Ursula von der Leyen's Mission Letter to Commissioner Hadja Lahbib](#)", December 2024.

⁵ "[European Commission Work Programme 2025](#)", February 2025.

⁶ "[Strengthening Europe's civil and military preparedness and readiness: Report by Special Adviser Niinistö](#)", October 2024.

⁷ "[HERA Review: Taking stock to reinforce health security in the EU](#)", March 2025.



To meet the European Commission's health security priorities, it is pivotal to clearly define HERA's competences. In light of HERA's review and the upcoming Multiannual Financial Framework (MFF) 2027 negotiations, **EUCOPE recommends that the following factors are considered and incorporated (or maintained) in a reinforced HERA mandate.**

1. Establish a broader mandate to act on health crisis preparedness and response

HERA should lead the EU's coordination efforts towards better health crisis preparedness and response capacities, ensuring that the EU and its Member States have aligned capacities to protect citizens against future health emergencies. Therefore, it is essential to empower HERA to develop its identity, with autonomy and clear responsibilities that allow it to fully deliver on its mission.

While other DGs may have related competencies, the fragmentation and overlap of responsibilities can hinder efficiency in achieving policy objectives, and several stakeholders have raised concerns about duplication risks and the lack of clarity regarding HERA's role⁸. It is evident that cross-DG cooperation is necessary and will continue to provide expertise and added value. Yet, whereas responsibilities for developing and coordinating initiatives on preparedness and crisis management may be shared, it is essential to consider how to best structure efficient cooperation and enhance synergies with HERA's mandate, which will contribute to an effective scaling-up of EU action. HERA's mandate should therefore grant it the responsibility to lead on strategic policy initiatives, strengthen its thought-leadership in the preparedness domain, and assume the driver's seat when coordinating with other stakeholders.

2. Develop a sustainable framework for the provision and development of critical medical countermeasures (MCMs)

Central to strengthening preparedness against health threats and crises, HERA should promote the availability, development and rapid access to MCMs. To effectively fulfil this role, it must prioritise certain actions and policies that will contribute to a robust ecosystem that facilitates provision. Additionally, it is important to ensure synergies with the EU Stockpiling Strategy, led by DG ECHO. In this context, **EUCOPE calls on HERA to maintain a focused approach and adhere to its current list of priority health threats in the context of MCMs**: pathogens with high pandemic potential; Chemical, Biological, Radiological and Nuclear (CBRN) threats; and antimicrobial resistance (AMR). HERA should remain firmly aligned with these priorities, supported by sustained investments to catalyse the availability of MCMs, boost manufacturing capacities, and foster the development of innovative MCMs.

EUCOPE emphasises the following elements for effectively achieving these objectives:

- **Availability of critical medical countermeasures (MCMs) stockpiles to address priority threats:** the ability to rapidly deploy MCMs is essential to an effective response to health emergencies. Establishing an EU-coordinated approach to MCM stockpiles, matched by related national measures (e.g., minimum level of local and EU supplies, where applicable), is pivotal. Stockpiles should primarily target products against known priority health threats that are needed quicker than production time will allow following an incident or outbreak (e.g. pathogens with high pandemic potential and Chemical, Biological, Radiological and Nuclear - CBRN threats). This will contribute to a rapid response mechanism, protection of first responders, healthcare professionals and civilians, and mitigation of the spread and impact of a disease or incident in the early stages of a health emergency.
- **Access to scalable manufacturing capacities:** sufficient and agile manufacturing capacities are crucial for the timely development and production of MCMs, especially during sudden surges

⁸ HERA Review, *Ibid.*



in demand. HERA should promote a diverse and inclusive industrial ecosystem that supports both large-scale manufacturers and small to mid-sized innovative enterprises. Financing, timelines, and contracting models must be adapted in view of fostering Research & Development (R&D) and manufacturing activities.

- **Fostering Innovation:** to catalyse innovation in pandemic preparedness, HERA should be supported by a broad range of policies, accompanied by fit-for-purpose financial tools. The allocation of end-to-end financial support to R&D activities is essential, particularly to small and mid-sized companies that strongly benefit from targeted financial support to develop innovative MCMs. HERA should therefore work with relevant stakeholders to identify and promote financial tools, risk-sharing approaches, flexible contractual frameworks and tender formats that are suitable to all parties. In addition, it should unlock further capital through public-private partnerships, national incentives, alternative business models, and targeted EU-level incentives. These mechanisms are critical to mitigating early-stage investment risks, providing greater market predictability and helping to catalyse the development of innovative MCMs.

3. Adopt a long-term and sustainable budget to deliver on policy objectives

HERA's current budget is limited, as it was allocated midway through the previous Commission mandate, in response to the unexpected COVID-19 pandemic. Moreover, additional cuts to its allocated budget have resulted in the limitation of planned activities⁹. Building on the past experiences and lessons learned from the pandemic, **it is essential that the upcoming MFF recognises the increasing importance of crisis preparedness and response and HERA's mission**, acknowledging the need for a larger and appropriate budget. While it may be challenging to single out an ideal budget in the context of a relatively new entity, policymakers could aspire to, in the long-term, reproducing suitable models from the role performed by other international role models, e.g. the US' Biomedical Advanced Research and Development Authority (BARDA) or the UK's Subscription Model for novel antimicrobials.

A long-term and sustainable budget will provide the flexibility needed for HERA to develop fit-for-purpose financial tools, allowing the conduction of its strategic objectives amid rapidly changing health security circumstances. By enabling HERA to implement the priorities outlined in the previous section, the EU will not only support better preparedness against health threats and future crises but will also cultivate a stable policy environment that will attract greater investments in the field.

4. Perform a coordinative and stimulating role, ensuring enhanced synergy with Member States

The COVID-19 pandemic exposed the varying levels of preparedness across the EU. Central to its mandate, HERA should **coordinate, stimulate and facilitate alignment across Member States on pandemic preparedness and health crisis management**. Provided that significant health security efforts need to come from national levels, HERA must ensure alignment, so that common objectives are pursued. There is still room for improvement regarding gaps between Member States; however, HERA's central coordinating role has hitherto been valuable in working towards standardised levels of preparedness and response capacities. The EU health governance framework has been bolstered by the set-up of groups such as the HERA Board, HERA Advisory Forum, and the Health Crisis Board – enhancing the EU's ability to prepare for and respond to emergencies.

As part of the Regulation on Serious Cross-Border Threats to Health¹⁰, the Commission will develop a Union-wide Prevention, Preparedness and Response Plan, outlining operational provisions to support

⁹ [HERA 2025 Work Plan](#), April 2025.

¹⁰ [Regulation \(EU\) 2022/2371](#) on serious cross-border threats to health and repealing Decision No 1082/2013/EU.



Member States. In line with this objective, HERA should lead coordination on preparedness and response operations with national authorities, assessing needs and stimulating cooperative solutions where applicable. This should include, for instance, the **possibility of expanding EU strategic stockpiles of critical MCMs**, such as those already being developed by the RescEU programme.

In an inter-institutional scope, HERA has been closely working with other EU agencies, such as the European Centre for Disease Prevention and Control (ECDC) and forged strategic partnerships with international partners e.g. the World Health Organisation (WHO), the Coalition for Epidemic Preparedness Innovations (CEPI) and the Africa Centres for Disease Control and Prevention (Africa CDC). These cooperation frameworks improve the streamlining and harmonisation of its policies, and should be continued and, where appropriate, strengthened.

5. Maintain active engagement and open dialogue with all stakeholders, fostering public-private partnerships

Since its establishment, HERA has implemented an inclusive and cooperative multi-stakeholder approach to strengthening preparedness through strategic engagement with all relevant stakeholders (Member States, EU Institutions, agencies and industry). This approach is crucial for ensuring a thorough understanding of the preparedness and response landscape. HERA has achieved this through establishing valuable fora for discussion, such as **the Joint Industrial Cooperation Forum (JICF)**, along with events including HERA Info Days in Member States, HERA Industry Days, and workshops with industry representatives¹¹. Systematic dialogue and coordination between the Commission, Member States, specialists and industry are vital to ensure that the EU is better prepared against future health emergencies.

These platforms strengthen knowledge-sharing and synergy among stakeholders. Closer coordination may help, for instance, to address potential bottlenecks concerning critical MCMs (e.g. in production or supply chains) and to inform decisions on whether strategic stockpiling of specific products or materials is needed. Bilateral and regular exchanges with industry developing and supplying MCMs are also crucial for the identification and rollout of procurement methods and tender frameworks that are suitable to all parts, supporting to approximate the understanding of different needs and objectives from both public and private perspectives. **These initiatives offer essential channels for direct communication between all stakeholders and should be continued.**

Public-private partnerships are important means to build multi-stakeholder (cross-border) collaborations, fostering the exchange of knowledge, co-innovation and risk reduction. Support and expansion of these partnerships will provide appropriate resources supporting the development of MCMs needed to strengthen the EU's health security framework. Such partnerships enable additional market predictability and guarantee, which are particularly valuable elements for small to mid-sized companies, which often have to prioritise their R&D programmes due to financial constraints.

HERA should therefore continue to serve as a direct point of contact between the public sector and industry, ensuring swift coordination in all phases. Such an approach facilitates the rapid development, production, and distribution of critical MCMs, including vaccines and CBRN products.

6. Implement a unified strategy to strengthen knowledge, skills, and awareness about health threats across the EU

To achieve robust resilience against crises, **HERA should be equipped with adequate capacities to strengthen knowledge and skills across the EU**. Its mandate should allow it to develop stress-test

¹¹ E.g.: "Breaking Barriers to Effective Funding for Innovative Medical Countermeasures", November 2024.

exercises to evaluate the EU's capacity to respond to threats, in close cooperation with all stakeholders. Knowledge-building efforts should also include assessments of manufacturing capacities for emergency response, including evaluating the support needed to scale up production during crises. These measures should be complemented by training and exercise programmes to foster awareness and knowledge about potential threats among public health officials. Such exercises should explore, for instance, how to deploy strategic stockpiles effectively in a crisis scenario.

These activities should complement parallel activities, further strengthening internal response capabilities. On an international level, it is equally important for HERA to collaborate with international partners, leveraging existing cooperation channels and establishing new mechanisms to ensure stronger cooperation during crises.