

# **From preparedness to action: HERA's role in the EU's public and global health security architecture**

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## SUMMARY

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The EU has reinforced its leadership in global health security by adopting a more proactive and cooperative approach to preparedness and response. Its health security framework seeks to enhance the EU's capacity to respond to cross-border health threats, strengthening both readiness and resilience.

The Health Emergency Preparedness and Response Authority (HERA) plays a critical role in anticipating risks, securing medical countermeasures and coordinating pandemic preparedness and response actions internally as well as with international partners. Amid ongoing geopolitical shifts and reductions in global health financing, HERA's mandate is increasingly important.

This report draws on a qualitative approach, coupling document analysis and stakeholder interviews, to explore how HERA can strengthen its role and the EU's broader health security framework. HERA's focus on medical countermeasures fills previous gaps in the EU system, establishing it as a credible and recognised actor in global health security. Yet stakeholders highlight ongoing challenges, including coordination across the European Commission services, the strategic allocation of funding and in designing partnerships that are both effective and equitable.

Alongside the EU's Stockpiling and Medical Countermeasures Strategies, the findings of this report underscore HERA's centrality in crisis preparedness. Yet without clear resources and coordinated mechanisms, its capacity to respond rapidly and effectively to emerging threats may be constrained, limiting the EU's leadership on the global stage.

To fully achieve HERA's potential and its contribution to global health preparedness and equity, a clearer, more integrated approach within the EU's global health framework is essential.



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## EXECUTIVE SUMMARY

With new strategies adopted in 2025, the European Union has reaffirmed its leadership in global health security, reflecting a more proactive, cooperative approach to preparedness and response. The EU's health security framework aims to strengthen the bloc's ability to respond effectively to cross-border health threats, increasing its readiness and resilience. The Health Emergency Preparedness and Response Authority (HERA) is an important part of this effort, whose role is to anticipate risks, secure medical countermeasures (MCMs), and coordinate action both within the EU and with global partners.

HERA works closely with the Directorate-General for Health and Food Safety, DG SANTE, which leads on health policy and strategic governance. It is tasked with ensuring coherence across HERA, the European Centre for Disease Prevention and Control, European Medicines Agency, and other European Commission services while integrating health security into broader EU policy frameworks. Since its establishment in 2021, HERA has played a key role in boosting EU preparedness and response capabilities for MCMs. HERA's role and mandate are crucial to the EU and its Member States. While its primary focus is on internal operations, its international activities, such as partnerships with global actors, are expanding.

This assessment, informed by a qualitative approach that integrates document analysis and stakeholder interviews, looks at both the internal and external dimensions of HERA. It pays specific attention to how HERA can more effectively fulfil its role and enhance the EU's broader health security framework.

It also examines the EU Stockpiling Strategy and the MCM Strategy, published in 2025, in relation to HERA's future role and scope, considering its internal and external remit. The EU Stockpiling Strategy sets important objectives for access, interoperability, and strategic autonomy. Yet, there are still unresolved questions over operational details, funding, and institutional responsibilities. Stakeholders see an opportunity for HERA to act as the Commission's central hub for planning, procuring, and deploying stockpiles, as well as fostering international partnerships.

The MCM Strategy positions HERA as the EU's 'watchtower' for health security, with responsibilities encompassing R&D, production, deployment, and global cooperation. Its emphasis on cross-sectoral collaboration, civil-military synergies, and EU-based production capacity has been welcomed. Nonetheless, concerns persist over fragmented coordination across Commission services and Member States, as well as missed opportunities to improve diagnostics and broaden surveillance beyond approaches to wastewater.

HERA has emerged as a central pillar of EU health security, yet its impact could be amplified by better governance and coordination, dedicated funding, and strategic partnerships.

Closer coordination with other DGs – especially in areas such as surveillance, diagnostics, and antimicrobial resistance – would help maximise synergies and expand the EU's leadership in global health security. In addition, a dedicated and flexible budget would increase HERA's ability to respond effectively to health crises, facilitating both rapid mobilisation and sustained investment in preparedness.

Finally, while HERA has made significant progress in expanding international partnerships, here too further attention could be given to coordination. Co-designed collaborations, particularly with low- and middle-income countries, would help to optimise impact, enhance capacity, and support equitable access to MCMs.

With ongoing geopolitical transitions and vast cuts in global health financing, HERA's role is ever more vital. A dedicated, flexible budget for crisis preparedness and R&I, alongside greater alignment with EU and international partners, is essential. These measures will enable the EU to ensure rapid, effective responses, support innovation and maintain its leadership in global health security.

## INTRODUCTION

Amid a rapidly evolving landscape for global health, marked by persistent gaps in funding, capacity, and response, the EU has reaffirmed its ambition to strengthen its leadership in global health security. The adoption of the Medical Countermeasures Strategy (MCM Strategy) and the EU Stockpiling Strategy in July 2025, and more broadly the [Union Prevention, Preparedness and Response Plan](#), underscore this commitment. They reflect a [shift](#) towards more proactive preparedness, deeper coordination with Member States and EU institutions, and stronger partnerships with global actors to bolster both European and global resilience.

With the adoption of the EU Global Health Strategy in 2022 and the Council conclusions in November 2024, Member States also endorsed a vision of Europe playing a comprehensive role in global health. It is rooted in equitable partnerships, human rights, and support for the multilateral system. Going beyond the EU's contributions as a development actor, the strategy positions health as an integral part of the EU's broader external relations agenda and strategic autonomy, including through the Global Gateway.

A cohesive and coordinated EU, including in its institutional architecture, is vital for EU and global solidarity and for advancing European strategic interests. However, so far little attention has been paid to the part played by different EU services and institutions in implementing the vision of the Global Health Strategy.

This tendency is apparent in the allocation of responsibilities between the European Commission, the European External Action Service and other EU bodies such as the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC). And it is even more the case for the latest addition to the EU's institutional architecture in this domain: the Health Emergency Preparedness and Response Authority (HERA). Set up as a European Commission service in 2021 during the Covid-19 pandemic, HERA has a mandate to both strengthen internal preparedness and response to emergencies and encourage international cooperation.

This analysis looks at both the internal and external dimensions of HERA. It pays particular attention to how HERA can more effectively enhance the EU's broader health security framework, while acknowledging the overlapping roles and responsibilities within the wider EU institutional set-up.

The analysis draws on findings from the recent external evaluation of HERA, which highlighted a shared consensus among stakeholders that HERA's collaboration with global actors brings important added value to the EU's core mandate. It also builds on the analysis from the [internal evaluation](#), which recognises HERA's close collaboration with the Commission and emphasises that working effectively with partners both inside and

outside the EU is vital to advancing collective progress. In this context, stakeholders also identified areas for improvement. Among them are the needs to strengthen synergies with EU services/institutions and Member States, enhance coordination and flexibility, ensure sustainable funding, and maintain clear and consistent communication. Such improvements are especially important given HERA's reduced budget for its [2025 work programme](#).

In addition, the analysis takes as its starting point a critical review of the EU Stockpiling and MCM Strategies. This further underscores the importance of clarifying HERA's roles and responsibilities within and beyond the EU, as questions remain around its scope moving forward.

## 1. METHODS

This analysis was carried out using a qualitative research approach, integrating document analysis and stakeholder interviews, to provide a nuanced examination of HERA's external role in global health security. It draws on existing literature and policy documents, including the European Commission's 2025 external evaluation report, [\*Study supporting the review of the Health Preparedness and Emergency Response Authority \(HERA\) with regard to its operations, structure, and governance\*](#) and internal evaluation report, [\*Review of the implementation of the operations of the Health Emergency Preparedness and Response Authority \(HERA\)\*](#).

Along with document analysis, nine semi-structured interviews were conducted with key stakeholders between July and August 2025, including representatives from EU institutions, Member State public health agencies, civil society, and international organisations. The interviews aimed to capture perceptions of HERA's added value, its coordination with internal EU institutions and external partners, and recommendations for a stronger HERA in meeting its mandate in the evolving global health order. Interview data were thematically analysed to identify recurring patterns and insights that complement the findings from published sources.

Together, these methods enabled the triangulation of information to reach a deeper understanding of HERA's internal and external positioning and its contributions to EU global health engagement, as well as identification of areas for more clarity on roles, scope, and opportunities.



## 2. SETTING THE SCENE – HERA'S ROLE IN PREPAREDNESS AND RESPONSE IN THE EU

HERA was established in 2021 in the wake of the Covid-19 pandemic and was formally confirmed as a European Commission Directorate-General (DG) in 2025. The main aim of HERA's activities is to strengthen the EU's internal preparedness and response capacities by coordinating the development, procurement, and distribution of MCMs. Its remit spans the full lifecycle of MCMs from threat assessment and research and development to procurement and deployment. HERA's core mandate is thus to ensure that the EU and its Member States are prepared and able to respond effectively to cross-border health threats. However, its activities are also increasingly expanding to the international domain through various partnerships and initiatives.

Concerted policy efforts are underway to advance the EU's continued leadership and capacity to respond to health threats, including through the new [Union Prevention, Preparedness and Response Plan](#) outlining the operational provisions to support Member States in a health crisis. It is pursuing closer collaboration with the World Health Organization (WHO), and targeted initiatives like the upcoming Medifence and the Chemical, Biological, Radiological, and Nuclear (CBRN) Preparedness and Response Action Plans for coordinated response and access to MCMs.

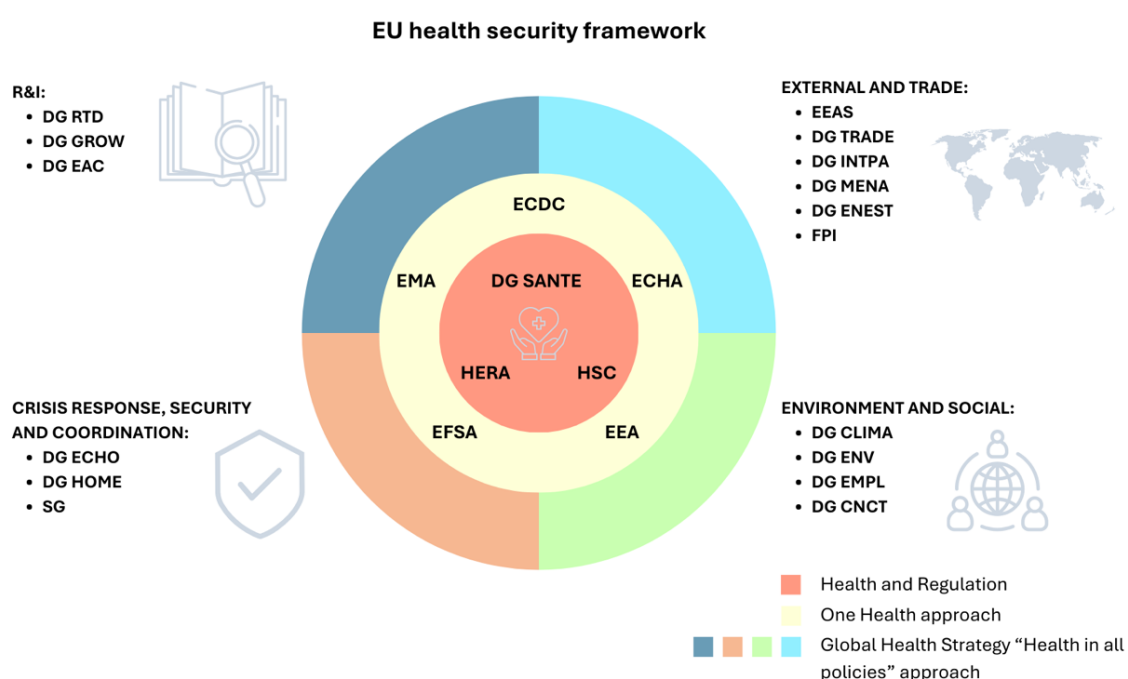
In March 2025, the European Commission and High Representative introduced the [Preparedness Union Strategy](#), aimed at enhancing Member States' capabilities and fortifying the EU's collective capacity to anticipate, prevent, and respond to emerging cross-border threats. These efforts align with broader initiatives such as [WHO/Europe's Preparedness 2.0 Strategy and Action Plan](#), which seeks to strengthen regional health emergency preparedness.

Preparedness and response are, by nature, multifaceted. In this context, HERA contributes to the anticipation of threats through intelligence gathering and foresight; supporting innovation in diagnostics, therapeutics, and vaccines; coordinating the stockpiling and distribution of critical supplies; and activating emergency mechanisms when crises occur.

Importantly, HERA operates within the EU's broader health security framework in close coordination with other Commission services, each acting in line with their respective mandates and expertise. Health in all policies, i.e. the mainstreaming of health across all relevant policy domains in the EU, is one of the key features of the Global Health Strategy; this is also reflected in the way HERA's work and scope cuts across the activity of many Commission services (Figure 1).

Responsibility for health policy and strategic governance lies with DG SANTE, which together with other parts of the Commission, ensures policy coherence across HERA, the ECDC, and EMA, while integrating health security into wider EU policy frameworks and partnerships. Collectively, these institutions constitute a complementary health security architecture under the [European Health Union](#). The EU's broader health security framework seeks to strengthen preparedness, response, and resilience to counter cross-border health threats, with HERA positioned as a central body to anticipate risks, secure MCMs, and coordinate both within the EU and with global partners.

Figure 1. Actors in the EU's health security framework

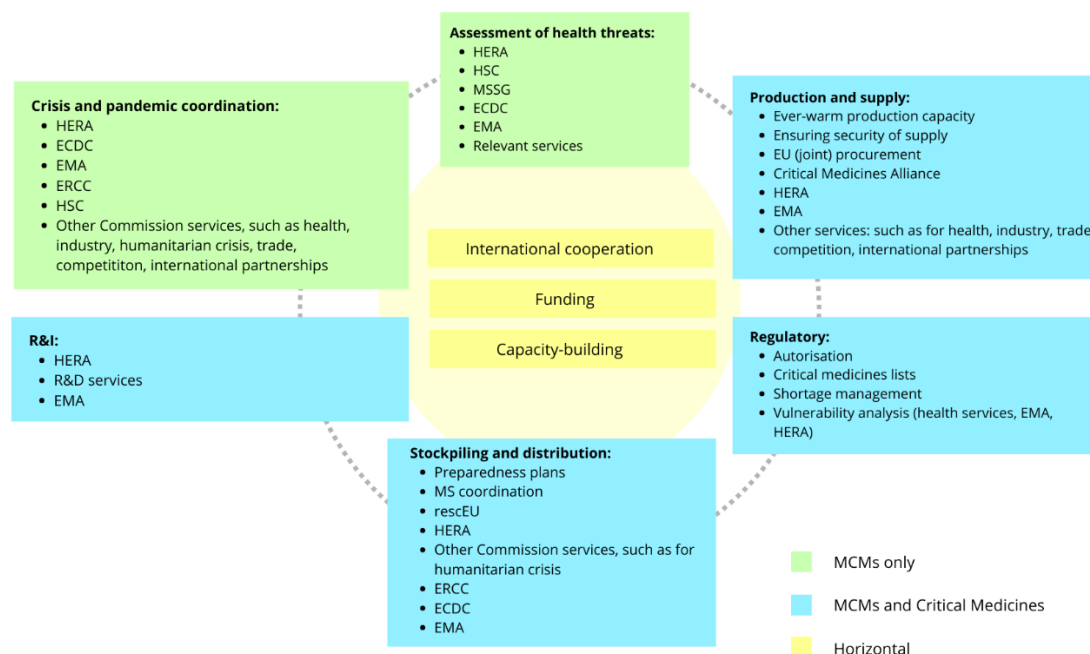


Source: CEPS.

Naturally, there are areas where responsibilities intersect. For instance, HERA contributes to [genomic surveillance and sequencing](#), helping to boost capacities across Member States. It also coordinates a global consortium on wastewater and environmental surveillance. In addition, HERA plays a role in [monitoring CBRN and antimicrobial resistance \(AMR\) threats](#), with the surveillance data it collects feeding into broader strategic foresight and intelligence efforts. This supports scenario planning and informs decisions on procurement, stockpiling, and emergency response. That said, HERA's central mandate remains focused on ensuring operational readiness and resilient MCMs. As Figure 2 below illustrates, the delivery of MCMs and critical medicines within the EU's health security preparedness and response framework relies on an [intricate system of actors and tools](#). This highlights the degree of HERA's coordination challenge in MCMs and the importance of clarifying its role in this interconnected decision-making system.

Figure 2. EU operations in the deployment of MCMs and critical medicines in responding to health crises

**Actors and tools in the delivery on medical countermeasures (MCMs) and critical medicines - HERA Report March 2025**



Source: European Commission (2025), Review of the implementation of the operations of the Health Emergency Preparedness and Response Authority.

HERA's mandate and role are crucial to the EU and its Member States, with its internal activities remaining the core of its remit. At the same time, HERA also has a growing international dimension, including through partnerships with global actors such as the WHO, Africa Centres for Disease Control and Prevention (Africa CDC), and low- and middle-income countries (LMICs). This role includes increasing global health security through the deployment of MCMs and associated actions and relies on close coordination and partnerships that bridge sectors, health domains, and geographies. For example, HERA has [donated](#) over 420 000 mpox vaccines, including 215 000 to Africa CDC, 200 000 to the Democratic Republic of Congo, and 5 420 to Rwanda.

A previous [CEPS report](#) found that in its international scope, particularly in LMICs, HERA has increased both its financial support and range of activities around intelligence gathering and threat assessment, research and development, production capacity, resource donations, and cooperation agreements, and as an international instrument in health. Some interviewed stakeholders nonetheless point to the underdeveloped (and under-resourced) global dimension of HERA's activities, including its capacity to address global concerns that disproportionately affect LMICs (such as AMR and climate-related health threats). This capacity seems needed even more today, as the US is gradually

reducing its contributions to global pandemic preparedness by de facto [emptying out](#) its administrative agencies in this policy domain, and [dramatically undermining](#) science-based policy.

As a relatively young DG, HERA brings unique expertise that is central to safeguarding the health security of the EU and, by extension, the global community. Understanding how HERA functions internally, particularly in implementing its mandate on MCMs, is key to clarifying its position, coordination mechanisms, and added value within the broader EU health security architecture.

Assessing HERA's internal mandate and activities allows for a clearer view of how effectively it operates, ensures coherence across EU institutions, and builds resilience against future health emergencies. As pandemics and cross-border health threats do not respect borders, HERA's engagement in the global health preparedness and response space is a critical complement to its EU-level mandate. Monitoring HERA's international activities is helpful in evaluating outcomes and impacts, aligning EU contributions with real global needs, identifying persistent gaps, and providing evidence to inform decisions on resources and partnerships. Exploring HERA's internal and external remits is essential to ensure that the EU's health security framework is coherent, impactful, and globally relevant.

### 3. DEFINING HERA'S ROLE: RESPONSIBILITIES AND AMBIGUITIES IN RECENT EU-LEVEL STRATEGIES

Under the EU Preparedness Union Strategy adopted in March 2025, the European Commission introduced two major initiatives in July 2025: the [EU Stockpiling Strategy](#) and the [MCM Strategy](#). Both are highly relevant to HERA and to its internal and external remits. While there is broad agreement on the significant value these strategies bring to the EU's preparedness agenda, certain aspects still require further clarification, which will also influence HERA's future role and scope under its mandate.

Importantly, these internal strategies shape not only how HERA can organise and deliver on its EU responsibilities, but also what kind of partner it can be internationally with LMICs, private entities, and bilateral actors. HERA's approach to stockpiling and implementing MCM-related activities will be an important measure of its credibility. It will showcase HERA's capacity to translate strategy into the delivery of essential countermeasures and thereby strengthen its ability to build effective and trusted cooperation with global partners. Clear and aligned internal strategies provide the foundation for HERA to successfully position itself as a reliable and strategic actor in EU preparedness and response as well as in the wider framework for global health security.

#### 3.1. EU STOCKPILING STRATEGY: FROM STRATEGY TO IMPLEMENTATION AND THE NEED TO CLARIFY ROLES AND RESPONSIBILITIES

The EU Stockpiling Strategy serves as a key first step towards strengthening the EU's material preparedness. It highlights seven areas of EU action to achieve the following objectives:

- improve access to essential goods;
- enhance the interoperability of stockpiling systems at both the national and EU levels;
- ensure material preparedness;
- support strategic autonomy for the EU, by reducing dependencies and vulnerabilities and enhancing EU production of essential goods.

Since publication of the strategy, two issues remain unclear that affect HERA's role and operations: the allocation of roles and responsibilities for the implementation of the strategy, and the operational details of the stockpiling, such as the sources of funding and the quantities of stockpile required.

A notable concern about the EU Stockpiling Strategy lies in the lack of clarity about its operationalisation, particularly the specific roles, responsibilities, and coordination

mechanisms among European Commission DGs. While the strategy frequently references the Commission, it does not specify which DGs will lead implementation, leaving institutional roles and coordination mechanisms unclear, including for HERA.

Further clarity is also needed on the coordination between the European Commission and EU Member States, especially on how HERA would address obstacles in cross-border delivery during health emergencies, such as potential border closures. Without clear instructions, the EU's response risks being fragmented or delayed. In addition, synergies between EU stockpiling efforts, humanitarian aid, and international partnerships, including the coordination between the DG for Civil Protection and Humanitarian Aid Operations (ECHO) and HERA, must be more clearly specified to avoid duplication and ensure coherency in crisis response.

The stakeholders interviewed also highlighted opportunities for HERA to take a more central role in the coordination of MCM stockpiling. Making HERA a primary point of contact at the Commission would enhance planning, procurement, management, and deployment of MCM stockpiles, improve identification of critical supply chain dependencies, support diversification strategies, and facilitate the sharing of best practices. Some stakeholders further urged the expansion of HERA's role in fostering international partnerships with public and private institutions in industry and academia, to leverage potential synergies.

Effective stockpiling requires technical expertise in determining which MCMs to stockpile, their quantities, storage requirements, and quality monitoring, and in managing shelf-life limitations. Stakeholders agree on the strategic value of MCM stockpiles. But clarification is needed on decision-making, funding sources (including HERA's budget), the duration and scale of stockpiling, industry engagement, fair allocation, and how funding priorities will be determined under the next Multiannual Financial Framework (MFF).

The development and stockpiling of MCMs is an area where interviewed stakeholders saw the potential for mutually beneficial cooperation and support between HERA and similar institutions in non-EU countries, to share intelligence on what stockpiles may be interesting to develop or the quantities of stock to have available.

Finally, stakeholders observed that enhanced preparedness for future health crises could be supported by more centralised storage of MCMs, managed by the European Commission. In such a system, its role would involve facilitating the rapid deployment of MCMs and ensure that their distribution is based on assessed needs from the start of a crisis, allowing for a more effective rationalisation and mutualisation of resources. Such a role would be suitable for HERA.

### 3.2. OPERATIONALISING HERA AT THE CORE OF THE MCM STRATEGY: CLARIFYING COORDINATION AND REALISING UNTAPPED POTENTIAL

Set up against the background of the [Niinistö](#) and [Draghi report](#) recommendations and under the umbrella framework of the [Preparedness Union Strategy](#) and the [Competitiveness Compass](#), the MCM Strategy aims at increasing the EU's preparedness for the next health emergency. It seeks to do so by ensuring the availability and access to MCMs at all times. With a comprehensive One Health approach, the strategy strives to (i) strengthen end-to-end MCM preparedness, from R&D to production and deployment, (ii) deepen cooperation with Member States and international partners, (iii) scale up public and private partnership, and (iv) enhance cross-sectoral collaboration.

HERA is central to the implementation of the MCM Strategy, which describes HERA as the 'watchtower' for preparedness and response in the area of MCMs, working in close collaboration with other European Commission services. In the external domain, it sets a path for HERA to expand its role in global health security: promoting global cooperation, coordination and R&D synergies with international partners; enhancing collective intelligence on health threats for MCMs; and supporting the development of regional production capacities and supply chain security.

Strengthening civil-military cooperation is one of the main ideas of the strategy. It proposes to develop a Medifence initiative in 2026 to ensure access to MCMs for CBRN security threats and foster civil-military R&I synergies, building on actions and funding from EU4Health, the European Defence Fund, the European Defence Agency and Member State initiatives. Stakeholders perceived an increase of civil-military synergies as a natural progression of HERA's maturation and the EU's integrated all-hazards approach, central to the EU Preparedness Union Strategy. However, coordination remains fragmented across Commission services (e.g. with DG SANTE and DG ECHO). Furthermore, in parallel the Member States engage in international fora, such as the NATO Joint Health Group. This fragmentation risks slowing down the EU's crisis response, duplicating efforts, and weakening the EU's credibility in international fora. HERA would benefit from a more central role in coordinating efforts, to mitigate these risks and improve efficiency in EU preparedness.

Stakeholders also welcomed the strategy's pragmatic approach of focusing on a set of four categories of severe and serious health threats that require a coordinated EU response in the area of MCMs. That is not only because of its clarity but also because it allows for resources and expertise to be concentrated where they are most needed, before expanding to address the full spectrum of potential risks. Nevertheless, stakeholders noted the need to embed a more gender-responsive approach in all stages of MCM

development, ensuring data disaggregation and prioritising innovation in gender-specific health areas.

The MCM Strategy takes into consideration greater engagement with the academic sector, including expanding the [DURABLE project network](#) globally. Stakeholders noted that similar models with strong ties to the academic sector had proved effective during Covid-19, enabling a swift pivot of research priorities and mobilising scientific expertise to support pandemic response.

Exploring expansion of the scope of [EU FAB](#) to enhance EU-based production capacity for MCMs in preparation for crises has been welcomed. Adding to a production capacity of 325 million vaccine doses that can be rapidly activated in the event of an emergency, the Commission plans to increase EU-based capacity to a wider range of products. It intends to assess the possibility of using EU FAB production capabilities in the preparedness phase as well, supporting civilian and military needs. Strengthening the security of supply chains, encouraging industrial readiness, and increasing the supply and production of MCMs will be key to faster mobilisation in health crises. As a previous [CEPS report](#) noted, it is not possible to include support of production capacity in LMICs in the EU FAB's scope due to operational constraints. Stakeholders would welcome HERA finding a tailored and optimised manufacturing solution to increase production capacity in LMICs in the future.

Overall, the stakeholders were particularly vocal about missed opportunities to enhance diagnostics in the MCM Strategy. The strategy augments the role of the [Global Consortium for Wastewater and Environmental Surveillance \(GLOWACON\)](#), announcing the launch of a Global Sentinel System for wastewater in 2026. Wastewater surveillance was identified as one of HERA's core actions when it was set up in 2021. In March 2024, HERA launched GLOWACON together with the Joint Research Centre to create an international sentinel system for the early detection, prevention, and real-time monitoring of epidemic threats and outbreaks.

Stakeholders noted that HERA's actions put an overemphasis on wastewater management. They underscored missed opportunities in the MCM Strategy to adopt a holistic approach to surveillance. Concerns were raised about the need for HERA to broaden its approach by integrating other types of surveillance, such as routine surveillance in the form of ongoing monitoring of potential health threats that were not included in the MCM strategy.

To broaden HERA's approach to surveillance and its operationalisation, stakeholders encouraged the integration of wastewater surveillance into other multiple, complementary methods for early detection and monitoring, rather than relying too heavily on a single surveillance approach. They also noted that current surveillance tools



lack sufficient incorporation of diagnostic and digital tools, which limits the rapid identification of and response to emerging threats.

The European Commission should consider the creation of a dedicated data space for health surveillance that integrates diverse data sources and enables AI-driven early detection and risk assessment. Such a platform would operationalise the MCM Strategy's objectives by boosting early detection capacities and data interoperability across surveillance systems. Improving digital and diagnostic tools, especially for pathogen diagnostics, would greatly help to develop a more coherent EU strategy for health surveillance to ensure the EU is better prepared for future crises.

Taken together, the Stockpiling and MCM Strategies underscore both the importance of HERA's mandate and the persistent ambiguities that continue to shape its role within the EU's architecture for preparedness. Stakeholders broadly recognise the added value of these initiatives and HERA's potential as a central actor. Yet, their reflections also reveal areas where there are still gaps in how synergies are built across the EU's system, how funding is allocated and used, and how partnerships are designed to be both strategic and equitable. These insights point to three overarching themes that merit closer examination.

## 4. MISSED OPPORTUNITIES TO BUILD AND LEVERAGE SYNERGIES IN EU HEALTH SECURITY, PREPAREDNESS, AND RESPONSE

HERA was established as the EU's operational arm for health crisis management, complementing the mandate, policy leadership, and technical expertise of other DGs. For the European Commission to sustain and advance its position as a global leader in health security, streamlined, inclusive, and coherent governance is essential. This requires addressing missed opportunities to create and leverage synergies, including those involving HERA.

HERA's focused mandate on the implementation of MCMs is widely regarded as a strength, filling a previous gap in the EU's health security architecture. Its importance was reaffirmed with the decision to establish HERA as a permanent DG and the appointment of a new Director-General in 2025. However, with the reduced budget outlined in the 2025 work programme, HERA must deliver more with fewer resources. This heightens the need for all relevant DGs to fulfil their respective mandates effectively, align activities with broader EU objectives, and prioritise horizontal and international collaboration.

In practice, some stakeholders have observed instances of tension or perceived competition where priorities and areas of work overlap across mandates. At the Commission, for example, these challenges can arise regarding the scope and budgetary responsibilities of HERA and other DGs. Externally, while HERA has invested substantially in raising its visibility and credibility among international partners, some stakeholders noted that its value is at times more readily acknowledged outside the EU than within.

HERA does not hold an independent budget. Financial oversight rests with other parts of the Commission, and workplan budgets require approval through processes involving multiple DGs and Horizon Europe governance bodies. This can lead to delays and make allocations vulnerable to broader political considerations.

HERA's work on MCMs is intrinsically linked to the mandates of other EU bodies: DG SANTE on policy leadership, the DG for Research and Innovation (RTD) on the research agenda, the ECDC on surveillance functions, and the European Health and Digital Executive Agency (HaDEA) on grant management, among others. While these complementarities are recognised, certain areas remain insufficiently delineated, particularly surveillance. Overlaps in scope can be productive, offering redundancy that enhances system resilience, but they require careful coordination to avoid duplication and operational inefficiencies. Lapses in leveraging existing activities, such as shared but fragmented investments in AMR-related R&I by HERA and DG RTD, illustrate the need for more effective integration across workstreams.

Stakeholders also spoke of the need for stronger cooperation between HERA and the EMA to better align regulatory and innovation pathways and to create incentive mechanisms that help bridge the 'valley of death' between clinical research and product development. This would accelerate R&I in priority areas, address persistent market failures such as AMR, and ultimately increase Europe's contribution to global health innovation.

External stakeholders spoke of missed opportunities in coordinated efforts across Commission services to align scientific innovation with implementation and development of more cohesive strategies for public health surveillance. Stakeholders noted the benefit of revisiting the broader European Commission strategy of public health surveillance (led by DG SANTE and under development), which should take into account more effective integration, cross-Commission perspectives, and a more unified focus on R&I.

In health intelligence, ECDC retains a well-established technical mandate for disease surveillance but lacks operational authority. HERA, with an operational focus, has increasingly taken on intelligence-related functions, including environmental monitoring through wastewater surveillance and laboratory capacity building, particularly in cooperation with African Union member states. While this expansion is valued by external partners, it underscores the importance of clearly defining institutional roles to ensure complementary rather than competing functions.

As noted above, concerns were also raised by respondents that an intense focus on areas such as wastewater surveillance could risk diluting HERA's MCM-centred mandate. Stakeholders acknowledged that wastewater surveillance is a valuable element of the broader surveillance and monitoring toolbox. Yet they emphasise that it should be one of several complementary tools receiving investment within the wider pandemic preparedness framework. Some have also questioned whether HERA's current level of concentration on this area is fully warranted. Stakeholders recognised the visible investments HERA has been making in surveillance, but at times have found it difficult to see how this investment fits within the broader strategic direction.

More broadly, EU-wide priorities need to be embedded more deliberately into individual DG actions, with a conscious effort to prevent overlap. Whether through formal agreements, memoranda of understanding, or operational collaborations, HERA has shown it can work effectively with EU institutions and global partners in implementing, delivering, and innovating MCMs.

Despite its mission to act rapidly in crises, HERA operates within the same procedural and bureaucratic constraints that affect other EU institutions: prolonged project cycles, extensive consultations, and multi-layered approvals that can often slow decision-making. These processes, while designed for accountability, are not optimised for emergency

contexts where agility and speed are critical. These structural limitations are compounded by constrained resources, making efficiency and coordination across the health security ecosystem more important than ever.

Interviewed respondents emphasise the role AI will play in epidemic preparedness, including in MCMs. They stressed the importance of the European Commission adopting a coherent and streamlined approach to AI that incorporates appropriate safeguards. In global health surveillance, respondents also noted the potential to deepen collaboration with other Commission services, such as the Joint Research Centre, where AI expertise could provide significant added value.

Given its operational mandate and external-facing role, HERA is uniquely positioned to serve as a central coordinator of MCMs, ensuring that its international collaborations and cooperative agreements are fully aligned with EU strategic priorities and complementary to existing activities. The evaluation report on HERA praised its role as being a central coordinating body for MCMs, stockpiling, and crisis preparedness. Strengthening this horizontal coordination, both across EU institutions and with external partners, would help avoid overlaps, bridge gaps between policy and implementation, and foster more coherent, mutually reinforcing actions.

More upstream dialogue between policymakers (HERA and DG SANTE) and implementers (HaDEA, DG RTD, the DG for International Partnerships (INTPA), and DG ECHO) is needed to ensure feasibility, maximise impact, provide clarity, and identify ideal 'handover points' between institutions and entities. While DGs view cooperation with HERA as generally constructive, stakeholders stress the importance of early engagement, clearer feedback loops, and shared learning from implementation experience. Without this, there is a risk of confusion and missed opportunities for synergy in joint preparedness and planning.

## 5. FUNDING AND FLEXIBILITY FOR A MORE EFFECTIVE AND AGILE HERA

Stakeholders broadly agree that HERA's ability to fulfil its mandate depends on having a more predictable, flexible, and dedicated funding framework. A previous [CEPS report](#) highlighted that HERA's budgetary resources are extremely fragmented and rigid, limiting HERA to solely concluding short-term funding agreements. The CEPS report also noted that the main source of funding for HERA's actions was [originally intended](#) to come from the Emergency Support Instrument in times of crisis.

However, HERA has adjusted its original approach, now [contemplating](#) the use of funds from EU4Health and Horizon Europe for emergencies. Although existing instruments such as EU4Health have played a valuable role in strengthening health systems and preparedness, they are not designed as primary crisis-response mechanisms. Proposal timelines under EU4Health often span several months, which can be challenging amid the urgent demands of crisis response. In emergency situations, such as pandemics or cross-border health threats, instruments like the Union Civil Protection Mechanism or DG ECHO have been better suited to rapid mobilisation of response efforts.

All the same, without a dedicated crisis-response budget, HERA's ability to act swiftly is constrained by the timelines and procedures of annual work plans. Allocating a reserved, flexible budget, sourced appropriately without reducing other essential preparedness investments, could speed up mobilisation in emergencies, avoiding the delays inherent in the current system.

The current funding structure under EU4Health also contains relatively few provisions specifically dedicated to crisis preparedness. This limited flexibility became evident during the mpox outbreak, when even the fastest tendering processes took over a month, while calls for proposals required three to four months. These timeframes are incompatible with crises response needs. Moreover, budgetary control for key areas, such as R&I under Horizon Europe, remains with other DGs, leaving HERA dependent on inter-DG negotiations and vulnerable to shifting political priorities. This has created uncertainty over whether HERA will have a dedicated budget in the next MFF.

Funding challenges are compounded by the political difficulty of prioritising investments in preparedness and stockpiling when no crisis is imminent, especially when other politically visible priorities are currently taking precedence. The unclear overlap of certain responsibilities and priorities between HERA and other DGs, such as DG RTD, can also limit efficiency and synergy, particularly for cross-cutting issues like AMR and vaccine manufacturing. While some proposed activities align with HERA's mandate, these can be excluded from funding on the basis that they fall under another DG's remit, leading to missed opportunities for coordinated action. One such example is funding research that

incorporates aspects of increased access to antibiotics that are not covered by DG RTD funding but are supported under EU4Health projects.

A more coherent and transparent financial framework, potentially through a stand-alone budget, would enable HERA to engage in long-term planning rather than negotiating annually for funds. This point is echoed in the recently published HERA evaluation. This approach would be particularly valuable for sustaining innovation pipelines, where predictable investment is essential for pre-clinical and early-stage R&D and critical for MCMs overall. Greater flexibility in funding modalities, such as moving beyond strictly activity- and output-based allocations towards portfolio funding, could further strengthen HERA's ability to spur innovation and respond to emerging needs. This is not to say change the whole funding structure, as the activity and output-based model under HERA is an asset in the view of partners, which allows for focused and concrete actions that largely align with partner goals.

At the same time, stakeholders caution that greater flexibility should be balanced with accountability and strategic focus. One of HERA's strengths, as noted by partners, is its clarity of purpose and targeted approach – qualities that should be preserved even as its funding base evolves. Maintaining this focus, while expanding flexibility, could position HERA as a more effective and agile body for advancing EU and global health security. Given the shifting global landscape, including reduced US leadership in global health R&D, the EU has an opportunity to assert itself more in this space, provided DGs, including HERA, are equipped with the resources and flexibility to lead.

To ensure HERA can deliver on its mandate, the next MFF could allocate a dedicated, flexible budget for crisis preparedness and MCM-related R&D, enabling both rapid emergency response and sustained long-term investment. At the moment, Horizon Europe does not have a dedicated MCM component. This should be paired with clearer budget ownership, better alignment with other DG funding streams, and simplified mechanisms to mobilise resources in real time. Embedding early-stage coordination between policymakers and implementers would further improve efficiency, while transparency in funding flows would enhance trust and strategic planning. Finally, elevating health security as a political priority within the Commission's broader competitiveness agenda would safeguard resources for preparedness, so that HERA remains both a focused and forward-looking entity for EU and global health resilience.

## 6. DEVELOPING MORE EQUITABLE AND STRATEGIC PARTNERSHIPS

Stakeholders emphasise that for HERA to fully realise its global health mandate, it must cultivate partnerships that are both equitable and strategically integrated within existing EU and international frameworks. Recent initiatives, such as the cooperative agreement with Africa CDC and ongoing discussions with the Pan-American Health Organization, demonstrate the potential for mutually beneficial collaboration.

Still, there are concerns that some partnerships risk being developed in parallel to, rather than in coordination with, existing structures. For example, Horizon Europe already maintains a formal agreement with Canada, yet HERA has pursued its own bilateral arrangement. This raises questions about whether opportunities for leveraging present channels are being fully exploited, such as the 2024 formalised Horizon Europe agreement with Canada. Similarly, stakeholders suggested that HERA play a more proactive role in ongoing negotiations on collaboration to promote coherence and prevent duplication. Those with Switzerland serve as an example, given its [recently announced eligibility to participate in several EU programmes](#), including Horizon Europe<sup>1</sup>.

Since 2022, HERA has expanded its global role through strategic partnerships with numerous organisations:

- Africa CDC
- African Medicines Agency
- US Department of Health and Human Services
- South Korea's Ministry of Health and Welfare
- Japan's Agency for Medical Research and Development
- Coalition for Epidemic Preparedness Innovations (CEPI)
- Gates Foundation
- WHO
- UN Environment Programme.

These collaborations centre around strengthening [MCMs, surveillance, and pandemic intelligence](#), reflecting a growing recognition of the need for coordinated international responses to global health threats. In 2025, it embarked on [formal cooperation](#)<sup>2</sup> with Health Emergency Readiness Canada on supply chains and preparedness. HERA also

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<sup>1</sup> See the EU Delegation to Switzerland and Liechtenstein, '[EU and Switzerland initial agreement on participation in Union programmes](#)', 3 April.

recently launched its [Stakeholders Hub](#), a digital platform connecting EU and global actors across health and pharmaceutical systems, including the Critical Medicines Alliance and Joint Industrial Cooperation Forum. a digital platform connecting EU and global actors across health and pharmaceutical systems, including the Critical Medicines Alliance and Joint Industrial Cooperation Forum.

A recurring concern cited by partners is the EU's difficulty in adapting its regulatory and funding frameworks to enable truly equal collaboration, particularly with LMICs. Rigid eligibility criteria and limited flexibility in R&I funding models can constrain the scope for co-designing initiatives with non-EU actors. This rigidity risks reinforcing a donor-recipient dynamic rather than fostering genuine co-ownership. External and international partners value their relationship with HERA but perceive a tendency for HERA to form partnerships that prioritise HERA's operational needs over shared strategic goals. This has, at times, resulted in one-sided dialogue and an overemphasis on financial transactions, rather than balanced technical and operational cooperation.

To mobilise follow-up funding and leverage resources more efficiently, it will be crucial for HERA to embrace a comprehensive global health approach that systematically accounts for the impact of EU actions on public health in LMICs. It should address threats that disproportionally affect LMICs, like AMR and emerging climate-sensitive diseases, while aligning more closely with other global actors such as multilateral organisations.

Stakeholders emphasise that given the established relationships and existing needs across the African continent, HERA should further commit to supporting African countries and institutions in building capacity and response capabilities. This will help to fortify epidemic preparedness, R&I, and the regulation and manufacturing of MCMs, and facilitate critical interventions – for both Africa and the EU – for example by technology transfer and data exchange. HERA should also strive to promote equitable access to MCMs through access conditions, technology transfer, and support for local production, particularly in LMICs.

Several examples illustrate the benefits of a more integrated and equitable approach. The Africa CDC partnership, developed in close collaboration with DG SANTE, DG INTPA and other Commission services, is seen as an illustrative model for aligning EU and regional priorities, leading to concrete joint activities like mpox response coordination. Similarly, the WHO's embedding of external representatives, such as seconded US CDC officials, in its incident management structure offers a model for deep operational integration. Stakeholders see value in HERA participating in such structures as well as hosting secondees from partner organisations, facilitating real-time information exchange and joint decision-making.



Looking forward, there is strong support for HERA to broaden its international footprint in ways that mirror the engagement of the US Biomedical Advanced Research and Development Authority with global health actors, while maintaining alignment with EU priorities. This could include deepening collaboration with CEPI, Gavi, and NATO's Joint Health Group. Strategic links could be forged with homologous institutions, such as the Swiss Federal Office of Public Health, the UK Health Security Agency, Japan's Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response, and the Korea Disease Control and Prevention Agency.

In doing so, HERA should aim to co-design initiatives from the outset, ensuring mutual benefit, shared governance, and a clear articulation of how partnerships fit within the EU's broader external architecture for health. A greater emphasis should be placed on upstream dialogue, early engagement, and feedback loops, particularly with implementing bodies such as HaDEA. This would help ensure that partnerships are not only technically sound but also grounded in operational realities. Continual clarification of mandates and remits vis-à-vis the other parts of EU machinery will also be crucial here.

By fostering more equitable, strategically integrated collaborations, HERA can strengthen both its credibility and its effectiveness, positioning itself as a trusted partner within the global health security landscape. This will require flexibility in funding models, deliberate avoidance of duplication, and a shift towards partnerships that embed shared responsibility and long-term mutual benefit at their core.

## 7. POSITIONING HERA IN THE EU'S GLOBAL HEALTH EFFORTS

The EU Global Health Strategy and its [implementation report](#) highlight Europe's ambitions for global health leadership. However, HERA is largely absent from both documents, which represents a missed opportunity to clarify HERA's role and its positioning within the broader EU framework. As a previous [CEPS report](#) noted, the relationship between the Health Crisis Board and HERA has remained ambiguous, raising concerns about whether HERA would have the necessary competence and autonomy to act effectively in matters pertaining to MCMs during a crisis. Clarifying these institutional relationships will be essential to fully leveraging HERA's operational mandate and ensuring coherent crisis preparedness and rapid response.

The external HERA review describes the rise of HERA as a credible and recognised player in global health security and response, valued by international partners. This sentiment was consistently echoed among the stakeholders interviewed, with some interestingly voicing that HERA's recognition is higher outside the EU than within the EU among the Commission and Member States. Although that is beneficial for raising the visibility of the EU in global health endeavours overall, it may give rise to issues in alignment or expectations between internal and external stakeholders and partners.

The evaluation of the Global Health Strategy spotlighted the success of Team Europe's response to the mpox outbreak in 2024 in Africa. Stakeholders concurred that mpox is a standout example of how the Team Europe approach can be successful when responding to a global health emergency. They perceived the EU's approach to mpox to be coordinated and effective, particularly in vaccine mobilisation and delivery, but noted some operational and coordination shortcomings and misalignment around regulatory approvals, which were rapidly resolved.

In future emergencies, a clearer division of roles among EU institutions and stronger global coordination will be needed, as well as measures to ensure a faster EU response. HERA and the WHO should work constructively within their mandates to pursue solutions, avoid duplication, and prevent mandate boundaries from creating tension. Closer coordination with global actors (e.g. Gavi and the WHO) will also be critical to prevent delays in the delivery of MCMs during crises. Stakeholders observed that as HERA matures, clearer predefined mechanisms and stronger leadership will be needed to reduce legal and procedural bottlenecks that slow down procurement and the deployment of MCMs.

## 8. HERA'S ROLE IN A CHANGING GLOBAL HEALTH WORLD

In its four years of operations, HERA has made a significant contribution to the EU's ability to prepare and respond by deploying MCMs – demonstrating the EU's capacity to move from a reactive mindset to a proactive one in terms of readiness. The HERA review, together with the EU's Stockpiling and MCM Strategies, confirm HERA's central role in EU health security and crisis preparedness. All the same, some competences and coordination mechanisms across European Commission services remain unclear.

Operational questions are emerging against a background of unprecedented challenges in global health governance. These are being amplified by the escalation of geopolitical tensions and, above all, drastic reductions in development financing over the past months. [Projections](#) show a decline of 19–33% in health-related official development assistance in 2025 compared with 2023 levels. This will lead to millions of lives lost and the inevitable need to reform the broader global health architecture.

In this complex and pressing context, streamlining efforts and avoiding duplication has become an urgent necessity for all actors and a new mantra. For the EU and Team Europe, navigating this constrained environment together, while managing sensitivities and budget reductions announced by European donors, will be critical. At a time when major global health agreements and institutions have either stalled or weakened, with the possible exception of the [Pandemic Agreement](#) adopted in May 2025, new challenges and opportunities for cooperation arise. Hence, [the EU must](#) expand its external engagement and multilateral cooperation, particularly on pandemic preparedness, response, and resilience.

Against this backdrop, HERA faces hurdles in fulfilling its mandate. It is operating with reduced resources under the 2025 workplan and must adapt to a rapidly evolving global health landscape. While the budgetary constraints are real, HERA's contribution remains indispensable: its role in ensuring the EU's health security and in improving global preparedness is not only uncontested but increasingly vital. Without targeted resources and strategic clarity, however, HERA risks being constrained in its ability to respond rapidly and effectively to emerging threats, limiting the EU's leadership in global health.

Fully realising HERA's potential and becoming a truly effective contributor to global health preparedness and global equity requires a clearer and more integrated approach within the EU's global health framework. Additionally, it is crucial to increase strategic alignment and cooperation with international partners, foster equal partnerships and avoid donor-recipient dynamics.

Looking ahead, safeguarding and leveraging HERA's capacity to deliver a fast and effective crisis response, despite resource pressures, will be essential to reinforce both the EU's

credibility and its leadership in global health security. To achieve this, it is vital to set aside a dedicated and flexible budget for crisis preparedness and MCM-related R&I, so that HERA can respond swiftly in emergency situations while making strategic investments in the long term.

The upcoming MFF presents a pivotal opportunity to rethink HERA's budget structure. This should be done with the aim of streamlining resources, strengthening crisis-response readiness, supporting innovation, and reinforcing strategic, global partnerships. That approach will not only maximise HERA's impact but also secure its role as a cornerstone of EU and global health preparedness.



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