



EU R&I and Health  
Policy to Tackle  
Global Challenges

# Driving innovation for global health security: how HERA can rally R&D forces across Europe and the world

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## SUMMARY

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Global health research and development (R&D) is entering a period of acute vulnerability. The US is withdrawing from multilateral health commitments it once anchored and major donors are cutting development funding, all while climate change and conflicts are accelerating the emergence of new health threats. Against this backdrop, the EU has signalled a renewed commitment to global health leadership, most notably through the announcement of the Global Health Resilience Initiative (GHRI), yet this ambition risks being undermined from within. The EU's sharpening focus on industrial competitiveness threatens to redirect priorities inward, crowding out global health when it demands greater investment.

Within this landscape, the Health Emergency Preparedness and Response Authority (HERA) is well placed to lead the EU's efforts to strengthen international R&D collaboration. It has made much progress on advancing bilateral and multi-stakeholder partnerships; however, its external mandate remains underfunded and its engagement with low- and middle-income countries is largely project-based rather than capacity-building oriented.

Drawing on an analysis of HERA's international partnerships and Horizon Europe funding flows, this paper examines how the upcoming GHRI and Multiannual Financial Framework can be leveraged to strengthen HERA's global health R&D footprint. It proposes concrete actions for the Commission to ensure that HERA is adequately resourced, strategically coherent, and positioned to deliver on the EU's global health ambitions.



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## EXECUTIVE SUMMARY

Global health research and development (R&D) is entering a period of heightened vulnerability. The US is retreating from global health commitments it once anchored and other major donors are cutting development funding, all the while climate change and conflict are accelerating the emergence of new health threats. In this context, the European Union (EU) faces growing expectations to assume a stronger leadership role in global health R&D.

The EU has signalled its intention to play a leading role through its Global Health Strategy and the upcoming Global Health Resilience Initiative (GHRI). Within this landscape, the Health Emergency Preparedness and Response Authority (HERA) is well positioned to lead the EU's efforts to strengthen R&D and international partnerships. Since its creation in 2021, it has made much progress: signing bilateral agreements with the US, Japan, South Korea, and Canada; co-investing with CEPI and the WHO; expanding surveillance networks and deepening partnerships across continents; and channelling Horizon Europe funding for global health R&D, among others.

But HERA has yet to live up to its full potential.

HERA's cooperation with high-income countries and multilateral organisations is relatively strong, but engagement with low- and middle-income countries is still largely project-based, with limited focus on long-term capacity building. Gavi also remains outside HERA's direct remit despite its centrality to vaccine equity. Bilateral partnership momentum does not always hold, as seen with the Japan-AMED partnership. Crucially, cooperation with India is at an inflection point, which HERA should build upon. Coordination complexity is also growing across multilateral and bilateral partners, with no systematic mechanisms to ensure HERA's technical intelligence informs DG INTPA's funding decisions before commitments are made.

On funding, HERA cannot realistically plan or sustain the R&D investment pipeline that its mandate requires without multi-year, flexible, and dedicated resources. Today, HERA's R&D budget has already started declining, with MCM-related allocations falling between 2024 and 2025 following EU4Health cuts. The EU's sharpened focus on industrial competitiveness, reflected in the Life Sciences Strategy and the broader Competitiveness Compass, risks crowding out global health as a funding priority. Under the next Multiannual Financial Framework (MFF), EU investment in global health R&D could quietly shrink when it is needed most. The proposed absorption of EU4Health and attachment of the Framework Programme to the European Competitiveness Fund risks redirecting priorities inward. Private sector underinvestment in crisis-critical MCMs remains structural, while HERA Invest's funding envelope is too modest to close that gap.

If navigated well, the upcoming GHRI and 2028–2034 MFF could represent a key opportunity for HERA to strengthen its global health footprint and thereby reinforce collective health security. To ensure these turning points are leveraged successfully, we propose the following actions to be taken either by the Commission or HERA itself.

#### **Sharpen internal Commission coordination**

- Clarify roles between HERA, DG SANTE, and DG INTPA on R&D coordination and partnership selection. Embed HERA's threat assessments into DG funding cycles and synchronise planning across DGs, so health security expertise shapes resource allocation.

#### **Expand bilateral and regional partnerships**

- Formalise cooperation with Switzerland's Federal Office of Public Health and the UK Health Security Agency.
- Build health security partnerships onto established EU frameworks (e.g. EU-India Strategic Agenda), rather than starting from scratch, and time signings to coincide with regional summits.

#### **Deepen multilateral engagement**

- Formalise the Gavi partnership, given its strategy on regional manufacturing and pandemic preparedness aligns directly with HERA's mandate.
- Expand engagement with WHO beyond the Berlin Hub to include regional offices.
- Establish a global Tech Watch mechanism to identify critical gaps in European access and guide joint R&D priorities.

#### **Respond to US withdrawal**

- Use the Be Ready Now Partnership as Europe's alternative to the terminated US CREID network.
- Engage countries losing US backing where European regulatory excellence and research capacity can generate genuine impact.

#### **Enhance the use of foresight and AI**

- Coordinate foresight between HERA, ECDC, EMA, and the WHO Hub. Scale AI applications for early pathogen detection, MCM monitoring, and biosecurity. Invest in interoperable data infrastructure with equity safeguards.

**Secure the right funding for HERA in the MFF:** We support the creation of *two high-level councils within the upcoming MFF*, aimed at bolstering Europe's R&I infrastructure in preparation for the subsequent Framework Programme, ensuring resources effectively address both internal security and global challenges. HERA should leverage the funding under these two councils differently:

- *Under the Council for Competitiveness and Security:* Frame MCM supply chains as strategic technologies eligible for the European Competitiveness Fund. Enable portfolio and at-risk investment approaches. Secure multi-year dedicated funding. Increase industry engagement through structural incentives, including push-pull mechanisms and pre-call dialogue.
- *Under the Council on Global Societal Challenges:* Reframe global health cooperation as a strategic investment. Expand R&D capacity building in LMICs beyond surveillance. Strengthen technology transfer and IP-sharing frameworks. Leverage multi-stakeholder co-funding.

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## 1. INTRODUCTION: THE EU'S RENEWED COMMITMENT TO GLOBAL HEALTH LEADERSHIP

Global health research and development (R&D) remains critically important for the European Union (EU). Investing in global health R&D is not just altruism: it is a prudent act of upstream preparedness and an instrument for [strategic autonomy](#), national security, and diplomacy. The immediate societal value, coupled with the broader ripple effects on the economy and innovation, makes global health R&D a clear strategic investment for the EU. Indeed, many health innovations initially developed for low- and middle-income countries (LMICs) have demonstrated considerable benefits for high-income countries (HICs), with an average of 85 % of global health R&D funding [remaining in Europe](#).

In this vein, global health security is more vital than ever, as the worsening impacts of climate change and ongoing global conflicts [heighten the risk](#) of emerging public health threats and disease outbreaks. Yet a kind of pandemic fatigue has set in, with funding and political commitment to global health increasingly under strain. The world faces renewed geopolitical tensions, with many nations significantly expanding their defence funding, increasingly at the expense of health. The substantial [scaling back](#) of global health and development funding, with health-related bilateral aid estimated to have dropped by 19-33 % in 2025, threatens the global community's preparedness and response capacities. The [retreat](#) of the US from multilateral affairs and its abrupt [defunding](#) of key institutions continues to profoundly [undermine](#) long-term global health initiatives and their progress. The US's global health funding is [expected to fall](#) from USD 10 billion to USD 3.8 billion in fiscal year 2026, while other major donors, including France, Germany, and the UK, are also reducing global health investments. This pandemic amnesia [risks a repeat](#) of an inadequate response to the next global health threat.

In this gloomy landscape, the EU's rhetorical commitment to leading health security efforts must be matched by meaningful action.

Adopted in 2022, in the middle of the COVID-19 pandemic, the EU's [Global Health Strategy \(GHS\)](#) represented a renewed commitment to positioning the EU as a key player in strengthening the global health agenda. By emphasising solidarity, equity, and partnerships with LMICs, it seeks to reinforce Europe's role in an increasingly complex global health architecture. Yet in practice the EU's handling of the arduous multi-year negotiations of the [Pandemic Agreement](#), a key goal of the GHS, was subject to some [criticism](#). For example, concerns were raised about the EU's stance on intellectual property rights and the transfer of pandemic-related technology, and about its approach

to research partnership with LMICs, which critics argued did not sufficiently ensure that LMIC voices were heard or that value was created at the local level.

Then, the EU's competitiveness era kicked in.

The [Life Sciences Strategy](#), launched in July 2025, appears to misalign with the EU Global Health Strategy, as its cross-sectoral framework and new opportunities to mobilise R&D funding prioritise the bloc's competitiveness rather than being globally oriented. With EUR 10 billion earmarked through 2029, it seeks to overcome long-standing fragmentation across pharmaceuticals, biotechnology, medical technology, and biomanufacturing. In this respect, it follows the same "[investment journey](#)" logic that the forthcoming Multiannual Financial Framework 2028-2034 should adopt for the whole EU budget, and in particular the European Competitiveness Fund. In September 2025, the EU Council explicitly called for [EU leadership](#) in life sciences, encompassing clinical trials, advanced therapy medicinal products, biotech, innovation value chains, regulatory frameworks, and skills development. While these conclusions reinforce the importance of life sciences as a key contributor to [EU competitiveness](#) and the logic proposed for the new MFF structure, they risk undermining the EU's ambition to lead global health efforts.

At the moment when the EU's commitment to global health was in question, President Ursula von der Leyen's [2025 State of the European Union](#) address came as an unexpected development. In her speech, she emphasised Europe's responsibility to lead on global health, signalling renewed strategic ambition to shape the evolving global health architecture. The announcement of a Global Health Resilience Initiative (GHRI) is expected to further strengthen the EU's ability to play a tangible role in global health, although the contours of the Initiative remain uncertain, including which financial instruments it will draw on.

In this context, a key role in the EU's global health agenda should be played by the Health Emergency Preparedness and Response Authority (HERA). Created in 2021 amid the COVID-19 pandemic to strengthen the EU's capacity to respond to the ongoing emergency as well as potential future cross-border health crises, HERA's main responsibility lies in ensuring that medical countermeasures (MCM) are developed, produced, procured, and distributed adequately among EU Member States, thereby aiming to contribute to health security within the EU.

Besides its main responsibility for internal coordination and funding within the EU, HERA was also designed to act externally and aims to build resilient health systems, promote innovation, and foster multilateral cooperation, including with countries that have limited resources to address public health threats. HERA has the potential to make a significant contribution to the field of global health, provided it deploys its instruments for

identifying R&D needs, de-risking innovation, and ensuring the equitable distribution of MCMs effectively. But its external mandate has been accompanied by a small budget and lack of clarity, risking HERA's capacity to become a more prominent player in global health security and a key protagonist in the upcoming GHRI. In particular, given the World Health Organization's (WHO) [persistent challenges](#) - including chronic underfunding, political constraints, and limited operational capacity, which can hinder its ability to respond effectively to health emergencies- HERA is uniquely positioned to step up as a regional actor and undertake functions that the WHO cannot.

While there is overall appreciation for HERA's activities and acknowledgement of what it has [achieved so far](#), further action is needed for it to live up to its potential. Recent CEPS research points to a need to [clarify](#) HERA's role, mandate, and powers, enhance the quality of communications, and strengthen feedback mechanisms. Challenges related to its [budget for international activities](#), coordination among European Commission services, and a lack of data for efficient monitoring of preparedness and response activities might hinder HERA's ability to fully deliver on its external dimension.

In this paper, we make proposals for the European Commission to effectively mobilise R&D funding and international collaborations for HERA to fully deploy its functions to strengthen the EU's role in global health security. Chapter 1 first takes stock of HERA's international activities using data and insights from existing research. Chapter 2 then reviews HERA's role in view of the upcoming Global Health Resilience Initiative, identifying potential challenges and formulating recommendations. Chapter 3 explores approaches to leverage the EU's 2028-2034 Multiannual Financial Framework to support HERA's R&D activities, both on the domestic and international front. Chapter 4 summarises the main findings of the paper.

## 2. MAPPING OF HERA'S GLOBAL HEALTH RESEARCH FOOTPRINT

Within the EU's R&I ecosystem, HERA targets investments across the MCM development pipeline, working with other Commission services to bridge fundamental science and deployable solutions. MCM development depends on global research networks, supply chains, and diverse clinical populations, making international collaboration central to HERA's mission.

HERA's external mandate also positions it as a key instrument of the EU Global Health Strategy, which places research at its core (Guiding Principle 5) and prioritises equitable access to vaccines, therapeutics, and diagnostics for emerging infectious diseases and antimicrobial resistance. HERA's R&D coordination role makes it a natural contributor to the GHS goal of building globally responsive research and clinical trial networks.

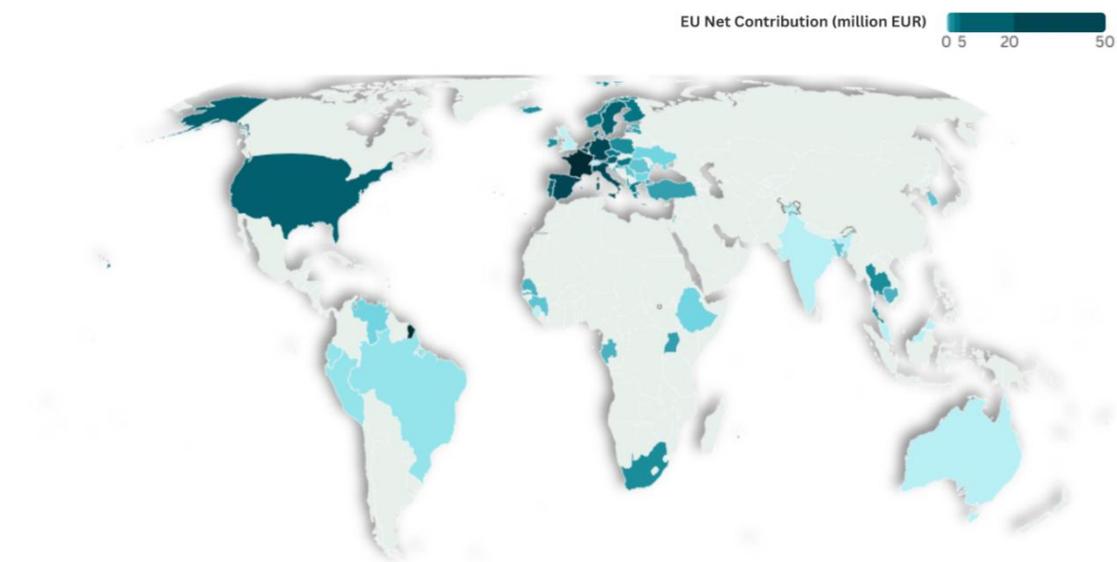
Against this backdrop, this section takes stock of HERA's international activities, focusing on the R&D dimensions. It provides insights into HERA's support for global health R&D through Horizon Europe- the EU's flagship R&I programme with a dedicated funding stream for health research (under Pillar 2). The section also highlights HERA's participation in multilateral partnerships, as well as collaboration with national and regional public health authorities worldwide.

### 2.1. HERA'S GLOBAL HEALTH ACTIVITIES THROUGH HORIZON EUROPE

European and global health security are intrinsically linked. LMIC participation in EU-funded projects is crucial for the development of globally relevant MCMs, such as vaccines for regional diseases. This inevitably strengthens EU health security by tackling threats at their source and aligns with the EU's [Competitiveness](#) Compass and its ambition for global health leadership. In this regard, assessing the distribution of HERA funding to LMICs through the lens of Horizon Europe projects is important for evaluating the strategic direction of EU investments in global health.

Figure 1 captures HERA's contributions to EU and global health R&D through Horizon Europe. Horizon [projects](#) are carried out in accordance with strict evaluation standards, making them a reliable basis for tracking resource allocation and impact. They not only fund scientific innovation but also directly strengthen health preparedness and research capacity in regions most affected by global health threats.

Figure 1- EU net contribution to ongoing HERA Horizon R&D projects

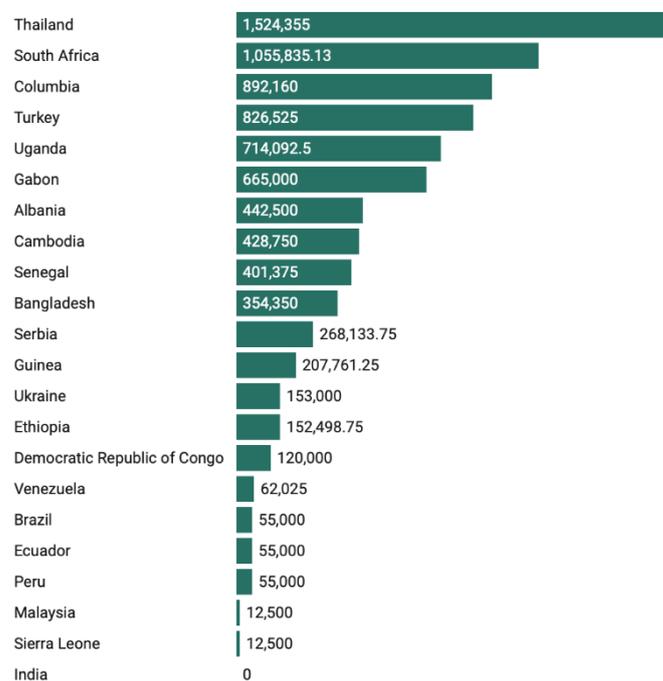


*Source:* Author's elaboration on data from HERA and CORDIS

*Note:* Countries in grey are not involved. Institutions from Australia, India, Switzerland and the United Kingdom are involved but received no EU funds from these HERA R&D projects.

Figure 2 further reflects the allocation of EU net contribution to research institutions in LMICs involved in ongoing Horizon projects managed by HERA. It includes information on Horizon projects signed and implemented until 2024. The dataset for the chart was compiled from a recent [CEPS report](#), which identified 34 HERA-marked Horizon projects engaging with LMICs. To create a more comprehensive overview, an additional 15 projects directly related to the same topic were included, bringing the total to 49 projects.

Figure 2- Net EU contribution to current HERA Horizon projects for LMICs in EUR



Source: Author's elaboration on CORDIS data

As highlighted previously, a significant portion of HERA-marked projects engage with LMICs. This is an important aspect of global health initiatives, as it [addresses](#) health challenges in regions that may have limited resources to tackle public health threats on their own. The allocation of funds, although smaller for LMICs compared to the EU Member States, is a direct investment in global health emergency preparedness and capacity building. This funding landscape demonstrates the EU's engagement with LMIC partners in strengthening global health preparedness through Horizon projects. Figure 2 depicts a diverse distribution of funding, where Thailand (EUR 1.52 million), South Africa (EUR 1.06 million), and Colombia (EUR 892,160) are the largest recipients. It is important to note that India is taking part as a partner institution in projects with zero EU net contribution.

## 2.2. HERA'S PARTICIPATION IN MULTILATERAL AND MULTI-STAKEHOLDER PARTNERSHIPS

A key element of HERA's international dimension is to foster multi-stakeholder collaboration, particularly in areas where market failures and shared risks (like pandemics, antimicrobial resistance (AMR), and vaccine equity) [require public-private](#) or public-philanthropic partnerships. Highlights of HERA's engagement with multi-stakeholder partnerships include [established ties](#) with the WHO, the Coalition for Epidemic Preparedness Innovations (CEPI), and the European and Developing Countries Clinical

Trials Partnership (EDCTP). However, other key global actors such as Gavi remain outside its direct funding remit.

More specifically, in 2022 HERA signed a five-year administrative agreement with the [WHO Hub](#) for Pandemic and Epidemic Intelligence. The agreement sets up a system of collaboration in sharing research roadmaps, coordinating work plans, exchanging information from existing epidemic intelligence systems, and exploring personnel exchange and joint training opportunities. This collaboration not only supports coordinated R&D on MCMs and analytic tools but also embeds HERA within a broader global intelligence ecosystem, thereby strengthening both EU and international preparedness capabilities.

Linked to the above, HERA has made a series of escalating investments to support AMR R&D initiatives. Under EU4Health, through a three-year initiative set up in May 2023, HERA committed [EUR 8 million](#) to a joint initiative with WHO and the Global Antibiotic Research and Development Partnership (GARDP), co-established by the WHO in 2016 to develop and ensure access to new antibiotic treatments for drug-resistant bacterial infections, with a strong focus on equitable access. As part of this, EUR 5 million was dedicated to GARDP's late-stage clinical development and regulatory work targeting critical areas like neonatal sepsis, gonorrhoea, and severe bacterial infections. Another part of the initiative directed EUR 2 million to WHO for R&D activities, with an additional EUR 1 million allocated to the WHO-GARDP SECURE programme for antibiotic access and market resilience. Under EU4Health 2024, a further [EUR 20 million](#) was committed to WHO and GARDP to continue this work. Most recently, in 2025, HERA committed [EUR 30 million](#) through KfW, with CARB-X and GARDP as key delivery partners. Beyond these dedicated AMR partnerships, HERA also supports AMR innovation through Horizon Europe research funding, innovation procurement under EU4Health (including TB vaccines, paediatric formulations for children, and AMR diagnostics), and HERA Invest.

Another key milestone in HERA's R&D partnership development is the signing of a [Letter of Intent with CEPI](#) in October 2022. Under this arrangement, HERA allocated [EUR 70 million](#) in 2023 and EUR 35 million in 2024 for joint activities concerning data exchange and bilateral working groups to support vaccine development and advance MCMs. Looking ahead, HERA has also [earmarked](#) EUR 39.3 million and EUR 34.4 million respectively in the Horizon Europe work programmes for 2026 and 2027 to contribute to CEPI's activities. These investments are aligned with HERA's broader goal of system-strengthening and reinforcing the global health security architecture, especially in the context of pandemic threats. A notable achievement of HERA's partnership with CEPI is the development of the first-ever Chikungunya vaccine, authorised by the European Commission in June 2024.

Beyond contributing to research results responsive to patients' future needs, HERA supports the development and scaling of successful research projects through financial tools which offset potential underinvestment by the private sector. In particular, HERA Invest provides funding for innovative European small and medium enterprises (SMEs) working on MCMs targeted at high-impact health threats. HERA Invest operates alongside the [Be Ready Now](#) – European Partnership for Pandemic Preparedness, a Horizon Europe initiative that HERA also supports, which is designed to strengthen Europe's R&I ecosystem against infectious disease threats.

Moreover, HERA is involved in the Team Europe Initiative on the European and Developing Countries Clinical Trials Partnership ([EDCTP3](#)). The Partnership aims to boost the development of health technologies for the identification, treatment and prevention of poverty-related and neglected infectious diseases. It also funds activities to support African researchers' career development and national health research systems more broadly. The initiative builds on previous EDCTP programmes and is a collaboration between the EU and the EDCTP Association, which includes various European and African member countries.

In addition, HERA is supporting the EU Joint Action on antimicrobial resistance and Healthcare-Associated Infections ([EU JAMRAI](#)), a multi-country initiative coordinated by INSERM (France) that brings together EU Member States, associated countries, and international partners under a One Health framework to address AMR and healthcare-associated infections. The second edition, [EU JAMRAI 2](#), launched in January 2024, involves more than 120 partners across 30 countries and focuses on several R&D elements, including surveillance strengthening, antimicrobial stewardship, infection prevention and control, and prioritisation of R&I for public health needs.

Finally, the Global Consortium for Wastewater and Environmental Surveillance for Public Health ([GLOWACON](#)), launched by HERA, brings together international partners to advance wastewater and environmental surveillance for early detection and response to infectious disease threats. The initiative serves as a global platform for research collaboration, data exchange, and capacity building. Since the establishment of GLOWACON, HERA has co-organised a series of regional conferences with leading partners in [Asia](#), [Africa](#) and [Latin America and the Caribbean](#). In 2025, HERA and its partners launched the [GLOWACON Aviation Programme](#) to expand wastewater and environmental surveillance in international airports, representing an applied research effort with direct implications for global biosecurity.

### 2.3. HERA'S COLLABORATION WITH BILATERAL AND REGIONAL PARTNERS

Besides multilateral partnerships, another critical pillar of HERA's international dimension is its cooperation with national authorities in various countries outside the EU. HERA has formalised partnerships with its [international homologues](#), i.e. national ministries or health institutes in several countries, including the United States, Japan, Korea, Canada, Australia, New Zealand, and India. This work contributes to peer learning and facilitates coordination in times of outbreaks and crises. Additional bilateral partnerships are underway in this regard. The main features of these partnerships are discussed below.

A key milestone was the [administrative arrangement](#) signed with the US Department of Health and Human Services in June 2022, as part of the [US-EU Agenda for Beating the Global Pandemic](#). The partnership focuses on R&I, epidemic and supply chain information, and production of vaccines and therapeutics. Its implementation is coordinated by HERA and DG SANTE on the EU side. On R&I, HERA has undertaken [regular exchanges](#) with the Administration for Strategic Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA).

The partnership agreement with the Japan Agency for Medical Research and Development (AMED) was signed in October 2023, focusing on the exchange of information on advanced R&D related to MCMs. HERA and AMED [communicated](#) that they would meet regularly and explore further collaboration, including on priority pathogens. In February 2024, a delegation from HERA [visited AMED](#) headquarters, including meetings with multiple AMED departments (such as SCARDA, Japan's Center for vaccine R&D) and reaffirmed the foundations for ongoing collaboration. However, no publicly available information has noted subsequent developments.

A formal agreement also exists with the Ministry of Health and Welfare of the [Republic of Korea](#) (MOHW). The [World Bio Summit](#) in November 2023 served as a critical operational touchpoint between HERA and MOHW, as the event initiated the implementation of their Administrative Arrangement and reinforced their cooperative framework.

More recently, an [administrative arrangement](#) was signed with the newly established Health Emergency Readiness Canada (HERC) in June 2025. The cooperation aims to strengthen collaboration on R&I, building on the previously established EU-Canada [Health Policy Dialogue](#) and the EU-Canada Strategic Partnership Agreement. During a series of high-level events in Canada in September 2025, HERA underscored the importance of [transatlantic cooperation](#) in addressing cross-border health threats. Key discussions focused on investment in innovative MCMs, AMR, and supply chain vulnerabilities. During a working group with HERC, HERA reaffirmed the EU's commitment to strengthening global resilience and ensuring equitable access to critical health technologies.

Regarding India, no formal agreement has been concluded. However, the roadmap to 2025 for the [EU-India Strategic Partnership](#) lists R&I in health security as a priority area for cooperation. The 16th EU-India Summit in January 2026 further provides an opening. Leaders renewed the [EU-India Science and Technology Cooperation Agreement](#) until 2030 and launched exploratory talks on India's association with Horizon Europe, which would move Indian institutions from unfunded participation in HERA-marked projects to full programme partners. Given India's pharmaceutical manufacturing capacity and its centrality to global vaccine supply chains, this creates a concrete opening for HERA to formalise a bilateral arrangement before the relationship diffuses into broader EU science diplomacy.

Finally, HERA has also worked together with regional partners, in particular in Africa. In this regard, HERA collaborates with Africa CDC. As part of the Team Europe Initiative "[Health Security using a One Health approach](#)", HERA is contributing EUR 6 million to an initiative on Genomic Sequencing, to be implemented in partnership with the African Society for Laboratory Medicine and the Africa Public Health Foundation and has supported the Africa CDC diagnostic response with close to [EUR 10 million](#) in the fight against mpox.

### 3. HERA IN THE GLOBAL HEALTH RESILIENCE INITIATIVE

The Global Health Resilience Initiative (GHRI) is the EU's direct response to the weakened health security architecture caused by the shifting global development and health assistance funding landscape, including the substantial cut of EUR 1 billion to the EU4Health programme in 2024, coupled with growing mis/disinformation undermining preparedness and response capacities. While the details of the GHRI remain unclear, DG INTPA, DG SANTE, and HERA are jointly working on putting this initiative forward, which is expected by mid-2026.

HERA is anticipated to play an important role in the GHRI, given its mandate to strengthen internal preparedness and response to emergencies, as well as foster international cooperation to bolster global health security. Nevertheless, HERA's effective contribution to the Initiative relies on several conditions. HERA functions as part of the EU's wider health security architecture, and as such, its close coordination with relevant Commission departments, each fulfilling their own mandates and areas of expertise, remains imperative. Additionally, HERA's budgetary autonomy remains a limitation in its ability to lead this initiative, with DG INTPA taking the reins given its available finances.

A deeper structural issue also looms under the next MFF, as EU4Health is proposed to be absorbed into the European Competitiveness Fund while the next Framework Programme for R&I (currently Horizon Europe) will also be tightly connected to the Competitiveness Fund. While HERA can in principle continue drawing on these programmes, the question is whether R&D activities funded through them will still be global health oriented, or whether the competitiveness framing will redirect priorities inward. HERA's dual mandate on the internal and external front risks being undermined not necessarily by loss of funding, but rather by a shift in what the funding is expected to deliver.

In this context, this section considers the potential challenges and areas for improvement to better position HERA to be a leading actor in the GHRI.

#### 3.1. REINFORCING HERA'S COORDINATION WITH OTHER PUBLIC HEALTH BODIES OF THE EU

Within the EU health security architecture, HERA has unique features which position it as having a unique value added. HERA is the only EU body with a dedicated mandate to align health security priorities with R&D investment and innovation across the [full](#) preparedness and response cycle. It is designed to have a flexible structure which can adapt the focus of its activities from preparedness to crisis modes of operating as the situation requires.

However, to effectively contribute to reinforcing the EU's public health security, HERA cannot rely solely on its own actions. The Authority needs to navigate a complex ecosystem of EU institutes and bodies with a public health mandate, in which leadership of the EU's public and global health initiatives primarily rests with DG SANTE, while DG INTPA manages international partnerships, and DG RTD promotes research excellence and innovation through funding programmes. In addition, the European Centre for Disease Prevention and Control (ECDC) provides surveillance of disease threats, while the European Medicines Agency (EMA) facilitates the evaluation and supervision of medicines. Effective health R&D requires close collaboration among all European bodies, not least because of the [overlapping responsibilities](#), especially when it comes to health security. For example, recurring concerns from stakeholders have centred on coordination gaps within the European Commission, particularly between DG RTD and DG INTPA<sup>1</sup>. Fragmented coordination across Commission services and lack of clear delineation of certain functions also risks undermining HERA's contribution to the [Medical Countermeasures Strategy](#). Specifically on the issue of synergies between different EU funding programmes on health security, HERA can leverage its position of contributing and leading actions under different funds to address funding fragmentation in the field of MCMs.

Mirroring the above situation, the March 2025 [internal review](#) of HERA's activities underpinned these coordination needs, emphasising that HERA's activities should be developed in close synergy with policies and programmes across other Commission services, EU agencies, and the European External Action Service (EEAS). This recommendation acknowledges that HERA cannot function as an isolated actor but must be embedded within the broader institutional ecosystem, requiring systematic mechanisms for inter-service coordination rather than ad hoc collaboration. The review highlights the indispensable role of HERA's flexible operating mode within the EU's institutional core, which is equipped for swift decision-making and rapid mobilisation of resources in times of crisis. In the face of strained budgets, this flexibility also enables HERA to act as the bridge between R&D, industrial capacity, and public health needs by deepening coordination with DG SANTE, DG RTD, and DG INTPA.

At a CEPS [roundtable](#) discussion in September 2025, HERA's leadership confirmed the recognition that health security cannot be achieved through any single institution or even single jurisdiction. HERA's support to Member States must therefore be understood not as duplicating their capacities but as enabling coordinated European positioning within the broader global health architecture. For instance, HERA possesses technical expertise

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<sup>1</sup> Stakeholder reflections from 'High-Level Roundtable on European Global Health Leadership in Tumultuous Times', hosted at the Wellcome Europe Office, co-organised by the Centre for European Policy Studies and the Danish Alliance for Global Health, 13 October 2025.

and network intelligence that could significantly enhance the targeting and effectiveness of DG INTPA's substantial financial instruments and operational partnerships. By positioning HERA as the technical intelligence layer informing DG INTPA's implementation capacity, the EU could achieve greater coherence between health security expertise and development cooperation resources.

Deeper clarity and distinction of DG functions would enable smoother coordination. Establishing explicit protocols defining where HERA leads operationally (R&D, surveillance networks, technical standard-setting) versus where it provides advisory input to DG INTPA's implementation (geographic targeting, partnership selection, programmatic design) is key. Establishing intelligence exchange mechanisms would help create systematic channels for HERA to share technical threat assessments, R&D gap analyses, and partnership evaluations with DG INTPA prior to major funding decisions or partnership agreements. Aligning HERA's technical work planning with DG INTPA's partnership development timelines would also ensure expertise informs rather than follows operational commitments. The GHRI provides an opportunity to more clearly institutionalise this division of labour between technical expertise and implementation capacity within a coherent strategic framework.

### 3.2. STRENGTHENING HERA'S COLLABORATION WITH PEER INSTITUTIONS IN OTHER REGIONS

HERA has established collaboration with homologous institutions in key geographical areas. Going forward, HERA has specified its aims to deepen its technical cooperation with global partners, and widen its geographic reach, particularly in regions like Asia and Latin America and the Caribbean (LAC). The above has provided a strong foundation for HERA to boost its collaboration with peer institutions in other countries and regions. Below, we propose several partnerships that HERA can pursue to strengthen prevention, preparedness, and response to current and emerging health threats.

HERA should consider deepening collaboration with countries associated under Horizon Europe, particularly within Pillar II, where there is demonstrated willingness to cooperate on health R&I. For example, HERA does not currently engage with non-EU Western European countries, such as the UK or Switzerland. The recent bilateral stabilisation and strengthening of Swiss-EU relations, with Switzerland able to participate in R&I programmes including Horizon since 2025, creates momentum for exploring cooperation between HERA and Switzerland's Federal Office of Public Health (FOPH). Additionally, the UK Health Security Agency (UKHSA) has indicated interest in establishing a more formal partnership with HERA, representing another high-capacity partnership opportunity in Europe's immediate vicinity.

HERA could also explore new partnerships built on existing frameworks for cooperation in research and health, such as Strategic Partnerships and Joint Agendas. The [New Strategic EU-India Agenda](#), adopted in September 2025, exemplifies this approach, identifying health security as a priority domain for enhanced bilateral cooperation. The framework outlines collaboration with India's disease control infrastructure, which holds a formal mandate on MCM research, and commits to strengthening data sharing on health threats, public-private collaboration for innovation, and research cooperation in health and digital technologies including AI for public goods. The 16th EU-India Summit in January 2026 and renewed EU-India Science and Technology Cooperation Agreement added further momentum. Given India's pharmaceutical manufacturing capacity and its centrality to global vaccine supply chains, HERA should move proactively to define a bilateral arrangement within this strengthened diplomatic framework.

Additionally, HERA could build on existing EU agreements and strategies when expanding into new regions. For instance, the [EU Strategy for Cooperation in the Indo-Pacific](#) aligns with several HERA objectives, including strengthening healthcare systems and pandemic preparedness in least developed countries while advancing joint research on communicable diseases through Horizon Europe. Stronger partnerships in the Indo-Pacific region could engage countries with established frameworks for cooperation in R&I and health, including Australia, [New Zealand](#) or the [Philippines](#).

Further potential areas for strategic engagement include Eastern Partnership countries (Moldova, Ukraine, Georgia), South Asia (Pakistan, India, Nepal, Bangladesh), Central Asia (Kazakhstan), and Southeast Asia (Vietnam, Indonesia). Despite commitments to increase partnerships with neighbouring countries, HERA has not systematically explored engagement with Southern and Eastern neighbourhood countries or the Western Balkans. An exception is that it [has engaged](#) with Ukrainian bodies relevant to public health emergencies.

The absence of systematic engagement with countries in Oceania (Australia, New Zealand) or bilateral partnerships with LMICs – where HERA has opted for multilateral engagement to date – contrasts with other policy areas such as raw materials, where the EU has signed numerous memoranda of understanding, including R&I cooperation components. This pattern suggests potential lessons from other policy domains about structuring bilateral partnerships that could be adapted to health security contexts.

Furthermore, HERA can leverage its participation in regional summits and political meetings as opportunities to widen its partnerships with regional organisations. By way of example, HERA has recently signed a five-year agreement with the Pan American Health Organization (PAHO) against the backdrop of the 2025 EU-CELAC summit. The summit provides a political platform to elevate this technical arrangement within broader

bi-regional partnership frameworks. By positioning health systems resilience as a priority area for EU-CELAC cooperation, the summit creates an opportunity to secure political commitment and potentially additional resources for strengthening prevention, preparedness, and response capacities across LAC countries. The HERA-PAHO arrangement demonstrates a strategic approach that could be replicated in other regions. By timing formal partnership agreements to coincide with major regional summits and political meetings, HERA can leverage existing diplomatic momentum to secure higher-level political endorsement and resource commitments for health security cooperation. Following a similar approach, HERA should systematically map forthcoming regional summits – including EU-African Union, EU-ASEAN, Eastern Partnership, and EU-Indo-Pacific forums – and develop corresponding partnership frameworks with regional health organisations in advance of these political moments.

### 3.3. STRENGTHENING HERA'S PARTICIPATION IN MULTILATERAL PARTNERSHIPS

At an international level, it is critical to ensure that European efforts reinforce rather than duplicate existing global health initiatives. In this regard, HERA has demonstrated capacity to reinforce existing and catalyse new R&D initiatives with international partners. The Commission's response to the 2024 mpox outbreak in Africa was the most recent example highlighting the benefit of HERA widening partnerships with global health security stakeholders, including Gavi, the Vaccine Alliance. Through a coordinated Team Europe approach, together with WHO, UNICEF, and Gavi, HERA supported the coordination of the procurement and delivery of vaccine donations during the outbreak. This experience also catalysed a new action to support the Africa CDC and the Africa Society for Laboratory Medicine.

However, HERA's engagement in global health partnerships remains sub-optimal. For example, while the EU through its Team Europe initiatives has contributed over EUR 500 million to Gavi since 2021, there is no formal HERA–Gavi partnership. This is notable given Gavi's relevance to equitable vaccine distribution and outbreak preparedness. Gavi's 6.0 High-Level [Pledging Summit](#), co-hosted by the EU in June 2025, presents a springboard to deepen the EU–Gavi partnership beyond financial support. [Gavi's new strategy \(2026-2030\)](#) prioritises regional manufacturing, pandemic preparedness, and equity, closely aligned with HERA's international agenda. Gavi 6.0 provides a strategic opportunity for HERA to move from internal EU preparedness to a global partner, aligned with both the EU's GHS and EU funding flows. Such a partnership could enable HERA to contribute technical and operational expertise to transform Europe's financial commitments into global preparedness, with a key focus on strengthening regional vaccine manufacturing, stockpiling of MCMs, and equitable distribution.

Strengthening support for WHO and its regional offices should remain another priority for HERA. Through continued cooperation with the WHO Hub and its recently rolled out public health surveillance system, the Epidemic Intelligence from Open Sources ([EIOS](#)) system, HERA can contribute to bolstering the EU's ability to detect and respond rapidly to emerging health threats. Further development is also planned for the WHO Collaboratory and the Market Intelligence Platform to enhance their capacity and reach. HERA's support for the set-up of the WHO Dakar Hub in Africa will bolster early warning systems for emerging health threats and facilitate the rapid deployment of MCMs. HERA should continue to expand collaborations with other regional hubs as a way of further strengthening the EU's integrated frontline defence of pandemic preparedness.

Going beyond financial contribution, HERA can support global partnerships by bringing in its expertise in crisis-relevant technologies. In this regard, industry stakeholders have [called](#) for establishing a Technology Watch in close collaboration with global partners as a way to strengthen preparedness in the EU. Such a mechanism would systematically monitor and assess emerging technologies, tools, and scientific innovations worldwide, with a focus on identifying areas where Europe faces critical gaps in access or capacity. By integrating these insights into preparedness planning, HERA could better anticipate technological needs before crises emerge and facilitate strategic partnerships and joint R&D initiatives with non-EU actors. The creation of the [RAMP UP](#) (Rapid Agile Manufacturing Partnership for Union Protection) network outlined in the Medical Countermeasures Strategy is a positive development in this sense.

### 3.4. FILLING THE GAP LEFT BEHIND BY THE US

The strategic imperative for HERA to expand and systematise its partnerships has become markedly more urgent given recent shifts in the global health security landscape, particularly in light of the retreat of the US from global health.

While the US has historically been a dominant force in global health security, its approach has often been characterised by political volatility, with shifts in administration leading to fluctuating foreign policy priorities. This unpredictability has been shown to [undermine](#) long-term global health initiatives and their progress, most acutely seen in 2025. The US has also tended to focus on [bilateral](#) engagements and [vertical](#) funding priorities, which have demonstrated meaningful improvements for health outcomes, but have not always aligned with multilateral goals nor contributed to building capacity, strengthening health systems, and transitioning countries to self-sufficiency.

In April 2024, the US launched its [Global Health Security \(GHS\) Strategy](#). That year the US expanded formal bilateral partnerships to over 50 countries, primarily LMICs in sub-Saharan Africa, Central Asia, South Asia, and Southeast Asia, and one regional group (the

Caribbean Public Health Agency or CARPHA). The 2024 US GHS Strategy also included an R&D component, channelled through agencies such as the National Institutes of Health (NIH), BARDA, and CEPI to advance health security objectives. However, the Trump administration announced the [withdrawal](#) of the GHS Strategy and its replacement with the [‘America First Global Health Strategy’](#) in September 2025. A key casualty of this shift in strategies is the closure of the Centers for Research in Emerging Infectious Diseases (CREID) Network, previously supported by the NIH’s National Institute of Allergy and Infectious Diseases. The network played a critical role in identifying and characterising emerging infectious diseases before, during, and after outbreaks. Its closure mirrors earlier US decisions, such as the termination of the [PREDICT programme](#) shortly before COVID-19, which severely undermines surveillance capacity and contributes to slower, less coordinated, and ultimately more costly responses to health threats. Amidst ongoing challenges to global health funding, the US administration has proposed in its FY2026 budget request to cut global pandemic preparedness funding by [half](#) – from USD 993.2 million in FY2025 to USD 493.2 million in FY2026 – leaving a USD 500 million shortfall in global health security.

The dismantling of surveillance and research networks by the US underscores both a strategic gap and opportunity for the EU. By adopting a CREID-like model, HERA could strengthen existing [surveillance systems](#) and ensure a pan-European mechanism for pathogen intelligence, early warning, and R&I priority-setting. This would strengthen Europe’s capacity for rapid, coordinated response, and reduce dependence on external networks, positioning the EU as a credible global leader in health security. The ongoing [Be Ready Now](#) – European Partnership for Pandemic Preparedness presents an opportunity in this regard, as it is designed to strengthen Europe’s R&I ecosystem against infectious disease threats. Its consortium spans partners from Norway, the UK, Ukraine, Moldova, Turkey, and New Zealand – reflecting a broad commitment to global collaboration in health security. The Partnership has specified a need to work [in synergy](#) with HERA, presenting an opportunity for new partners as well as an alternative platform to the recently terminated CREID network, ensuring new opportunities for coordination, data sharing, and early warning across European and global partners.

Beyond the Be Ready Now project, HERA can also leverage other platform infrastructures that could serve as anchor points for international R&D collaboration. The [European Vaccine Hub](#), launched in 2025 with EUR 102 million over four years, is already operational and designed to develop first investigational vaccines against any new threat within four months of emergence. A European Diagnostics Hub, announced in the MCM Strategy, is due to be launched in 2026 to develop next-generation, rapidly scalable diagnostic tools. The [DURABLE](#) network, involving 19 partners from academia and public health institutes

providing biological intelligence and critical MCM research, is another credible and growing infrastructure base from which HERA can ground international partnerships.

As the US retreats from global health security, many of its previous bilateral partner countries may seek new alliances. The EU could partly fill in the gaps left by the US, and HERA could play a critical role in leading these partnerships, strengthening Europe's role as a reliable partner in global preparedness and response. Rather than attempting to fill gaps left by US retrenchment through direct financial substitution, Europe can leverage its comparative advantages in regulatory excellence, research capacity, and convening power to empower partners and co-create solutions. This approach requires focusing partnership investments where they can generate the greatest impact, supported by robust monitoring and evaluation frameworks with clear indicators.

### 3.5. ENHANCING THE USE OF FORESIGHT AND ARTIFICIAL INTELLIGENCE IN HEALTH GOVERNANCE

To strengthen its role as a forward-looking authority in health emergency preparedness, HERA can harness innovative tools such as strategic foresight and artificial intelligence (AI) to enhance its analytical, planning, and response capacities.

Foresight approaches are [key to preparedness](#) for emergencies, enabling anticipatory rather than reactionary measures to health shocks. As the practice of exploring and anticipating possible future developments, it looks both at slow, continuous changes and sudden disruptions. Foresight is not about predicting the future, but rather about exploring different possible futures, alongside the opportunities and challenges they might present. Within the EU health security architecture, foresight activities should be better integrated across health governance structures, aligning efforts between HERA, the ECDC, the EMA, relevant DGs, and the WHO Hub for Pandemic and Epidemic Intelligence in Berlin. Building on HERA's 2022 Work Programme commitment to regular threat prioritisation exercises, such coordination would ensure that foresight is embedded systematically into preparedness planning and risk assessment.

AI can dramatically enhance foresight exercises by turning vast, fragmented data into actionable early warning insights. Machine learning models already support disease forecasting, outbreak detection, and health-system stress testing by analysing signals from genomics, mobility, climate, and social data. When integrated into foresight approaches, AI enables dynamic scenario generation, identifies emerging threats faster, and [helps decision-makers](#) test the effectiveness of interventions before crises unfold.

In [2025](#), HERA advanced the integration of AI to strengthen pandemic preparedness and response. In collaboration with other European Commission services, including DG SANTE and the ECDC, HERA continues exploring AI applications across key areas such as early

detection of emerging pathogens, MCM development, supply and demand monitoring, biosecurity, and metagenomics. Its 2025 Work Programme committed HERA to “leverage the power of AI to enhance capabilities for threat identification, assessment, intelligence gathering, and strategic foresight related to MCMs.” Alongside a Horizon Europe 2025 research call, HERA commissioned studies to identify effective AI practices and policy measures to guide future implementation, with findings due by the end of 2025.

In January 2026, HERA published its first [Comprehensive Health Threat Prioritisation Assessment](#), identifying four priority cross-border health threats: pandemic-potential respiratory viruses, vector-borne epidemics, antimicrobial resistance, and chemical, biological, radiological and nuclear (CBRN) scenarios. The Assessment is designed to steer research funding, procurement, stockpiling, and industrial readiness across EU institutions and Member States, marking a shift from foresight as internal analysis to a practical instrument for coordinated action. Each of the four threat categories also provides a concrete reference point for AI model development, since distinct data signatures and countermeasure timelines make it possible to calibrate tools against specific, known risks rather than across an undefined threat landscape.

Looking ahead, the EU and HERA should sustain investment in interoperable data ecosystems, transparent and ethically governed AI models, and joint ‘AI-for-foresight’ hubs linking public health agencies, academia, and industry. The shared threat categories established by the Assessment reduce the coordination costs of multi-actor data-sharing and provide a common frame for aligning AI tool development across institutions. Building synergies with initiatives such as the [Innovative Health Initiative](#) (IHI) can accelerate development of AI-driven tools for preparedness. Priorities should include building capacity in LMICs, ensuring equity in data access, and embedding evaluation metrics to assess predictive accuracy and real-world impact.

Done right, AI-powered foresight can shift pandemic preparedness from reactive crisis management to proactive resilience planning, thereby strengthening both EU health security and global health equity. Regular updates to the Prioritisation Assessment will be important in maintaining this momentum, ensuring the framework remains responsive as the threat landscape evolves. To remain credible and effective, foresight should continue to be science-based, while also integrating strategic and security insights from Member States to provide a comprehensive intelligence picture.

## 4. HERA IN THE 2028-2034 MULTIANNUAL FINANCIAL FRAMEWORK

### 4.1. THE ONGOING DOWNSCALING OF HERA-MARKED ALLOCATIONS IN THE CURRENT MFF

As HERA was established after the current MFF launched, it has had to rely on existing programmes, which limit flexibility given their rules and parameters. Within the current MFF, HERA coordinates relatively modest funding streams from multiple EU instruments – primarily Horizon Europe, EU4Health, and InvestEU – channelling these resources toward strategic health security R&D priorities. After a surge in its budget since its establishment in 2021, HERA is facing a downscaling of funding sources since 2025, impacting the funding of activities under its R&D and international dimensions (Figure 3).

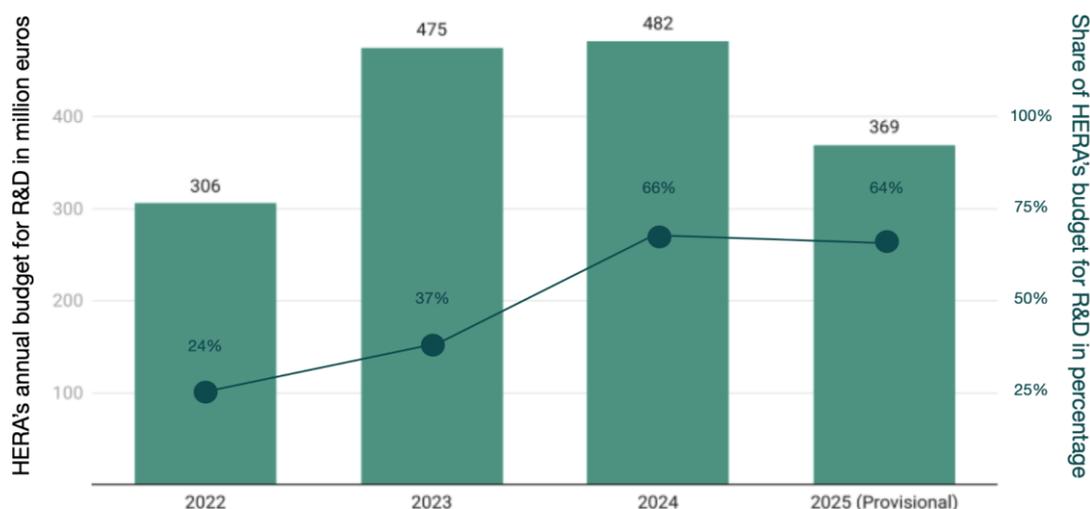
Horizon Europe, the EU’s flagship R&I programme with a budget of EUR 93.5 billion (2021–2027), supports collaborative R&D across Member States and beyond. As part of Pillar 2, EUR 6 billion is managed by HaDEA within the framework of Cluster 1 on Health research throughout this period, with EUR 840 million allocated in 2025. Horizon Europe funding allocated to HERA has been declining since its inception, with EUR 223m available in 2025, down from EUR 259.75m in 2024 and EUR 389m in 2023.

EU4Health, with a budget of EUR 4.4 billion for the 2021 – 2027 period, complements Horizon Europe by focusing on capacity-building, preparedness, and crisis response within the EU. The 2025 EU4Health work programme total stood at EUR 571 million, of which HERA is exclusively allocated EUR 357 million. Following a steady annual increase until 2024, the current allocation represents a decline from the total work programme amount (EUR 752.4 million) and the funding dedicated to HERA in the preceding year (EUR 470.8 million), driven in large part by the reduction of EUR 1 billion to the EU4Health programme in 2025. In response to the substantial budget cut to EU4Health, HERA has reduced the amount of its funds directed to promoting advanced R&D of MCMs and related technologies for the first time, from EUR 482 million in 2024 to an expected EUR 369 million budget in 2025, representing a 23 % decrease (Figure 3). The share of HERA funding reserved for promoting advanced R&D of MCMs and related technologies out of the total HERA budget had been steadily increasing, from 24 % in 2022 and 37 % in 2023 to 66 % in 2024. In 2025, the figure dipped to 64 %.

In addition to the above funding programmes, HERA also manages HERA Invest – a EUR 100 million mechanism launched under the broader InvestEU framework in collaboration with the European Investment Bank (EIB). This funding tool provides targeted support to SMEs in the late-stage clinical development of promising MCMs. It aims to de-risk innovation, accelerate the development of critical products, and reduce Europe’s

dependency on non-EU suppliers during health emergencies. Funding for HERA Invest and clinical trials was adjusted in 2025 in view of the reduced EU4Health budget, to avoid undermining the scale of innovation and preparedness activities.

Figure 3- Evolution of HERA's annual funding for promoting advanced R&D of MCMs and related technologies (2022-2025)



Source: CEPS's elaboration of data from HERA 2025 Work Plan

## 4.2. PERSPECTIVE OF FUNDING GOVERNANCE UNDER THE NEXT MFF

HERA's funding situation contributes to the broader picture of EU health R&D funding. Health and [health research](#) innovation have strategic importance for Europe's competitiveness and security yet have not been prioritised as such in the new MFF proposal. There is a need for a significant [overhaul](#) of Europe's often fragmented, slow, and misaligned R&I governance system to position R&D at the heart of EU action. The modest available budget and pressing geopolitical, industrial, and sustainability challenges make the governance overhaul and set-up of new structures particularly urgent.

In this context, the reform of the next MFF is instrumental. As part of this transformation, the newly proposed [European Competitiveness Fund](#) (ECF) represents a major restructuring in how the EU manages long-term investment. The ECF follows the European Commission's [Competitiveness Compass](#) from January 2025, which highlighted that Europe's competitiveness is hindered by fragmented EU spending, which is spread across numerous overlapping programmes that often support similar initiatives but with varying rules, making it difficult to coordinate and combine funding effectively. By consolidating multiple programmes into a single, flexible 7-year funding mechanism and

enabling more dynamic, politically responsive decision-making, the ECF would grant the European Commission greater agility and discretion in funding allocation, ultimately streamlining innovation funding through a single instrument.

The establishment of the ECF offers a valuable opportunity for the EU to strengthen and align its health funding with other priorities. Under the ECF, a bold new Framework Programme for Research and Innovation (FP10) is [expected to feature simplified](#) and accelerated funding for, among other areas, research on health and biotechnology.

For HERA, this structure could be transformative. A more flexible and centrally managed funding pool would allow HERA to rapidly mobilise resources during health crises – ensuring timely EU and global responses – and invest strategically in innovation, manufacturing, and supply chain resilience for MCMs. By enabling Europe to act as a coordinated, well-resourced industrial and strategic health player, the ECF could strengthen the EU’s global influence in health security. The proposed [combination](#) of civil protection and health emergency preparedness measures into one financing bloc presents opportunities for better synergies, flexibility, and agility in managing the funding instrument.

Meanwhile, the merging of different EU funding instruments also poses a risk of diluting available funding for HERA. Crises are inherently multi-dimensional and extend beyond medical measures, yet clear allocations for HERA, coupled with the [availability](#) of ad-hoc funding instruments, are necessary to ensure sufficient budget and allow for planning of multi-year R&D endeavours.

To strengthen Europe's R&I ecosystem ahead of the next Framework Programme, ensuring it effectively addresses both internal security and external global challenges, CEPS has [proposed reforms, building on the](#) Heitor-led expert group’s recommendations as part of the interim [evaluation report](#) of Horizon Europe, for the creation of two high-level councils under the next MFF.

- The *Council on Research and Innovation for Competitiveness and Security* (CRICS) would focus on dual-use innovation, including defence against biological threats, and support industrial sovereignty in life sciences and medical technologies.
- Meanwhile, the *Council on Global Societal Challenges* (CGSC) would address global health, public health resilience, and the Sustainable Development Goals (SDGs), fostering openness and partnerships beyond EU borders. These councils could streamline governance, enable rapid fund reallocation, and promote coordinated efforts across sectors and borders.

HERA should be strategically integrated within both councils, considering both its internal and external dimensions, thereby strengthening Europe's ability to respond swiftly and effectively to emerging health emergencies and global challenges. In this way, HERA can play an important role in strengthening Europe's resilience, security, and technological sovereignty.

Against this backdrop, the following sections put forward our proposals for HERA to improve its budgetary autonomy and fully realise its leading role in EU's global health actions through properly navigating the funding streams under these two councils.

### 4.3. HERA UNDER THE COUNCIL FOR COMPETITIVENESS AND SECURITY FUNDING STREAM

Under the Council on Research and Innovation for Competitiveness and Security (CRICS), HERA should seek to **position health security as an integral part of European competitiveness**. Resilience and strategic autonomy are inherently linked and play a key role in strengthening the continent's competitiveness. MCM supply chain vulnerabilities represent systemic economic risk, as demonstrated by the COVID-19 pandemic. In this regard, in September 2025 [EU health ministers](#) discussed the urgency of strengthening Europe's preparedness for cross-border health threats. Particular focus should be directed towards securing supplies of critical medicines, boosting Europe's life sciences sector to deliver innovative treatments, and coordinating responses to AMR. Boosting European competitiveness will depend on a multipronged approach to bolster health security.

The Critical Medicines Act (CMA), proposed on 11 March 2025, represents a strategic opportunity to reduce Europe's dependence on imported medicines, which has increasingly [weakened](#) the continent's defence and resilience. The Act reframes pharmaceutical supply chain resilience as a matter of strategic autonomy and collective security rather than purely a public health concern. By securing stable and reliable medicine supply chains, the EU aims to improve its preparedness and [strengthen its overall security](#) posture in an increasingly volatile geopolitical landscape. To stay competitive, the EU must also invest heavily in biotechnology and next-generation therapeutics in line with the Life Sciences Strategy, especially as it faces growing innovation gaps with other major economies. As such, HERA and stakeholders should continue to frame [health security as a pillar of European strategic competitiveness](#).

Linked to the above, HERA should position dual-use MCMs as a strategic investment that generates compounding returns across health security, defence preparedness, and industrial competitiveness. Indeed, health security is a key aspect of strengthening European security generally: MCM manufacturing strengthens both civilian health

security and defence preparedness. The MCM Strategy recognises this and outlines the dual-use nature of countermeasures for chemical, biological, radiological, and nuclear (CBRN) threats. By supporting innovation, the MCM Strategy also contributes to reinforcing the competitiveness of the EU's health and biotech sectors. Moreover, the health security infrastructure under the Critical Medicines Alliance (including EU FAB, RAMP UP) qualifies as competitiveness-enhancing industrial capacity, serving dual civilian and defence preparedness functions. HERA's coordination of these capabilities, combined with its mandate for threat intelligence and strategic foresight, positions it uniquely to operationalise the CMA's vision of end-to-end supply chain resilience. MCM manufacturing and supply chain security need to be designated as strategic technologies, eligible for financing under the ECF, thereby reducing dependencies on external suppliers.

During a [CEPS roundtable](#) in September 2025, HERA emphasised that MCM supply chain security logically falls within the scope of the ECF, though it is not yet reflected in the Fund's architecture. This reframing can therefore address the fundamental challenge where the artificial separation of funding streams and policy domains fragments what is inherently an integrated security challenge. Also during the above roundtable, the Director-General of HERA noted that military industry stakeholders have emphasised the indispensable role of HERA in providing them with MCMs.

To enhance the EU's competitiveness and security, another critical element that the next MFF should feature is a portfolio approach and at-risk investment of public health R&D financing. The former is a strategy that manages multiple R&D projects collectively in which resources can be reallocated dynamically based on project progress and potential. The latter is an R&D funding approach where resources are committed before the full approval of the products, i.e. before the products obtain market authorisation from public authorities. These [funding strategies](#) accept the inherent risk of failure when rapidly developing critical medical technologies during public health emergencies. They allow for a higher chance of developing technologies successfully in times of urgency and uncertainty.

During the COVID-19 pandemic, the EU did not fully leverage these investment approaches in funding vaccine candidates. Compared to international R&D counterparts such as the US, the EU's R&D investment was considered [marginal](#) in amount and focused on a later stage of the development cycle. This contributed to the [delay](#) in accessing vaccines in the bloc, particularly in the first half of 2021, which likely cost lives and economic losses. Looking ahead, it is desirable for HERA to adopt a portfolio approach and at-risk investment in financing R&D, particularly during times of crisis, allowing it to adjust R&D funding based on milestones achieved and support the early phase of research on critical MCMs.

Additionally, the design of the next MFF should consider [multi-year and dedicated funding for HERA](#), enabling more predictable multiyear funding for the Authority. While HERA Invest currently aims to bridge the gap between early-stage research and market-ready solutions to some extent, its limited budget constrains the attainment of the above objective. There is a need for more flexible, multi-year financing models and a broader [rethinking of EU funding mechanisms](#) to better align with HERA's focus on late-stage development and deployment. This involves diversifying beyond purely activity- and output-based financing to include more innovative financing mechanisms, such as portfolio funding as discussed above. The specificities around [greater flexibility](#), including faster disbursement, risk-tolerant financing, and ability to fund industrial scale-up beyond early-stage R&D, will also determine the robustness of the EU's contribution to global health security. These aspects are all yet to be determined for the final upcoming MFF. At the same time, it is imperative to balance greater flexibility with strong accountability and governance to ensure investments achieve tangible public health impact and maintain trust among Member States and stakeholders.

To support late-stage development of crisis-critical MCMs, HERA's funding under the next MFF can also strengthen support for better engagement of private players. Public support plays an essential role throughout the value chain of public health R&D, from basic research to late-stage development of medical technologies. One proven benefit of using public R&D funding is to [bring in](#) private funding, particularly for late-stage development where the products are close to market but face a funding gap (the so-called 'valley of death') which makes the transition from research to deployment impossible.

While initiatives like HERA Invest and the InvestEU programme channel funding to SMEs and support innovation, current EU research funding is largely geared towards basic and pre-clinical research. Moreover, the annual funding streams currently available to HERA are unsuitable for the realities of R&D and clinical trials, which require sustained, predictable investment over multiple years to ensure continuity, de-risk innovation, and bring promising products to market. Through HERA, the EU has addressed this challenge to some extent. [HERA Invest](#), the financing mechanism supporting innovative SMEs with loans in the early and late phases of clinical trials, has [assisted companies](#) in investing in market-failure areas. However, the current budget of HERA Invest is considered modest in scale (EUR 100 million and subject to even further reduction in 2025 due to EU4Health's budget cut). The scale of HERA Invest's [budget](#) cannot match HERA's [ambition](#) for late-stage development. In this respect, contractual solutions include introducing a minimum share of funding for industry (both large companies and SMEs) in a consortium, or

promoting single-entity contracts for products requiring market authorisation<sup>2</sup>, inspired by the funding model of BARDA in the US.

Other solutions include using innovative funding mechanisms combining both [push incentives](#) (to ensure a wide pipeline of health innovations) and [pull incentives](#) (to help the technology reach the market). In this respect, the HERA [Study](#) on bringing AMR MCMs to the market explores various pull incentives, such as revenue guarantee, lump sum market-entry rewards, and milestone-based rewards. Finally, HERA can set up bidirectional dialogue with the industry (together with other stakeholders) prior to the call being launched to ensure a close alignment between the desired MCM and industrial capacity.

While it is critical to engage companies more meaningfully in HERA's R&D portfolio, the EU should also make sure to strike a balance between the private sector's incentive to innovate and public health interest. This issue is further discussed in the section on intellectual property below.

#### 4.4. HERA UNDER THE COUNCIL ON GLOBAL SOCIETAL CHALLENGES FUNDING STREAM

On the international front, as the EU seeks to advance wellbeing and sustainable development globally, its Framework Programmes (FPs) are well-positioned to address transnational health challenges and foster scalable solutions. HERA's contributions are vital to enhancing resilience and supporting global public goods like pandemic preparedness and response. As such, HERA's involvement in the Council on Global Societal Challenges (CGSC) could help ensure LMIC participation and multi-stakeholder partnerships are fully leveraged for robust and respectful international cooperation and science diplomacy.

Through multi-stakeholder R&I initiatives, HERA could accelerate the development and deployment of innovative solutions, ensuring agility even under constrained budgets. To make up for inevitable funding gaps, co-funding rules could be integrated into the Framework to enable HERA to use funds effectively across multi-stakeholder partnerships on global health, for example for preparedness measures and R&D initiatives such as vaccine development or novel antimicrobials. Given the likelihood of constrained budgets, HERA should prioritise R&I delivery partnerships that enable rapid, coordinated action across industry, academia, and governments. HERA's participation in multi-stakeholder partnerships is discussed in detail in Chapter 2 above.

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<sup>2</sup> While the Health cluster under Horizon Europe normally requires consortia, EU4Health projects can also allow single entities.

Within this context, it is also necessary to reframe global health cooperation beyond traditional Official Development Assistance (ODA) narratives. Rather than positioning investments as charitable contributions, key EU stakeholders have advocated articulating global health as a strategic investment in European health security, economic competitiveness, and scientific excellence. This framing aligns with the growing recognition that health security functions as a global public good with tangible returns for European citizens – from preventing climate-sensitive infectious disease threats and AMR to catalysing breakthrough technologies with broad economic applications.

HERA's support for greater involvement of LMICs in global health R&D can also contribute to attaining the goal of the CGSC. Investment in building R&D capacity in LMICs brings about several benefits, including leveraging pools of research talent in LMICs and enhancing research robustness (e.g. through building on more representative clinical trials). Additionally, local R&D can also be linked directly to local value chains of MCM, lowering costs and accelerating the speed of production, which are critical during international health crises. However, in many LMICs, these potentials remain untapped due to a lack of ecosystems that [support](#) research infrastructure, [build](#) research skills, and bring innovations to the market.

HERA's global health R&D actions have so far not fully leveraged this potential. While HERA's R&D collaboration with authorities and organisations in HICs has made considerable progress since its establishment and focused on R&D collaboration<sup>3</sup>, funding initiatives to build R&D capacity in LMICs have been more discrete. The majority of funding still targets building detection and surveillance capacity (e.g. genomic sequencing capacities and diseases with pandemic potential), contributing to quicker identification and characterisation of pathogens in LMICs, which would have international impacts<sup>4</sup>.

Timely sharing of research findings and intellectual property (IP) is pivotal in ensuring rapid and affordable access to critical MCM during international health crises. [Technology transfer](#) allows for decentralised production of crisis-relevant medicines, with local manufacturing lowering costs and enhancing access for LMICs. Even before its establishment, HERA was expected to play a key role in supporting the [transfer agreement](#) with pharmaceutical and medical device companies to boost manufacturing in the EU and globally. It has supported this task to some extent, through its financial contributions to the WHO's COVID Technology Access Pool (CTAP), now transitioned to the Health Technology Access Pool (HTAP), which encourages voluntary sharing of IP, knowledge, and data. However, the EU (including HERA) can take bolder action to ensure optimal

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<sup>3</sup> For example, in 2025, HERA carried out consultation with Korea on the R&D funding agenda, collaborated with Japan on advanced R&D of MCMs, and with the US CARB-X on push funding for AMR R&D.

<sup>4</sup> HERA Work Programmes [2024](#) and [2025](#); HERA Annual Reports [2022](#) and [2023](#).

technology transfers, though establishing binding mechanisms remains challenging due to tensions between public health interests in broad access and commercial interests in IP protection. This difficulty is exemplified by the failed TRIPS waiver for COVID-19 vaccines and contentious negotiations in the Pandemic Agreement, supported by HERA, ultimately adopted on 20 May 2025 with consensus on technology transfer on 'mutually agreed' terms (Article 11), which stakeholders from the Global South argue maintains voluntary approaches that risk constraining developing countries' access to critical technologies in future health crises.

Meanwhile, funding for building R&D capacity in LMICs, (i.e. capacity to originate or demand research, coordination between researchers and policymakers to enhance research utility, enabling research infrastructure, and sustainable local career pathways for researchers) has [received less attention](#). The exception is HERA's funding support for the EDCTP3. While EDCTP's primary mandate is to support clinical research on vaccines and treatments for infectious diseases affecting the African region, it also includes activities to strengthen research capacity for sub-Saharan Africa, e.g. through research network building and fellowship programmes.

Through HERA, the EU should provide resources to [build](#) scientific capacity in LMICs. This support mechanism of mobilising resources for capacity building can help [reduce external dependencies](#) in LMICs during times of peace and crises and position the EU to execute its 'soft' form of global influence in LMICs.

Moreover, the geographical coverage of HERA's R&D collaboration with LMICs can also be strengthened. Currently HERA's actions in this area focus primarily on the African region, with the EDCTP3 being a notable example of success. While HERA does provide funding support for global initiatives which (partly) aim at R&D of MCM for infectious diseases impacting [LMICs](#), as mentioned above, many of them are still not optimal in building R&D capacity globally.

It has been reasonable for HERA to [prioritise](#) its R&D support initiatives for Africa, given that health research capacity of the region remains low compared to other regions. A positive development is that the region ranks high in terms of [capacity](#) to attract international research funding. However, in the longer term, R&D collaboration with other parts of the world is also needed, given that many LMICs face a similar pattern of high R&D need and low capacity. HERA's plan to explore opportunities to expand its global health collaboration follows this direction.

## 5. CONCLUSION

The EU stands at a critical juncture in global health security. Global health R&D is a strategic imperative for the EU, serving not only humanitarian aims but also its own security, autonomy, and economic resilience. With major donors cutting global health funding, the EU's sustained leadership has become increasingly critical. Recent EU initiatives, including the 2022 Global Health Strategy, the 2025 Life Sciences Strategy, and the announced Global Health Resilience Initiative, reflect an ambition to strengthen Europe's role in a fragmented global health landscape and to reinforce partnerships with LMICs. Within this architecture, HERA stands out as a key actor capable of enhancing Europe's leadership in global health research.

HERA has established its global health research footprint through a multi-pronged approach to pandemic preparedness, integrating EU health security with international collaboration and capacity building. Through Horizon Europe, HERA has channelled substantial R&D funding for global health research, including to LMICs, albeit to a more limited extent. HERA has embedded itself within the global health architecture through multilateral partnerships with WHO, CEPI, and EDCTP3, among others. Complementing these multilateral engagements, HERA has formalised bilateral arrangements with key partners, including its homologues in the US, Japan, South Korea, and Canada. However, the concentration of partnerships in high-income countries and limited engagement with emerging economies and various regions beyond Africa suggest opportunities for more equitable geographic diversification aligned with the EU Global Health Strategy's principles.

While the above effort to advance HERA's position in global health is remarkable, it can still further realise its full potential. The upcoming Global Health Resilience Initiative and the EU 2028–2034 MFF present important opportunities for HERA to evolve from a crisis-response mechanism into a strategic connecting node for European health security and global preparedness. This transformation depends on specific structural reforms, including formalising coordination protocols, expanding partnerships beyond traditional allies, integrating AI-powered foresight across surveillance systems, and securing flexible multi-year funding that enables innovative financing mechanisms.

The recommendations below chart a path forward to enable HERA to more optimally mobilise R&D funding from EU instruments and international collaborations to strengthen the EU's positioning in global health security:

## Recommendations to better position HERA as a leading actor in the Global Health Resilience Initiative

Strengthening HERA's Coordination Role. HERA cannot work in isolation. Its value lies in connecting R&D expertise with implementation capacity across the EU's health security landscape. Practical steps to improve coordination include:

R1. Deeper clarity and distinction of DG functions. Define explicit protocols showing where HERA takes the lead (R&D coordination, surveillance networks, technical standards) versus where it advises DG RTD and DG INTPA on implementation decisions like partnership selection and funding allocation. This removes ambiguity that stakeholders consistently flag as problematic.

R2. Share intelligence systematically. Create regular channels for HERA to provide technical threat assessments and R&D gap analyses to DG INTPA before major funding or partnership decisions. This ensures technical expertise drives, rather than follows, operational commitments.

R3. Synchronise planning cycles. Align HERA's work planning with DG INTPA's partnership timelines and DG RTD's funding cycles so that health security expertise shapes resource decisions from the outset.

HERA should strategically expand its international partnerships to match the geographic scope of health threats. Three approaches would extend its reach:

R4. Engage high-capacity partners in Europe's immediate vicinity. Formalise cooperation with non-EU Western European institutions - particularly Switzerland's Federal Office of Public Health and the UK Health Security Agency, which has already expressed interest. Switzerland's renewed participation in Horizon Europe since 2025 removes a key obstacle to collaboration.

R5. Build on existing diplomatic frameworks. Use established bilateral agreements, like the EU-India Strategic Agenda or the Indo-Pacific Strategy, as a springboard for health security partnerships. This leverages existing political momentum rather than building relationships from scratch. Priority regions include South and Southeast Asia, Eastern Partnership countries, and underexplored areas like the Western Balkans and Southern neighbourhood.

R6. Time partnerships to coincide with regional summits. The recent HERA-PAHO agreement, signed during the 2025 EU-CELAC summit, shows how diplomatic moments can elevate technical arrangements. Map upcoming regional summits, including EU-African Union, EU-ASEAN, Eastern Partnership forums, and prepare partnership frameworks in advance to secure political endorsement and resources.

Strengthening HERA's Multilateral Engagement. HERA has shown it can add value to global health initiatives, as demonstrated by the effective coordination with WHO, UNICEF, and Gavi during the 2024 mpox response. Yet HERA's multilateral partnerships remain underdeveloped relative to EU financial commitments, which suggest opportunities to:

R7. Formalise the HERA-Gavi partnership. Gavi's 6.0 strategy (2026-2030) focused on regional manufacturing, pandemic preparedness, and equity aligns directly with HERA's mandate. The June 2025 Pledging Summit offers a clear entry point to convert financial support into operational collaboration on regional vaccine manufacturing, MCM stockpiling, and equitable distribution.

R8. Deepen WHO engagement beyond the Hub. Expand cooperation with WHO's regional offices and newly deployed EIOS surveillance system to strengthen early warning capabilities. Continue supporting the Dakar Hub in Africa and explore partnerships with other regional hubs to build an integrated frontline defence system.

R9. Establish a Technology Watch mechanism beyond the EU. Working with global partners, create a systematic monitoring function for emerging crisis-relevant technologies. Such a mechanism would identify critical gaps in European access or capacity, inform preparedness planning before crises hit, and guide strategic partnerships and joint R&D initiatives with non-EU actors.

Responding to US Withdrawal from Global Health Security. The US retreat from global health security creates an opening for HERA to position Europe as a stable, long-term partner distinct from US political volatility. Three proposed responses include:

R10. Continue to support a European pathogen intelligence network. Use the Be Ready Now Partnership (spanning Norway, UK, Ukraine, Moldova, Turkey, and New Zealand) as Europe's alternative to the terminated CREID network. This provides pan-European early warning capacity and reduces dependence on external surveillance systems.

R11. Engage countries losing US partnerships. The US previously partnered bilaterally with over 50 countries, primarily in sub-Saharan Africa and Asia. Target strategic engagement with these partners where European regulatory excellence and research capacity can generate impact.

R12. Leverage comparative advantages, not direct substitution. Rather than replacing the US funding gap, Europe and HERA should focus on what they do best, namely regulatory frameworks, research collaboration, and building sustainable capacity with clear performance indicators.

Enhancing Foresight and Artificial Intelligence in Health Governance. Strategic foresight and AI can shift HERA from reactive crisis management to proactive resilience planning. Foresight

must remain science-based while integrating strategic and security intelligence from Member States to provide a comprehensive threat assessment.

R13. Coordinate foresight across EU health architecture. Integrate foresight activities between HERA, ECDC, EMA, relevant DGs, and the WHO Hub in Berlin. Building on HERA's 2022 commitment to regular threat prioritisation exercises, ensure foresight is embedded systematically into preparedness planning rather than conducted in silos.

R14. Scale AI applications for early warning and scenario testing. HERA's 2025 Work Programme already identifies AI applications for pathogen detection, MCM development, supply monitoring, and biosecurity. The studies completing in late 2025 should inform rapid implementation. Machine learning can analyse genomic, mobility, climate, and social data to identify emerging threats faster and test intervention effectiveness before crises unfold.

R15. Build interoperable infrastructure with equity safeguards. Invest in data ecosystems that link public health agencies, academia, and industry through 'AI-for-foresight' hubs. Leverage synergies with the Innovative Health Initiative to accelerate development. Prioritise LMIC capacity building, equitable data access, and evaluation metrics for predictive accuracy and real-world impact.

### Recommendations for HERA's positioning in the 2028–2034 MFF

CEPS has put forward reform proposals involving the establishment of two high-level councils within the upcoming MFF framework, aimed at bolstering Europe's R&I infrastructure in preparation for the subsequent Framework Programme, with the goal of ensuring available resources deliver effectively on both internal security and external global challenges.

*Under the Council on Research and Innovation for Competitiveness and Security (CRICS), which would concentrate on dual-use innovation, including defence against biological threats, while advancing industrial sovereignty in life sciences and medical technologies:*

R16. Designate MCM supply chains as strategic technologies. Frame health security as integral to European competitiveness and strategic autonomy. The Critical Medicines Act already recognises pharmaceutical resilience as collective security. HERA and relevant stakeholders should extend this logic to position MCM manufacturing and supply chain infrastructure (EU FAB, RAMP UP) as strategic technologies eligible for ECF financing. This addresses the artificial separation between health and defence domains that currently fragments integrated security challenges.

R17. Enable portfolio and at-risk investment approaches. The EU's conservative approach during COVID-19, namely the limited funding concentrated in late-stage development, delayed vaccine access compared to US counterparts. HERA requires authority to commit resources

before market authorisation, reallocate dynamically based on milestones, and accept inherent failure risks when rapidly developing critical technologies during emergencies.

R18. Secure multi-year dedicated funding with flexible disbursement. Annual funding streams are incompatible with multi-year R&D realities and clinical trial timelines. Current HERA Invest budget cannot support late-stage development at scale. Establish predictable multi-year allocations with risk-tolerant financing mechanisms and ability to fund industrial scale-up, balanced with strong accountability frameworks.

R19. Increase industry engagement through structural incentives. Introduce minimum co-funding requirements for industry consortia, promote single-entity contracts for products requiring market authorisation (following BARDA's model), and deploy combined push-pull incentives including revenue guarantees and milestone-based rewards. Establish pre-call dialogue with industry to align desired MCMs with industrial capacity.

*Under the Council on Global Societal Challenges (CGSC), which would tackle global health issues, public health preparedness, and SDG implementation, while encouraging international collaboration and openness that extends beyond EU borders:*

R20. Reframe global health cooperation as strategic investment, not aid. Move beyond ODA narratives to position global health as investment in European security, competitiveness, and scientific excellence with tangible returns, from preventing climate-sensitive infectious diseases and AMR to catalysing breakthrough technologies with broad economic applications.

R21. Expand R&D capacity building in LMICs beyond surveillance. Current funding concentrates on detection and genomic sequencing. Increase investment in research infrastructure, skills development, researcher career pathways, and innovation ecosystems that enable LMICs to originate research and link local R&D to local MCM value chains. Expand geographic coverage beyond Africa to regions with high R&D needs and low capacity.

R22. Strengthen technology transfer mechanisms. While HERA supports WHO's Health Technology Access Pool, establish more robust frameworks for IP sharing and decentralised manufacturing. The "mutually agreed terms" compromise in the May 2025 Pandemic Agreement maintains voluntary approaches. Pursue binding mechanisms that balance public health access with commercial interests.

R23. Leverage multi-stakeholder partnerships under constrained budgets. Integrate co-funding rules enabling HERA to pool resources across industry, academia, and governments for global health R&I delivery partnerships on vaccine development, antimicrobials, and preparedness measures.



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