EU R&I and Health Policy to Tackle Global Challenges

Scoping paper on HERA's engagement with low- and middle-income countries

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SUMMARY

The Health Emergency Preparedness and Response Authority (HERA), established in 2021, aims to strengthen the EU's response to Covid-19 and potential future health crises. Global health security is one of HERA's core mandates to support the EU's leadership in global health.

This report provides an independent observation of HERA's global health activities three years on from when it first began to operate, assessing its engagement with low- and middle-income countries between 2022 and 2024. It introduces a set of indicators to quantify HERA's international activities, offering a baseline for tracking future progress.

The findings show that HERA has expanded its global efforts both in budget and scope. Its global health activities cover six key areas: intelligence gathering and threat assessment, research and development, production capacity, resource donations, cooperation agreements and an international instrument on health.

Looking ahead, HERA has affirmed its ambition to strengthen its global health activities by broadening its geographic reach and implementing the cooperation agreements concluded with strategic partners. As HERA's international dimension develops, this report recommends more systematic and frequent monitoring and evaluation of its activities as well as a shift in the focus of HERA's role from primarily financial contributions and advisory support for EU bodies towards a deeper involvement in technical cooperation with global partners.

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List of abbreviations

Africa CDC	Africa Centre for Disease Control and Prevention
AMED	Japan's Agency for Medical Research and Development
AMR	Antimicrobial resistance
ASPR	US Administration for Strategic Preparedness and Response
BARDA	US Biomedical Advanced Research and Development Authority
CARB-X	Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator partnership
CDC	US Centers for Disease Control and Prevention
CEPI	Coalition for Epidemics Preparedness Innovations
CEPS	Centre for European Policy Studies
CHPIA	International Conference on Public Health in Africa
DG ECHO	Directorate-General for European Civil Protection and Humanitarian Aid Operations
DG ENV	Directorate-General for Environment
DG INTPA	Directorate-General for International Partnerships
DG RTD	Directorate-General for Research and Innovation
DG SANTE	Directorate-General for Health and Food Safety
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EDCTP	European and Developing Countries Clinical Trials Partnership
EEAS	European External Action Service
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EU	European Union
FAO	Food and Agriculture Organization
GARDP	Global Antibiotic Research and Development Partnership
GloPID-R	Global Research Collaboration for Infectious Disease Preparedness
GLOWACON	Global Consortium for Wastewater and Environmental Surveillance for Public Health
HADEA	European Health and Digital Executive Agency
HERA	Health Emergency Preparedness and Response Authority
JRC	Joint Research Centre
KDCA	Korea Disease Control and Prevention Agency
LMICs	Low- and middle-income countries
MCM	Medical countermeasure
MOHW	Korea's Ministry of Health and Welfare
mRNA	Messenger ribonucleic acid
PAVM	Partnerships for African Vaccine Manufacturing
PGI	Pathogen Genomic Initiative
R&D	Research and development

SECURE	Expanding Sustainable Access to Antibiotics
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TEI MAV	Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa
UN	United Nations
UNEP	United Nations Environment Programme
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WHO AFRO	WHO Regional Office for Africa
WHO CA+	WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response
WHO Pandemic Hub	WHO Hub for Pandemic and Epidemic Intelligence

A. INTRODUCTION

This scoping paper aims to map those activities, initiatives and tools proposed, organised and implemented by the European Union's (EU) Health Emergency Preparedness and Response Authority (HERA) which feature an international dimension.

HERA was established in September 2021, in response to the Covid-19 pandemic and in preparation for future health crises, with a primary focus on preventing, detecting, and responding to health emergencies. The Covid-19 pandemic demonstrated that health threats transcend borders, emphasising the need for EU actions to extend beyond national territories. Therefore, strengthening the EU's engagement and collaboration with international partners is essential for preventing and managing future pandemics. Particular focus could be on engagement with countries with lower levels of economic development and income, and therefore fewer resources to tackle public health threats.

This paper is part of a broader outcome that analyses HERA as a pillar of the EU's Global Health Strategy. It focuses on the international dimension, specifically by assessing the degree to which HERA has engaged and cooperated with low- and middle-income countries (LMICs)[1] during the past three years. Our research is the first of its kind aiming to measure HERA's contribution to the global health agenda by quantifying and introducing a set of indicators for its international activities. These indicators establish as a baseline for tracking HERA's progress moving forward.

After outlining the methodology (Chapter B) and providing an overview of HERA's global health actions (Chapter C), this paper examines six specific areas of HERA's actions, addressing both LMICs and global contexts (Chapter D). These areas include: 1) intelligence gathering and threat assessment as crucial pillars to enhanced preparedness; 2) research and development (R&D); 3) manufacturing capacity; 4) donation and contribution; 5) cooperation agreements and participation in international events; and 6) global health instrument. The initiatives presented in these six sections aim to strengthen global resilience and ensure more effective responses to future health threats. They feature the importance of these dimensions as key and complementary pillars of preparedness, addressed through the broader framework of international cooperation and international partnerships.

This analysis is followed by a concluding section (Chapter E), which looks ahead to possible future avenues for a stronger HERA in the global health emergency preparedness and response, as well as inputs for further in-depth reports under the same project. As highlighted in our conclusions, HERA's international dimensions and efforts should be

[1] This paper follows the classification of countries in terms of income level by the World Bank. See https://blogs.worldbank.org/en/opendata/world-bank-country-classifications-by-income-level-for-2024-2025.

strengthened, particularly with regions where it has not yet established stronger cooperative partnerships, such as Latin America and the Caribbean and Asia.

This scoping paper is one of the first outputs of the *EU R&I and Health Policy to Tackle Global Challenges* project, funded by the Gates Foundation. The findings of this paper will feed into a forthcoming research report on how HERA can mobilise R&D funding and international collaborations with peer institutions to strengthen the EU's positioning in global health security – partly analysed under one of the sections of this report – within the framework of the same project.

B. METHODOLOGY

We employed a mix of research methods including desk research, expert consultations and indicator development to identify and measure HERA's global health actions.

Desk research comprising secondary sources on HERA's international dimension was a preliminary activity, with a particular focus on LMICs. The research relied on multiple sources, including HERA's annual activity reports, HERA's work plans, the European Commission's website, and the websites of HERA's partner initiatives (the Pandemic Fund, CEPI, EDCTP, the World Bank, WHO, TEI MAV, etc). This research provided insights into HERA's international activities, their budgets (if applicable) and timelines, and key partners involved.

To complement the findings of our desk research, CEPS conducted several rounds of consultations with HERA. The discussions aimed to: i) fill knowledge gaps that could not be addressed through desk research; ii) verify the accuracy of the reported activities; iii) understand HERA's plan for assessing international activities, especially in light of its ongoing review; and iv) gain insights into HERA's future strategy for international activities, with a particular focus on LMICs. Following an initial meeting between the two organisations, CEPS shared a questionnaire and supporting documents for HERA's input, to which HERA has been contributing on an ongoing basis. HERA also engaged CEPS as an observer in its workshop held on 27 November 2024: 'Breaking barriers to effective funding for innovative medical countermeasures'. Participation in this event provided critical insights pertaining to the R&D dimension of the paper.

HERA's activities featured in this report included both initiatives explicitly targeting LMICs and those with international elements. While some activities clearly target LMICs, some initiatives occur at a global level, engaging or benefiting LMICs to different extents – directly or indirectly. The coverage of both LMIC-focused and international initiatives ensures a comprehensive understanding of HERA's actions and allows for the identification of potential synergies between them.

A set of indicators were identified to quantify the degree of HERA's international dimension, using the primary and secondary data collected. The indicators provide a baseline to track the development of HERA's global health actions over time. The selection of the indicators was based on several criteria:

- measurability (they are quantifiable or able to be assessed through observable data)
- specificity (they are clear and precise, defining what is being measured)
- feasibility (they are practical to collect and analyse)
- temporality (they have a clear timeframe for when the measurement takes place).

It is highly likely that the indicators presented in this report underestimate HERA's contribution to global health security. They are based solely on HERA's activities for which we can assign measurable numbers, potentially overlooking other less quantifiable impacts of HERA's international efforts.

C. An overview of HERA's global health actions

Public health threats transcend borders. As an authority working on public health, HERA should coordinate with international actors to achieve its mission, as international collaboration is one of the fundamental pillars of its work. The Commission's Communication introducing HERA affirms one of its core mandates as 'contributing to strengthening the global health security architecture for preparedness, prevention, detection of, and response and recovery to health emergencies'. International activities have been primarily mapped to Task 6 of HERA's annual work plans since 2022. With the EU's pre-Covid-19 international health actions considered under-leveraged and rather inward-looking (Bengtsson, 2022), the establishment of HERA has presented tremendous potential to support the EU's leading role in global health, notably through the implementation of the EU Global Health Strategy (Reiss, 2022; Renda et al., 2023).

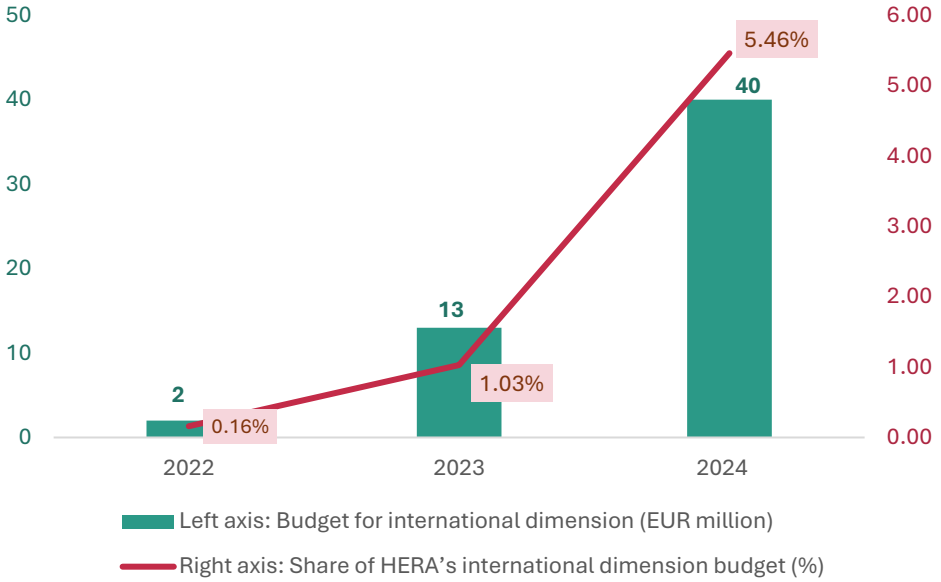
Since HERA's establishment, commentators pointed to the need to match HERA's ambition for an international mandate with sufficient resources. There were also calls for HERA to set up coordination with a wide range of stakeholders, including EU services working on international cooperation (ECDC, EMA, DG INTPA, EEAS), homologous agencies globally (e.g. BARDA, UK Health Security Agency, Africa CDC, KDCA, Japanese Infectious Disease Surveillance Centre), intergovernmental platforms (G7, G20), international organisations (WHO, FAO, World Organisation for Animal Health, development banks), and multistakeholder partnerships (GAVI, CEPI, CARB-X, the Global Health Security Agenda) (Bengtsson, 2022; Reiss, 2022; Renda et al., 2023). Importantly, HERA was expected to collaborate with LMICs to exchange data and resources and improve their production, stockpiling and procurement of critical medical countermeasures (MCMs) (McKee et al., 2023; Reiss, 2022; Renda et al., 2023; Wouters et al., 2023). Stakeholders also anticipated HERA would take a leading role in supporting the EU's actions in global health architecture, notably in the negotiation and monitoring of an international instrument on pandemic prevention, preparedness, and response (the 'pandemic accord') (Renda et al., 2023; Wouters et al., 2023).

Since 2022, HERA has incrementally expanded its international activities. HERA's budget for Task 6 (the international dimension) was EUR 2 million in 2022, which is relatively small (0.16 %) compared to its total budget of EUR 1,284 million for the same year. The absolute amount and share of international activities in HERA's budget grew in 2023 (EUR 13 million, 1.0 % respectively) and 2024 (EUR 40 million, 5.5 % respectively) (Table 1). The higher share of international activities in HERA's total budget is attributed to two factors. First, the absolute amount allocated to HERA's international budget has increased from 2022-24. Second, HERA's total budget significantly decreased in 2024, primarily because of the substantial reduction in the budget for Task 4 ('Ensuring the provision of

MCMs'). In 2022 and 2023, under this Task, EUR 581 million and EUR 636 million were allocated for the purchase and stockpiling of critical MCMs, particularly Covid-19 vaccines. However, in 2023, WHO declared that Covid-19 was no longer a global health emergency, thereby leading to the end of HERA's vaccine procurement budget for this crisis.

Areas of action have also been diversified, covering intelligence gathering and threats assessment, R&D, manufacturing capacity, donation of MCMs, cooperation agreements and international instrument. And while international activities are officially mapped to Task 6, some of HERA's actions under Task 1 (intelligence gathering and threats assessment) and Task 2 (R&D) also feature international elements.

Table 1. Share of international activities in HERA's budget over year



Source: HERA's work plans for 2022, 2023 and 2024; unit: EUR million

Note: The graph includes only HERA's budget for international activities under Task 6 (International Dimension) of its annual work plans for 2022 to 2024. It excludes the budget for global health-related activities under Task 1 (Threat Assessments and Intelligence Gathering) and Task 2 (Research and Development of MCMs) because their annual values were unavailable.

This paper aims to provide an independent observation of HERA's global health actions three years into its operation. Table 2 presents a set of indicators for HERA's international activities. The quantification of HERA's actions can serve as a baseline for tracking its progress in the future. Some limitations cannot be avoided, notably because HERA's role varies across different activities. It takes the lead in some and provides support to others and it is more difficult to measure and quantify HERA's direct contribution to the actions for the latter. For example, HERA has provided expertise and advice for the identification of projects under the Team Europe Initiative on Manufacturing and Access to Vaccines,

Medicines and Health Technologies (TEV MAV+). The closest possible proxy to measure the impact of this action could be the number of countries receiving projects to boost their production capacity under this initiative, while it is much more difficult to quantify HERA's direct contribution to these actions.

Chapter D provides a detailed analysis of HERA's global health activities. The actions are categorised by six main areas: intelligence gathering and threats assessment; R&D; manufacturing capacity; donation of MCMs; cooperation agreements; and international instrument.

Table 2. Indicators of HERA's international activities

Indicator	Metric	2024 baseline
Share of budget for the international dimension (Task 6) in the total HERA budget	Proportion of 'International dimension (Task 6)' under the total HERA budget	5.46 %
Support for enhancing the intelligence gathering, genomics and surveillance capacity in LMICs	Cumulative funding for intelligence gathering, genomics and surveillance capacity of LMICs	EUR 17.4 million
	Cumulative funding for intelligence gathering, genomics and surveillance at global level	EUR 12 million
R&D of crisis-relevant medical countermeasures (MCM)	Cumulative funding for R&D in LMICs with epidemic and pandemic potential	EUR 273.43 million
Support for local production capacity under TEI MAV+ (Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa)	Number of approved projects under TEI MAV+	12
	Number of LMICs receiving projects to boost their production capacity	6
Donation/contribution of resources	Share of Team Europe's donation of Covid-19 vaccines to COVAX	41 %
	Share of Team Europe's donation of mpox vaccines to Africa CDC	10 %
	EU's contribution to the Pandemic Fund	EUR 247 million
	Number of projects funded by the Pandemic Fund	19
	Number of recipient countries of the Pandemic Fund	37
HERA representing the Commission in international events on public health	Cumulative number of events, conferences, meetings, missions on public health focusing on LMICs in which HERA participated	7
Cooperation with non-EU countries and international organisations on global health	Cumulative number of HERA's agreements signed with counterpart authorities in LMICs	2
	Cumulative number of HERA's agreements signed with international/multilateral organisations	4
HERA's support for the Commission's negotiations on a pandemic agreement	Whether the Pandemic Agreement has been reached (in progress)	No

D. THE SIX AREAS OF HERA'S GLOBAL HEALTH ACTIONS

1. INTELLIGENCE GATHERING AND THREAT ASSESSMENT

Metric	2024 baseline	Remarks
Cumulative funding for intelligence gathering, genomics and surveillance capacity of LMICs	EUR 17.4 million	Sum of HERA's funding for the four initiatives: - Joint funding for Africa CDC's Pathogen Genomic Initiative 2.0 - Collaboration with the WHO Regional Office for Africa (AFRO) to address the threat of emerging infections on the African continent - Support the establishment of a new WHO hub in Africa
Cumulative funding for intelligence gathering, genomics and surveillance at global level	EUR 12 million	Sum of HERA's funding for the two initiatives: - Establishing GLOWACON (Global Consortium for Wastewater and Environmental Surveillance for Public Health) - Signing of a contribution agreement for the WHO Pandemic Hub to increase global intelligence capacities

Pathogen Genomic Initiative 2.0 – Advancing molecular diagnostics and genomic surveillance in Africa

HERA has provided support to strengthen molecular diagnostics and genomic surveillance in Africa. This capacity is crucial for the early detection and tracking of pathogen evolution, assisting public authorities in designing tailored intervention. In 2022, HERA earmarked a budget of EUR 6 million, which was translated into a grant agreement of the same amount between HERA and the Africa CDC in 2024. The grant supports Africa CDC's Pathogen Genomics Initiative 2.0 (PGI). Building on the sequencing capacity developed in Africa in response to the Covid-19 crisis, this initiative aims to advance the region's sequencing capacity for future emerging pathogens. It relies on four main pillars: building capacity and workforce, implementation of high-priority use cases, sharing of genomic data at regional and global level, and reinforcement of the regional community of practice. An example of PGI projects receiving funding support from HERA is PGI-DETECT, which aims to reinforce molecular diagnostic and sequencing capacity in 12 member states of the African Union.

HERA's role: funding contribution

Amount: EUR 6 million; source: EU4Health

Partners: Africa CDC, African Society for Laboratory Medicine, Africa Public Health Foundation

WHO AFRO – Expansion of intelligence gathering and threat assessment capacities in Africa

HERA has assisted the WHO Regional Office for Africa (AFRO) in expanding the continent's intelligence gathering and threat assessment capacity. In December 2022, as part of its 2021 Work Plan, HERA has signed a financial contribution of EUR 2 million to expand clinical sequencing and environmental surveillance capacities in different regions in Africa. These capacities are expected to contribute to better detection of public health threats in the region.

HERA has also supported the establishment of the WHO AFRO Dakar Hub- a new WHO regional emergency hub in Africa[2], mandated to reinforce the region's response to health emergencies. Being one of the first partners of the Hub, HERA participated in the inauguration ceremony in December 2023. Through a budget of EUR 2 million, which was signed in 2023 and runs until 2025, HERA has facilitated the hub's intelligence-gathering activities. In addition, HERA contributed another amount of EUR 7.4 million for the support of the WHO Blueprint on vaccines and therapeutics clinical trials against filoviruses, using the budget from its Work Plan 2022. This funding support was signed in 2023 and will run until 2025.

HERA's role: funding contribution, setting up of information centre (Dakar hub)

Amount: EUR 2 million (2022), EUR 9.4 million (2023); source: EU4Health

Partners: WHO AFRO

Mpox surveillance- Enhancing access to mpox diagnostics and genetic sequencing for Africa

In August 2024, the Africa CDC officially declared mpox as a Public Health Emergency of Continental Security. In response, HERA has taken swift actions to support the diagnosis and prevention of this disease in African countries. Beyond its donation of mpox vaccines (discussed in more detail in section 4), HERA has committed to providing a grant of

[2] WHO AFRO has set up three emergency hubs in the region: the Nairobi hub in 2022, the Dakar hub in 2023 and the Pretoria hub in 2024, https://www.afro.who.int/news/senegal-who-launch-regional-emergency-hub-bolster-africas-response-health-crises.

EUR 9.4 million to support the region's diagnosis and genetic sequencing of the virus. The grant is expected to be signed in 2025.

HERA's role: funding contribution, donation of medical countermeasures

Amount: EUR 9.4 million (2025); source: EU4Health

Partners: Africa CDC

GLOWACON - Establishing a global consortium for wastewater and environmental surveillance for public health

Wastewater surveillance presents significant potential in the early detection of emerging infectious diseases. It can complement clinical data, providing unique insights about the presence and developments of pathogens (Levy et al., 2023). Wastewater surveillance has gained increasing attention, especially after the pandemic, as a tool for early detection, effective management and response of infectious diseases. Nevertheless, wastewater surveillance has not yet been fully integrated in public health, particularly because of suboptimal data sharing and insufficient capacity and coordination among stakeholders (European Commission, 2023; Grassly et al., 2024; Levy et al., 2023).

In 2023, HERA started the preparatory process to set up GLOWACON - the Global Consortium for Wastewater and Environmental Surveillance for Public Health - in collaboration with the Joint Research Centre (JRC) and international players such as WHO and the Gates Foundation. The mission of this multistakeholder consortium is sharing knowledge and resources, advocating for the integration of wastewater surveillance in health systems, identifying funding opportunities, and developing a global sentinel system for early detection, prevention and real-time monitoring of disease outbreaks. HERA and JRC officially launched GLOWACON in March 2024.

Following up, in 2024, HERA intends to take an additional step in this area by jointly creating a Global Wastewater Sentinel System, a network to facilitate the sharing of information and resources across sentinel systems. The ultimate aim of this initiative is to strengthen the global capacities to detect and address emerging public health threats.

HERA has organised and participated in a series of events on wastewater surveillance, contributing to increasing the visibility for its work in this field. HERA's involvement in these events are presented in detail in section 5 of this chapter.

HERA's role: knowledge sharing, capacity building, development of infrastructure

Amount: EUR 8 million, 2024; source: EU4Health

Partners: JRC, WHO, Gates Foundation, CDC, Africa CDC, and 300 other collaborators

WHO Pandemic Hub – Gathering of global public health intelligence

HERA and the WHO Hub for Pandemic and Epidemic Intelligence (WHO Pandemic Hub) have established their collaboration through the signing of an agreement in December 2022. The two institutions, which were both set up in September 202, share a common mandate of public health intelligence gathering. The agreement features their consent to jointly share data, methodologies and practices regarding intelligence, contributing to public heath risk assessment and identification of crisis-relevant MCMs. Other dimensions of the collaboration include the mutual consultation of work plans of the two organisations to ensure the synergies of their work, exchange of personnel to share institutional perspectives, and development of training in public health intelligence.

In 2022, HERA followed up with a financial contribution agreement of EUR 4 million for strengthening global intelligence capacities, notably through supporting a global market intelligence system. As the contribution agreement continues until 2025, HERA is unable to disclose the milestones of the system, but stressed the positive work achieved up to now.

HERA's role: funding contribution; sharing of data, information and expertise

Amount: EUR 4 million (2022); source: EU4Health

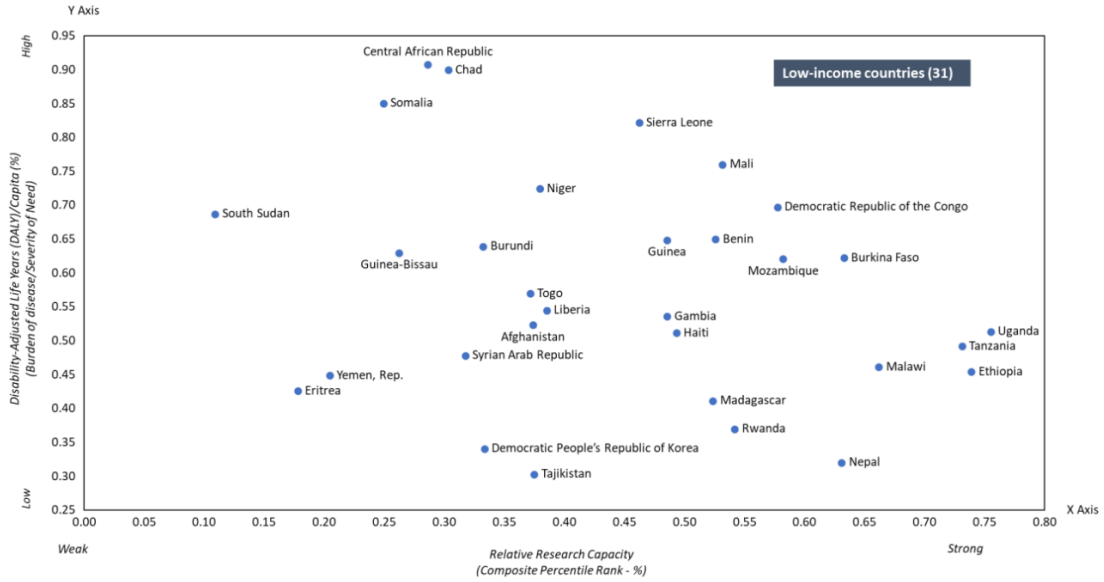
Partners: WHO HUB

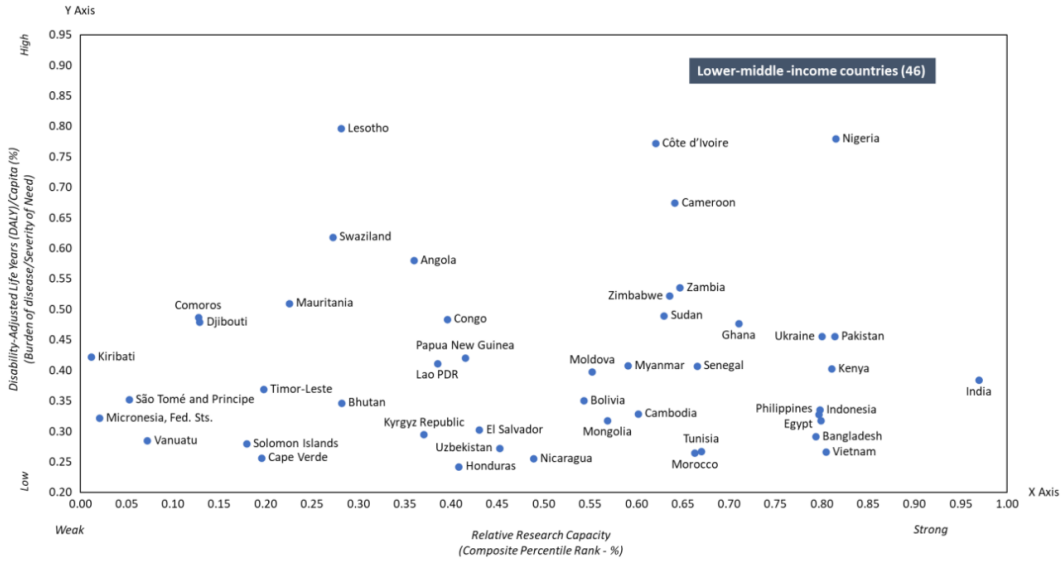
2. RESEARCH AND DEVELOPMENT

Metric	2024 baseline	Remarks
Cumulative funding for R&D in LMICs with epidemic and pandemic potential	EUR 273.43 million	Sum of HERA's financial contribution to international/global actions on R&D of MCMs relevant for LMICs, including CEPI, EDCTP, IHI, WHO initiatives on AMR and GloPID-R

Many emerging health threats cannot be addressed by existing MCMs but require the research and development of new products. The Covid-19 crisis or several AMRs only curable with novel antibiotics are a few examples among many other emerging threats that necessitate global R&D effort. International R&D collaboration in health technologies presents remarkable advantages: it helps pool research resources and expertise, avoid duplication and gaps in R&D, and ensure robustness and effectiveness of the MCMs across different populations (e.g. through joint clinical trials). International R&D collaboration is of particular importance for LMICs as these countries often have high need for new MCMs to address emerging diseases while their health R&D capacity remains limited (Figure 1).

Figure 1. Research capacity and urgency of needs in LMICs





Source: Eigbike, 2020

A major task for HERA is to promote the R&D for prevention, preparedness and response. The Commission Communication introducing HERA in 2021 did not include R&D collaboration in its international dimension, raising concerns from stakeholders (Renda et al., 2023). However, throughout its operation, HERA has conducted R&D collaboration, for example with WHO or multistakeholder partnerships such as CEPI or EDCTP. These activities are mapped not only to Task 6 (international dimension) but also Task 2 (research and development) of HERA.

CEPI - Support for late-stage development of vaccines

HERA has established its collaboration with the Coalition for Epidemics Preparedness Innovations (CEPI) – the global multistakeholder partnership on vaccines and MCMs to address endemics and pandemics. The two organisations signed a Letter of Intent in October 2022. This document lays down areas of potential collaboration, notably the exchange of data and information, and the creation of bilateral working groups.

HERA's annual funding allocation for CEPI uses the budget of the Horizon Europe programme and is agreed between HERA and Directorate-General for Research and Innovation (DG RTD) based on the scope of supported topics. Following the signing of the agreement with CEPI, HERA started allocating funding contribution to CEPI, disbursing a budget of EUR 35 million in 2023 (using the budget from its 2022 Work Plan). This budget was complemented by the same amount (EUR 35 million) disbursed in 2024, using the budget line under the 2023 Work Plan. According to HERA, further budget has not been calculated because the assessment is made based on actual results and HERA's 2025 Work Plan has not yet been adopted.

HERA's funding support for CEPI focuses on late-stage development of vaccines against emerging pathogens such as Chikungunya, Lassa fever, MERS, Nipah and Rift Valley fever. One highlight is CEPI's work on Chikungunya – a disease for which no vaccines have yet been developed. HERA's support for CEPI has facilitated the regulatory approval of the vaccine in endemic regions, and accelerated access for LMICs[3].

In addition to funding support, the two organisations held a roundtable in October 2023 on vaccine development for outbreak, epidemic and pandemic threats. The roundtable reviewed ongoing initiatives and accomplishments in vaccine development, identified synergies and explored potential complementary financing opportunities. It also engaged international partners like WHO, Africa CDC, the Gates Foundation, and the US BARDA.

HERA's role: funding contribution

Amount: EUR 35 million (2022), EUR 35 million (2023); source: Horizon Europe

Partners: CEPI

EDCTP3 and Innovative Health Initiative – contribution to institutionalised partnership on research and innovation for MCMs

This section highlights HERA's contributions to two institutionalised partnerships in research and innovation for MCMs: the European and Developing Countries Clinical Trials Partnership and the Innovative Health Initiative. These two activities are combined because they are reported altogether, and their estimated budget allocations are aggregated in HERA's Work Plans for 2022-2024.

❖ The European and Developing Countries Clinical Trials Partnership (EDCTP)

Since 2022, HERA has contributed funding to the European and Developing Countries Clinical Trials Partnership (EDCTP) (currently EDCTP3). This initiative aims to advance clinical research on poverty-related communicable diseases in sub-Saharan Africa. The Partnership engages African countries and several European Commission services in the development of MCMs for infectious diseases impacting Africa, particularly those with epidemic or pandemic potential. Currently, 15 European and 29 African countries are members of this partnership[4]. EDCTP funding supports joint R&I projects, R&I capacity

[3] https://cepi.net/accelerating-access-worlds-first-chikungunya-vaccine.

[4] https://www.edctp.org/about-us/governance/general-assembly/members-of-the-general-assembly/.

building for African countries, alignment of national R&I agenda, and the promotion of multistakeholder networks and partnerships in global health.

As a Joint Undertaking, EDCTP3 receives funding directly from the Horizon Programme, and mostly works independently in defining its Work Programme. HERA does not have a fixed annual budget allocation for EDCTP3. Instead, along with DG RTD, HERA assesses a posteriori the topics proposed and projects chosen of EDCTP, identifies the ones within HERA's scope of activities and deducts their values from HERA's HE available budget. Therefore, the final values of HERA's contribution cannot be disclosed and will only be determined closer to the end of the current multiannual financial framework of the EU, covering 2021-2027. HERA's estimates of its contribution to EDTCP can be found in its annual work plans and can be only used as reference.

Besides providing funding, HERA has reportedly collaborated with Commission services in this initiative. HERA's acting Director-General is currently sitting on the governance board of EDCTP3, together with other Commission services including DG RTD, DG INTPA, GROW, and DG SANTE. The governance board makes decisions through voting on various issues, including strategy, work plan, rules and funding of actions of the Partnership. HERA is also informed of relevant results of the Partnership.

❖ The Innovative Health Initiative (IHI) Joint Undertaking

HERA has been providing financial support for the Innovative Health Initiative (IHI). This is a public-private partnership of the European Union and European life science industries. It has engaged international research partners in a wide range of countries, including LMICs. The initiative's funding focuses on projects aimed at facilitating the development and deployment of MCMs relevant for cross-border health threats.

HERA's role: funding contribution, governance board

Amount: EUR 70 million (2023), EUR 80.75 million (2024); source: Horizon Europe

Partners: EDCTP, Africa CDC, European life science industries, research institutes in EU and non-EU countries including LMICs

WHO initiatives on antimicrobial resistance - support for developing and accessing novel antibiotics

Antimicrobial resistance (AMR) is on the rise globally. Its prevalence is particularly high in LMICs because of common challenges such as poor stewardship and low awareness, and specific difficulties in low-resource settings, such as limited access to sanitary and clean water, and the widespread availability of spurious and adulterated drugs (Pokharel et al., 2019; Sharma et al., 2022; Wasan et al., 2024).

HERA's support for WHO initiatives on AMR is part of its overall framework in this area, aligning with the Council's recommendation on AMR. Flagship initiatives in this area include HERA's commissioned studies on stockpiling and bringing of AMR medical countermeasures to the market, reservation of production capacities, and preparation of the forthcoming 'One Health Anti-Microbial Resistance' partnership in collaboration with the Directorate-General for Research and Innovation.

In the same vein as those activities, in December 2022 HERA signed a contribution agreement of EUR 8 million to support WHO's actions in the (late-stage) development of novel antibiotics and facilitation of access thereto, notably through the GARDP-SECURE initiative[5]. The funding covers 2023-2025[6]. Concretely, GARDP has received EUR 5 million to support clinical development, regulatory and access activities focusing on serious bacterial infections, sexually transmitted infections and children's antibiotics. SECURE has been allocated EUR 1 million to speed up the access to essential antibiotics, while the remaining EUR 2 million has been allocated to WHO-supported R&D activities. Additionally, HERA's financial contribution also goes to WHO's work on prioritisation of AMR pathogens and pipeline analysis and design of target product profiles. Currently, HERA is in discussion with GARDP and other international partners about further support for GARDP, as outlined in the EU4Health 2024 Work Programme[7]. According to HERA, the agreement is expected to be signed in 2025, for an amount of EUR 20 million.

HERA's support for GARDP is a concrete pillar of the partnership between HERA and WHO on pandemic preparedness and response under the EU4Health Programme, established in December 2022.

[5] GARDP (the Global Antibiotic Research and Development Partnership) is a not-for-profit research entity set up in 2016 by WHO and the Drugs for Neglected Diseases Initiative (DNDi). Its mission is to develop new antibiotics against WHO's list of priority drug resistant pathogens. SECURE (Expanding Sustainable Access to Antibiotics) complements GARDP. This public health consortium is mandated to support catalytic actions (particularly push incentives) to promote countries' access to antibiotics including both new registered and generic essential ones.

[6] https://gardp.org/hera-who-and-gardp-join-forces-to-counter-the-growing-threat-of-antimicrobial-resistance/.

[7] Under the call 'CP-CA-24-92 Supporting the development of antibiotics to strengthen global preparedness and response'.

HERA's role: funding contribution

Amount: EUR 20 million (2025); source: EU4Health

Partners: WHO, GARDP-SECURE, GARDP's priority countries

GloPID-R – the worldwide network of research funders supporting research on infectious disease preparedness

GloPID-R is the Coordination and Support Action under Horizon Europe, led by the EU's Directorate-General for Research and Innovation. The initiative was launched in 2022, officially started in 2023 and is ongoing until 2025. According to HERA, its contribution for this action equals the total action amount of EUR 1.6 million in 2022, and additional support was not required for 2024 and 2025. As HERA continues to work closely with the GloPID-R consortium, further support will be decided at a later stage, contingent on the action's results and continuance.

HERA's role: funding contribution

Amount: EUR 1.6 million (2022), source: Horizon Europe

Partners: Gates Foundation, Wellcome Trust, CEPI, GAVI, EDCTP, WHO, European Commission, national research institutes

Other actions under Horizon Europe that are HERA-marked

Several projects under the Horizon Europe Programme feature activities in LMICs and align with HERA's mandate in scope and content. As a result, they are designated as HERA-marked. The following list of project identifiers is provided by HERA, and can be found on the CORDIS platform.

101137311	101137192	101137459	101137132	101136281
101086640	101136531	101137033	101136380	101080544
101137157	101137383	101137283	101080692	101137419
101094188	101095619	101137242	101137506	101080528
101080889	101133191	101137183	101137092	101086521
101080462	101137185	101137229	101137248	101095516
101095444	101080309	101095606	101137006	

3. MANUFACTURING CAPACITY

Metric	2024 baseline	Remarks
Number of approved projects under TEI MAV+	12	As of 25/11/2024
Number of LMICs receiving projects to boost their production capacity	6	Egypt, Ghana, Nigeria, Rwanda, Senegal and South Africa as of 25/11/2024

HERA's support towards strengthening the capacity to manufacture crisis-critical MCMs internationally has a twofold benefit. It allows for the lower production cost of health technologies, and it improves access to these products for the local populations, especially LMICs, which face higher risks of unmet need (Kumraj et al., 2022).

TEI MAV+ - Support for local production capacity in Africa, Latin America and the Caribbean

Since 2022, HERA has supported the Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+ in Africa and its sister initiative in Latin America and the Caribbean). A focus on Africa can be explained by the urgent need to increase vaccine manufacturing capacity in this region: 99 % of the vaccines and 94 % of the medicines used in Africa currently rely on imports. TEI MAV+ is in cohesion with the EU's Strategy with Africa as well as the Partnerships for African Vaccine Manufacturing (PAVM).

Led by DG INTPA, this initiative aims to create an enabling environment for local production in Africa in three dimensions: incentivising and derisking investments in local pharmaceutical and biotech companies; consolidating local markets; and strengthening regulatory frameworks to address substandard or falsified products and boost trust in local products. The initiative is designed to contribute to the African Union's goal of

producing 60 % of its vaccines by 2040. The initiative has entailed concrete results at both regional and country level. At regional level, the EU funding has supported the newly established African Medicines Agency and the WHO mRNA technology transfer hub, as well as the governance and programmes of the Partnership for African Vaccine Manufacturing (PAVM). At national level, Egypt, Ghana, Nigeria, Rwanda, Senegal and South Africa have received support packages to increase their vaccine manufacturing capacity, strengthen their medicines' regulatory framework and create an ecosystem for investment in local manufacturing[8]. This selective approach to allocating funding support to a number of countries is explained by their relatively high potential to expand manufacturing[9].

Reportedly, HERA has provided technical and scientific expertise and advice for DG INTPA to identify and prioritise investment opportunities and projects under TEI MAV+. In 2024, HERA also plans to support the logistical operations for MCMs in Africa. This close cooperation also aligns with the Communication Introducing HERA, which tasks HERA with 'contributing to supporting low- and middle-income countries' manufacturing and distribution capacities, building on the current experience in Africa under the Team Europe Initiative for manufacturing of vaccines, medicines, and health technologies'.

The budget of MAV+ was announced in May 2021 with an initial amount of EUR 1 billion, backing from the EU budget and the European Investment Bank, and complemented by EU Member States' contributions. HERA does not contribute directly with EU4Health budget to the MAV+ initiative.

HERA's role: advisory support, support for logistical operations

Partners:

o Commission services: e.g. INTPA, DG GROW, EEAS, EMA, EIB, EDFIs, EU MS

o WHO, Gates Foundation, EDCTP

o African Union Commission, Africa CDC, African Union Development Agency, African Medicines Agency (AMA), WHO's mRNA technology transfer hub, African governments and national regulatory agencies, e.g. Egypt, Ghana, Senegal, Nigeria, Rwanda, Senegal and South Africa

[8] https://international-partnerships.ec.europa.eu/policies/team-europe-initiatives/team-europe-initiative-manufacturing-and-access-vaccines-medicines-and-health-technologies-africa_en; https://capacity4dev.europa.eu/resources/team-europe-tracker/partner-countries/sub-saharan-africa/manufacturing-and-access-vaccines-medicines-and-health-technology-products-africa_en?refpage=search.

[9] https://ec.europa.eu/commission/presscorner/detail/en/fs_21_2601.

Under discussion - Support for manufacturing capacity for LMICs during preparedness time

HERA has considered the possibility of using the EU FAB to support LMICs. EU FAB is one of the flagship initiatives of HERA, under which the EU enters into agreement with manufacturing facilities to reserve production capacities in its territory in case of public health emergencies. While the principal objective of EU FAB is to ensure access to critical MCM for EU Member States, HERA's 2022 Work Plan mentioned an assessment of the possibility of using EU FAB production capacities to support LMICs during preparedness. This idea was identified as an early-stage concept when EU FAB was launched in 2023. However, it was not possible to include production capacity in LMICs in the EU FAB's scope owing to operational constraints: EU FAB facilities are working on their normal production during normal operations and there is no downtime available for LMIC operations.

HERA and its partners are currently discussing a more tailored and optimised manufacturing solution for LMIC contexts in LMIC countries.

4. DONATION AND CONTRIBUTION

Metric	2024 baseline	Remarks
Share of EU's donation of Covid-19 vaccines to COVAX	41 %	COVAX has shipped 802 million doses of vaccines to LMICs, including 328 million doses donated by Team Europe, as of 1 December 2022
HERA's share in Team Europe's total donation of mpox vaccines	37 %	HERA is committed to donate 215 000 doses to Africa CDC, out of the EU and Member States' 580 000 doses to be donated to Africa CDC. The data cut-off date is 14 November 2024.
Team Europe's share in global donation of mpox vaccines	10 %	The total number of doses available to Africa CDC by the end of 2024 is over 5.85 million, including the 580 000 doses from the EU and Member States. The data cut-off date is 6 November 2024.
EU's contribution to the Pandemic Fund	EUR 247 million	As of 28/11/2024, the EU has contributed a portion of the total amount. An additional EUR 208.32 million will be transferred in the future, bringing the total to EUR 408 million.
Number of projects funded by the Pandemic Fund	19	As of 28/11/2024
Number of recipient countries of the Pandemic Fund	37	As of 28/11/2024, recipient countries include: Antigua and Barbuda, Belize, Bhutan, Bolivia, Brazil, Burkina Faso, Cabo Verde, Cambodia, Chile, Colombia, Dominica, Ecuador, Ethiopia, Grenada, Guyana, Haiti, India, Jamaica, Kazakhstan, Kyrgyz Republic, Moldova, Mongolia, Nepal, Paraguay, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines,

		Suriname, Tajikistan, Togo, Trinidad and Tobago, Turkmenistan, Uruguay, Uzbekistan, West Bank and Gaza, Yemen, Zambia

Donations and contributions of resources play a crucial role in supporting public health initiatives and medical research, as well as in fostering partnerships and mutual engagement. They not only provide essential financial support, actions and treatments aimed at preventing, mitigating, or responding to health threats, but also strengthen collaborative efforts between various stakeholders, including governmental agencies, international organisations and the private sector.

Since its establishment, HERA has been contributing to various initiatives, playing a role in implementing the 'global health architecture' (Gostin et al., 2023). These efforts are part of an ongoing attempt to expand its areas of interaction with neighbouring countries, such as Ukraine, and globally, particularly targeting LMICs. LMICs, in fact, often require tailored strategies to address public health emergencies, as they often face specific challenges such as export bans during pandemics. Ensuring access to MCMs in these contexts demands effective interventions, including R&D funding, pooled procurement, stockpiling, intellectual property transfer, and demand forecasting (UNICEF, 2023).

HERA's donations and contributions can be grouped into two main categories, based on the type of support provided: medical countermeasures (MCMs) and funding. In both cases, these efforts have played a crucial role in addressing pressing health challenges.

Donation of medical countermeasures

HERA has supported the EU's and Member States' donation of MCMs to both LMICs-mainly in Africa[10], and neighbouring countries such as Ukraine, in response to various health crises.

❖ Donation of MCMs in response to mpox

An example of this support includes HERA's effort to help respond to the mpox outbreak in Africa.

HERA has been taking joint actions with DG INTPA and DG ECHO, specifically in the coordinated EU response to the mpox outbreak in Africa, through the deployment of MCMs and other health and pandemic prevention, preparedness and response interventions. Notably, the delivery of EU Member State vaccine doses to African countries was made possible through the utilisation of DG ECHO's European Humanitarian Response Capacity, under the overall coordination and steer of HERA with Member States and international partners.

HERA has been collaborating with Bavarian Nordic to deliver over 215 000 doses of the MVA-BN vaccine to the Africa Centre for Disease Control and Prevention (Africa CDC)[11]. HERA's donation is part of the EU and its Member States' broader engagement of donating 580 000 doses to Africa CDC. This effort responds to Africa CDC's recent declaration of mpox as a Public Health Emergency and its call for 2 million vaccine doses[12]. As of 6 November 2024, Africa CDC expected to receive 5.85 million doses of mpox vaccines by the end of the year. Besides the EU and its Member States, other main donors include the US, Canada, Japan (currently the largest donor, contributing 3 million doses), Gavi and UNICEF[13].

HERA's role: vaccine donation

[10] HERA has been actively engaged in collaborative efforts to strengthen health initiatives across Africa since 2022, leading to its commitment of EUR 6 million in 'substantial support' to the African Union (AU). See: https://health.ec.europa.eu/latest-updates/team-europe-mission-hera-and-african-union-take-concrete-steps-boost-cooperation-2024-02-20_en. See also the recently signed Joint Africa CDC – European Commission Initiative on Genomic Sequencing: https://health.ec.europa.eu/latest-updates/team-europe-mission-hera-and-african-union-take-concrete-steps-boost-cooperation-2024-02-20_en.

[11] https://health.ec.europa.eu/latest-updates/mpox-hera-donate-over-215000-vaccine-doses-africa-cdc-amid-urgent-outbreak-2024-08-14_en and Procurement of vaccines for Africa Mpox outbreak (europa.eu).

[12] In this effort, the EU and its Member States committed to donate 580 000 mpox vaccines to the Africa CDC, with more than 205 000 doses already provided. Additional deliveries from other EU Member States were anticipated towards December 2024.

[13] https://africacdc.org/news-item/joint-press-release-vaccine-doses-allocated-to-9-african-countries-hardest-hit-by-mpox-surge/.

Amount: 215 000 doses of the MVA-BN vaccines in total (175 420 doses by HERA)

Partners: Bavarian Nordic, Africa CDC

❖ MCMs in response to Covid-19

HERA has also supported the EU and its Member States in donating Covid-19 vaccines through COVAX[14] and other bilateral arrangements. Team Europe (comprising the EU, its Member States, and financial institutions) was a major contributor to COVAX. By December 2022, Team Europe had shipped 328 million doses to LMICs through COVAX, contributing to the 802 million doses donated globally through this mechanism.

The COVAX programme came to a close on 31 December 2023, following WHO's declaration that Covid-19 was no longer a global health emergency. Throughout its operation, COVAX achieved several significant milestones in previous years. It is estimated to have delivered nearly 2 billion vaccine doses to 146 economies, preventing approximately 2.7 million deaths in lower-income Advance Market Commitment (AMC) countries. Its comprehensive efforts enabled these economies to achieve a two-dose vaccination rate of 57 %, compared with the global average of 67 %.

In 2024 and 2025, Gavi, the Vaccine Alliance, will continue providing Covid-19 vaccines and logistical support to low- and lower-middle-income countries, with 83 million doses already requested by 58 economies for 2024.

HERA's role: support Team Europe's vaccine contribution

Amount: 328 million doses

Partners: COVAX members

[14] Conceived as 'a historic multilateral effort co-led by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), the World Health Organization (WHO) and UNICEF from 2020 through 2023 [...], COVAX aimed to accelerate the development and manufacture of Covid-19 vaccines and to guarantee fair and equitable access for every country in the world'. See: https://www.who.int/initiatives/act-accelerator/covax.

❖ HERA's support to EU's neighbouring countries

HERA has also supported the EU's neighbouring countries, especially Ukraine, through its involvement in the 'Stand Up for Ukraine[15]' campaign. As part of this initiative, the European Commission established a system to direct in-kind donations from the private sector to Ukraine, Moldova, and neighbouring EU Member States to meet the needs of internally displaced people and refugees[16]. HERA has coordinated with the Belgian Ministry of Health, Belgian civil protection authorities, the EU Civil Protection Mechanism, and the pharmaceutical industry (including the Sanofi Foundation) to provide essential medicines and childhood vaccines for these countries. The Sanofi Foundation, in particular, contributed 200 000 childhood vaccines for Ukraine and 70 000 for Czechia, Slovakia, and Moldova[17].

HERA's role: campaign supporter

Amount: in-kind donations

Partners: Belgian Ministry of Health, Belgian civil protection authorities, the EU Civil Protection Mechanism, Sanofi Foundation

Funding and financial contributions

HERA has played a significant role in the EU Pandemic Fund, the 'first multilateral financing mechanism[18]', established in September 2022. Hosted by the World Bank with WHO as the technical lead, the Fund is guided by a consortium of donor countries, governments of potential implementing countries, foundations, and civil society organisations. In its first round of funding, WHO-awarded projects covered all six WHO regions, channelling important resources into critical areas such as laboratory capacity, disease surveillance, and health workforce development.

The European Commission has been one of the primary donors and a board member of the initiative since its establishment. HERA does not contribute directly through the

[15] https://www.globalcitizen.org/en/events-broadcasts/ukraine/.

[16] https://civil-protection-humanitarian-aid.ec.europa.eu/news-stories/news/stand-ukraine-private-sector-can-now-donate-kind-support-new-system-2022-03-29_en.

[17] http://www.czechcompete.cz/pipeline/european-commission-stand-up-for-ukraine-private-sector-can-donate-in-kind-support-vie-new-system.

[18] https://www.thepandemicfund.org/what-we-do/frequently-asked-questions.

Pandemic Fund, i.e. values given by the European Commission to the Pandemic Fund are not counted as budget consumption from HERA.

Specifically, HERA is one of the key services consulted before every board decision, including in the design of calls for funding proposals and other strategic documents such as the Fund's Strategic Plan and Investment Case. This collaborative approach to identifying priorities and targets ensures that the Pandemic Fund's investments are maximised for impact, addressing the most critical gaps in global pandemic preparedness and response. The Fund aims to strengthen pandemic prevention, preparedness, and response through critical investments, prioritising LMICs[19].

HERA's role: advisor

Amount: EUR 247 million; source: European Commission

Partners: DG INTPA, DG SANTE

[19] https://fiftrustee.worldbank.org/en/about/unit/dfi/fiftrustee/fund-detail/pppr.

5. COOPERATION AGREEMENTS AND PARTICIPATION IN INTERNATIONAL EVENTS

Metric	2024 baseline	Remarks
Cumulative number of events, conferences, meetings, missions on public health focusing on LMICs in which HERA participated	7	3 in 2024, 3 in 2023, 1 in 2022. *Non-LMICs focus: in 2023, HERA also took part in (1) an event on AMR and how to develop strategies to mitigate global health threats.*
Cumulative number of agreements signed with counterpart authorities in LMICs	2	HERA's working agreements with Africa (Africa CDC, Africa Medicines Agency). *Non-LMICs focus: in 2022: agreement with the US; in 2023: agreement with South Korea and Japan.*
Cumulative number of agreements signed with international/multilateral organisations	4	Structured cooperation with WHO, UNEP, BMGF and CEPI

Participation in international events

Participation in international fora is essential for HERA to expand the EU's global presence, build strategic partnerships, and ensure a more unified and effective approach to managing cross-border health crises. In the past few years, HERA has participated in different health events, with both an LMIC and global scope, to exchange knowledge and lessons learnt, align strategies, and contribute to shaping global health policies.

❖ Events on the resilience of health system

In December 2022 and November 2023, HERA participated respectively in the 2nd and 3rd International Conference on Public Health in Africa (CHPIA). This is an African-led forum where leaders from across the continent share insights and lessons learnt in health and science, aiming to build more resilient health systems. In 2022, HERA's Director-General presented in a panel 'Building Resilient Health Systems for future pandemics: Learning from Past Pandemics and Readiness for the Future Era', exploring 'what makes health systems truly "resilient", drawing on the experiences of national, regional and global authorities' and setting priorities to better prepare Africa's health systems (CPHIA, 2022:31). The following year, HERA represented the European Commission at the same conference.

❖ EU's delegation in Ethiopia

In February 2024, HERA strengthened its relationship with the African Union by participating in the EU's delegation to Ethiopia for the High-level dialogue to Strengthen

the Health Partnership between Africa and Europe. Building on previous collaborative efforts, the event aimed to accelerate equitable healthcare access, strengthen the EU-Africa partnership, and tackle health challenges in alignment with the priorities set by the EU Global Health strategy and the Team Europe Initiatives supporting it.

❖ A series of events on wastewater surveillance

HERA has organised and participated in several events on wastewater surveillance, particularly contributing to promote the HERA-led initiative on Global Consortium for Wastewater and Environmental Surveillance for Public Health (GLOWACON).

In October, 2023, HERA attended the Grand Challenges Annual Meeting, organised by the Gates Foundation and co-hosted by Institut Pasteur de Dakar in Senegal. On this occasion, HERA moderated a discussion on wastewater pathogen surveillance in global pandemic preparedness. During this event, HERA highlighted its commitment to expanding wastewater-based surveillance as part of a global early warning system, strengthening ties with African partners.

In addition, HERA also strengthened strategic partnerships with the Institut Pasteur de Dakar to discuss vaccine manufacturing in Africa and with WHO-AFRO on collaboration opportunities, aiming to enhance laboratory capacities and cross-border health threat preparedness in the EU and Africa.

In November 2023, HERA and the JRC launched a three-day international conference in Frankfurt am Main 'Towards a Wastewater Surveillance System for Public Health'. The event highlighted the potential of wastewater surveillance for early detection of pathogens and pandemic preparedness while addressing challenges like data sharing and collaboration. The conference has laid the ground for the establishment of GLOWACON- a global consortium to harness wastewater monitoring for improved health crisis prevention (more information about GLOWACON can be found in section 1 of this chapter)[20].

Following the establishment of GLOWACON, HERA has been organising several international conferences. The first GLOWACON 2024 Regional Conference Asia took place 24-25 June 2024 in Singapore. It focused on regional and international perspectives on wastewater and environmental surveillance, including bioinformatics, data modelling, and information sharing. It also emphasised the need for capacity development, regional research priorities, and the co-creation of collaborative projects. This event was organised in partnership with institutions from Singapore, including the Programme for Research in

[20] Conference proceedings can be found here: https://publications.jrc.ec.europa.eu/repository/bitstream/JRC137385/JRC137385_01.pdf.

Epidemic Preparedness and Response (PREPARE), the National Environmental Agency, Temasek Foundation, and the Asia Pathogen Genomics Initiative (PGI) at Duke-NUS Medical School, as well as the Gates Foundation. A second Regional Conference, held in Addis-Ababa 9-10 December 2024 and organised in collaboration with the Africa Centres for Disease Control and Prevention (Africa CDC) and WHO, has served as a platform to share insights and outline strategies for tackling key challenges in wastewater and environmental surveillance in Africa.

❖ Event on antimicrobial resistance

HERA took part in the Antimicrobial Resistance Experts Meet for In-person TATFAR Meeting in November 2023, together with other Commission's DGs (DG SANTE, DG RTD, DG ENV, and the JRC), EU agencies (ECDC, EMA, EFSA) and other national governments' representatives. Panellists discussed how to enhance collaboration to tackle shared challenges in AMR and on jointly developing strategies to mitigate urgent global public health threats.

HERA's role: event organiser, speaker and participant

Partners:

- Africa: African Union, Africa CDC, Institut Pasteur de Dakar, and other African stakeholders
- Asia: Singaporean institutions including the Programme for Research in Epidemic Preparedness and Response (PREPARE), the National Environmental Agency, Temasek Foundation and the Asia PGI at Duke-NUS Medical School
- EU bodies: Joint Research Centre
- EU Member States: German Federal Ministry of Health, the State of Hesse and its development agency, Hessen-Trade-and-Invest-GmbH
- International organisations: World Health Organisation, Gates Foundation
- Others: Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) as organiser

Cooperation agreements

Cooperation is fostered not only through active participation in international events but also by establishing formal cooperation agreements, which help strengthen partnerships and ensure sustained collaboration across various initiatives. Since 2022, HERA has signed different cooperation agreements, both bilaterally – for example, with specific non-EU countries or partners – or with LMICs' public health institutions, as in the case of the Africa CDC or the recently-created Africa Medicines Agency.

While most agreements are established with African partners, no agreements have been finalised with Asia-Pacific, Latin America and the Caribbean regions in 2024.

❖ Agreements with LMICs' public health authorities

Since 2022, HERA has been establishing cooperation agreements with LMICs' public health institutions. Among them, the Africa CDC and the African Medicines Agency. In this cooperation effort, HERA contributes to boost MCMs for infectious diseases and to enhance sequencing-based surveillance for outbreak detection in Africa. It contributes EUR 6 million to a genomic sequencing initiative, supporting projects with the African Society for Laboratory Medicine and the Africa Public Health Foundation.

HERA's role: party of the cooperation agreement

Amount: EUR 6 million

Partners: Africa CDC, African Medicines Agency

❖ Bilateral cooperation agreements with non-EU countries

In June 2022, HERA signed an administrative agreement with the U.S. Department of Health and Human Services, in order to enhance cooperation on preparedness and response to public health threats and contribute to building a robust global health framework. On this occasion, HERA undertook regular exchanges, particularly with the Administration for Strategic Preparedness and Response's (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA).

In the same year, HERA also started negotiations with South Korea and Japan to sign strategic collaboration agreements. This has led, respectively in May and October 2023, to the administrative and working arrangement with Korea's Ministry of Health and Welfare (MOHW) and the working arrangement with Japan's Agency for Medical Research and Development (AMED).

The strategic cooperation between HERA and Korea, formalised in a five-year Administrative Arrangement, aims to support the enhancement of epidemic and supply chain intelligence, the development of tools for testing, tracing, and detecting pathogens, research and production of MCMs (such as vaccines, therapeutics, and diagnostics), the stockpiling and preparedness for health emergencies, and the sharing of expertise in data science and modelling.

The working agreement with Japan, from its part, focuses on sharing research information, coordinating efforts on MCMs, and identifying joint projects, particularly on priority pathogens. The initial arrangement will last three years, with a possibility for extension.

Both HERA's agreements with South Korea and Japan aim to boost global intelligence capabilities, enhance intelligence collection, and foster cooperation on strategies for preventing, preparing for, detecting, and quickly responding to major health threats that transcend borders (HERA Report 2023: 7).

HERA's role: party of the cooperation agreement

Partners:
U.S. Department of Health and Human Services
Korea's Ministry of Health and Welfare (MOHW),
Japan's Agency for Medical Research and Development (AMED)

❖ Bilateral agreements with international partners

Since 2022, HERA has been collaborating with the Gates Foundation. The main area of collaboration has been wastewater surveillance, manifested in HERA's involvement in the BMGF Grand Challenges event.

As mentioned in section 2 of this chapter, HERA has collaborated with CEPI since 2022 on the R&D of several vaccines against emerging pathogens. In October 2023, HERA and CEPI hosted a roundtable with global health partners, including WHO and Africa CDC, to enhance collaboration on vaccine and MCMs for epidemic threats.

HERA has also established formal cooperation with different UN agencies. In December 2022, HERA signed a five-year administrative arrangement with the WHO Hub for Pandemic and Epidemic Intelligence, as discussed in section 1 of this chapter. The partnership aligns with the EU's Global Health Strategy and the commitment to achieving health-related SDGs to enhance global health security through joint efforts on MCMs. It

involves coordinated work plans and research agendas, supporting the broader EU-WHO cooperation to address cross-border health risks more effectively.

In 2023, a cooperation agreement was established with the United Nations Environment Programme (UNEP), aiming to strengthen global surveillance and response to health threats while ensuring synergy, complementarity, and alignment of priorities on an international scale.

HERA's role: party of the agreement

Partners:
Gates Foundation
CEPI
WHO Hub for Pandemic and Epidemic Intelligence
United Nations Environment Programme (UNEP)

6. GLOBAL HEALTH INSTRUMENT

Metric	2024 baseline	Remarks
Whether the Pandemic Agreement has been reached (Yes/No)	No	Some key timelines of the negotiation process: - 2/2022: first meeting of the Intergovernmental Negotiating Bodies (INB) - 6/2024: the mandate of INB was extended to finish its work as soon as possible - 5/2025 or earlier: INB to submit its final outcomes to the World Health Assembly

The Covid-19 crisis sent a strong reminder that infectious diseases have no borders, and that an effective response requires coordinated action across different countries and regions. Establishing clear commitments and protocols – for example, via a legally binding international agreement – is crucial for strengthening global preparedness, ensure rapid responses, and prevent future health crises and pandemics.

Since the outbreak of the pandemic, the EU has been working, under the WHO Constitution, on the implementation of an international instrument on pandemics and response, officially designed as the 'WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response ("WHO CA+")'.

More commonly known as the 'Pandemic Accord' or 'Pandemic Agreement', the negotiation process involves 194 Member States of WHO, various UN bodies, and other non-State actors officially affiliated with WHO.

Timeline of the negotiation of the Pandemic Accord: an ongoing process

- November 2020: the agreement was first announced by the President of the European Council, Charles Michel, at the Paris Peace Forum. If approved, it will be legally and internationally binding.
- March 2022: the World Health Assembly agreed to initiate the drafting and negotiations for this tool, with the EU Council approving negotiations.
- March 2023: WHO Member States began discussions on a preliminary 'zero draft', followed by a progress report presented by the negotiating body at the 76th World Health Assembly in May 2023.
- During the last Assembly in May 2024, it was decided to extend the negotiations for another year.
- Once WHO member countries reach a consensus, the agreement will become a legally binding part of WHO's framework.

The proposed international agreement will encourage a unified global approach that would improve preparedness and responsiveness to future pandemics, including by supporting the One Health Approach.

The objectives and principles of this agreement mainly focus on improving global surveillance, real-time data-sharing, resilient supply chains, rapid research collaboration, and ensuring equitable access to health solutions to reduce disparities. Additionally, the agreement seeks to rebuild trust in the international health system by enhancing transparency, accountability, and information reliability, with measures to combat misinformation and improve public communication.

HERA is supporting the European Commission in the negotiation process, with DG SANTE taking the lead, particularly in discussions on MCMs. Specifically, HERA contributes through written consultations and interservice meetings, providing regular feedback, comments and input into the draft negotiating text, EU's drafting proposals and position papers.

HERA's role: advisory support for the Commission

Partners: DG SANTE, WHO, other UN agencies

E. Looking ahead

HERA has affirmed its ambition to strengthen and expand its international activities. While aiming to continue its collaboration with the African nations, HERA also seeks collaboration opportunities with other regions, as mentioned in its Work Plan for 2024. Through initiatives such as GLOWACON on wastewater surveillance, HERA attempts to support early warning in Asia, Latin America and the Caribbean. The Authority is also looking to expand its engagement with Latin America and other regions to contribute both to preparedness objectives and strengthening of supply chains for critical medicines. Stronger cooperation is also planned with the Western Balkans and Ukraine to strengthen local production capacities, improve supply chains, and support preparedness and access to critical medicines. Additionally, HERA is planning to continue and expand its existing engagement with strategic partners such as Africa CDC, the US, Japan, and Korea, focusing on the ongoing implementation of cooperation arrangements signed with these entities.

HERA plans to assess and monitor its international activities in the context of the ongoing Review, in accordance with Article 8 of Commission Decision C(2021) 6712. The Review is being conducted by the Secretariat-General of the Commission. The scope of the review encompasses all activities performed by HERA, including those aimed at reinforcing the global health emergency preparedness and response architecture. This exercise is also informed through several consultation activities, including public consultation, call for evidence, targeted surveys and interviews, assessing the effectiveness, efficiency, coherence, relevance and EU added value of HERA's actions. According to HERA, while it is not possible to prejudge the outcomes of the review at this stage, the assessment may be subject to limitations, given the short review period with HERA becoming operational in 2022 and many ongoing actions.

With HERA's international dimension taking shape, it is desirable to establish more systemic and frequent monitoring and evaluation of its activities in this sphere. Currently, data about the results of HERA's international activities are mostly at operational level, i.e. the direct products or services produced by HERA's initiatives. More data about the effects of the activities at outcome and impact level would contribute to effectively measuring HERA's actions. This, in turn, can help match HERA's global actions with actual needs, identify gaps, and provide evidence to advocate for further resources and collaboration.

Finally, while HERA's role in its international initiatives has been evolving, much of its current focus remains on financial contributions and advisory support for EU bodies. Greater involvement in technical collaboration with international partners would be highly desirable. HERA-initiated actions, such as GLOWACON, its support for establishing the WHO regional emergency hub in Africa, and its technical assistance to enhance Africa's diagnosis capacity for mpox, exemplify HERA's proactive approach to strengthening preparedness and response in LMICs and globally.

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