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ANNEX

**ANNEX**

*to the*

**COMMISSION DECISION**

**on the annual work plan for 2025 of the Health Emergency Preparedness and Response  
Authority**

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## ANNEX

### HERA work plan for 2025

#### I. Introduction

This is the fourth annual work plan of the Commission's Health Emergency Preparedness and Response Authority (HERA). HERA has become well-established over the last three years, having experienced a phase of growth and structural organisation, with a focus on operational efficiency. As the new College of Commissioners has taken office, a strong and efficient HERA consolidates the health security framework and enhances the European Union's capacity to respond swiftly to crises involving medical countermeasures (MCM).

For the HERA work plan for 2025 to be put into action, the 2025 Horizon Europe and EU4Health work programmes must first be adopted. This will involve further consultation.

In 2025, HERA will continue to deliver on its mandate and advance its mission by building on the instruments set up and milestones achieved in recent years. These include joint procurement, DURABLE<sup>1</sup>, wastewater surveillance (EU-WISH<sup>2</sup> and GLOWACON<sup>3</sup>), support to innovation including through the clinical trials coordination mechanism and HERA Invest, the stockpiling of MCM and strong international partnerships. In line with its mission, the Commission will develop, under HERA's lead, and in close collaboration with other services, a new strategy to boost MCM preparedness and better support responses to public health threats by expanding on existing measures such as joint procurement, MCM stockpiling, and innovative financial instruments that can support MCM development from research to manufacturing.

Joint procurement, such as for pandemic influenza vaccines or COVID-19 therapeutics, has demonstrated its value by ensuring access to vital therapeutics and personal protective equipment (PPE). This approach will continue to enhance preparedness through long-term contractual relationships with MCM producers. The EU FAB contract<sup>4</sup>, which reserves capacity for a total of 325 million vaccine doses annually, is another crucial component in keeping the EU prepared for public health emergencies requiring substantial vaccine production.

In addition to these well-established duties, HERA will continue to provide support to DG SANTE on collaborative procurements under the Critical Medicines Act, given its experience in this area and the overlaps between critical medicines and MCMs.

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<sup>1</sup> [Home - DURABLE](#)

<sup>2</sup> [Home | EU-WISH](#)

<sup>3</sup> [EU4S](#)

<sup>4</sup> [Framework contract signed under EU4Health to guarantee a fast response to future health crises - European Commission](#)

HERA also intends to continue to engage, where needed, with the Critical Medicines Alliance, established in April 2024<sup>5</sup>, and to which HERA has been providing a Secretariat function.

Despite the EUR 1 million reduction in the EU4Health budget<sup>6</sup>, which will impact HERA's overall budget for 2025 as well as 2026 and 2027, HERA aims to continue to fulfil its core tasks even if the ambition and scope of some of its actions will need to be scaled back. It will support new projects while sustaining and expanding ongoing activities that have reinforced the EU's pandemic preparedness and response related to MCM.

For 2025, HERA remains committed to enhancing capabilities in terms of threat identification, characterisation, and intelligence gathering related to MCM, in synergy with the work of other services of the Commission and EU agencies, particularly epidemic surveillance system operated by the European Centre for Disease Prevention and Control (ECDC).

HERA plans to continue advancing the development of MCM in 2025. The regularly updated threat prioritisation process will guide HERA's support for the development of vaccines, treatments, diagnostics and other crisis-related products, with a focus on innovation of MCM for health threats posed by pathogens with pandemic potential, chemical, biological, radiological and nuclear (CBRN) threats, environmental threats and antimicrobial resistance (AMR). Funding for HERA Invest and clinical trials will be adjusted in view of the reduced EU4Health budget, impacting the scale of innovation and preparedness activities.

Ensuring rapid access to critical products during emergencies will remain a key priority in 2025. Support for the EU FAB network will continue, ensuring quick vaccine production scale-up during health emergencies, with potential expansion to other MCM.

HERA further intends to continue to support Member States in quantifying stockpiles and establishing a network of regional stockpile and distribution hubs, as well as developing and deploying new technologies for stockpile management. The actions may involve shelf-life extension of MCM. HERA plans to contribute to a new, wider EU stockpiling strategy, led by DG ECHO, covering a wider range of resources going beyond MCM to enhance the Union's preparedness<sup>7</sup>. HERA aims to implement the strategic actions outlined in the background paper for the HERA Board on a common approach to stockpiling<sup>8</sup>, such as ensuring clear procedures and a toolbox for deployment of MCM within and outside the EU, in close collaboration with the EMA.

To further strengthen preparedness, HERA's training and exercise programme will increase the capacity of public health officials to manage MCM to prepare for and respond to serious cross-border health threats<sup>9</sup>. Covering the entire management cycle of MCM – from development to distribution – the programme will incorporate workshops, e-learning, exercises and an initiative aimed at strengthening skills, improving coordination and providing policy support for EU Member States.

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<sup>5</sup> [HERA launches the Critical Medicines Alliance to tackle shortages of critical medicines - European Commission](#)

<sup>6</sup> <https://www.consilium.europa.eu/media/69866/20240201-special-euco-conclusions-mff-ukraine-en.pdf>

<sup>7</sup> Commissioner Hadja Lahbib – [Mission letter](#)

<sup>8</sup> To be found here: [Register of Commission expert groups and other similar entities \(europa.eu\)](#)

<sup>9</sup> The training programme will be aligned with the training of healthcare staff and public health staff implemented by DG SANTE under Article 11 of the Regulation (EU) on serious cross-border threats to health

In terms of emergency readiness, HERA will continue to strengthen the EU's and Member States' capacity to respond swiftly and effectively to health emergencies with the appropriate MCM, in close coordination with other Commission services and existing instruments. The emergency response protocol, which outlines HERA's process for responding to emergencies, will be refined based on lessons learned from the 2024 tabletop exercises and updated to reflect the latest developments in emergency framework governance. Additional simulation exercises will be organised in 2025, in close cooperation with DG SANTE. The response blueprint, a living document which complements the emergency response protocol by outlining measures HERA may take in any emergency, will be updated continuously.

In 2025, HERA plans to continue to prioritise strong engagement with Member States, industry, civil society and international partners through its established governance structures. Central to this effort is the HERA Board, which assists and advises the Commission in the formulation of strategic decisions and ensures close cooperation with Member States on key issues such as MCM development and preparedness. The HERA Advisory Forum and its sub-groups will continue to serve as a platform for gathering input from Member States' experts as well as industry representatives and civil society, ensuring that a broad range of perspectives is taken into consideration in the planning and execution of HERA's activities. HERA also intends to ensure that the outermost regions are considered in the implementation of its actions, ensuring equitable access to MCM and preparedness tools across all parts of the EU.

Finally, HERA aims to continue to work closely with all relevant Commission services, international health emergency authorities and partners to implement its mandate more effectively, contribute to the EU global health strategy, strengthen collaboration and exchange best practices, particularly in the areas of early threat detection and access to MCM.

## **II. Strategic orientations for crisis preparedness in the area of MCM in 2025**

As outlined in Commissioner Hadja Lahbib's mission letter, HERA will help shape a new strategy to support MCM against public health threats. This strategy intends to utilise tools such as joint procurement, stockpiling and innovative financial instruments to support the entire lifecycle of MCM, from research through to manufacturing or improving market access. The strategy will establish a framework for EU health policies related to MCM, setting policy priorities and guiding principles to enhance preparedness and identifying concrete lines of action. The work will be undertaken in cooperation with all relevant Commission services and EU agencies and special attention will be paid to a cross-sectoral approach and strengthened civil-military cooperation by including relevant EU military expertise and networks.

In addition, and in line with its establishing decision, HERA will continue to mitigate the risks of future health threats in the preparedness phase by pursuing the following core tasks:

- (1) conducting threat assessments and intelligence gathering relevant to MCM,
- (2) promoting advanced research and development of MCM and related technologies,

- (3) addressing market challenges and failures and boosting the EU's open strategic autonomy as regards MCM production and relevant critical medicines under a prioritisation exercise and a vulnerability assessment,
- (4) ensuring the provision of MCM,
- (5) strengthening knowledge and skills in preparedness and response with regard to MCM, and
- (6) strengthening HERA's international activities on MCM to contribute to improving global health security.

## **Task 1. Threat assessment and intelligence gathering**

HERA is committed to enhancing capabilities for threat identification, assessment, intelligence gathering, and strategic foresight related to MCM. In 2025, HERA aims to continue to improve health security and preparedness, by focusing on critical projects such as ATHINA, the Global Wastewater Sentinel System, the DURABLE consortium, the Epidemic Intelligence from Open Sources (EIOS) initiative and other initiatives from the WHO Hub for epidemic and pandemic intelligence (e.g. the WHO Collaboratory). These initiatives will support threat and MCM prioritisation, early threat detection and public health intelligence gathering, ultimately informing the development of MCM.

HERA aims to continue to conduct its threat prioritisation exercise, collaborating with Member States through its governance structures to identify priority areas requiring MCM. This will be supported by further mapping of relevant MCM and assessment of gaps and needs. The objective is to anticipate and inform HERA's interventions to improve innovation and access to MCM. In addition, HERA intends to continue to systematically assess emerging and ongoing health and MCM-related events to ensure timely and appropriate responses, continuing to ensure HERA's intelligence gathering function complementing that of ECDC and EMA.

The COVID-19 crisis highlighted the European Union's need for mechanisms to rapidly identify and characterise pathogens so as to then accelerate the development or update of relevant MCM, and their adequate manufacturing, procurement and distribution. HERA has made significant investments in this domain, focusing on key areas:

- *Advancing technological development and deployment of relevant intelligence gathering tools such as EIOS<sup>10</sup>, the WHO Collaboratory<sup>11</sup> and the EU4S-DEEP – Wastewater Observatory for Public Health – Digital European Exchange Platform<sup>12</sup>.*
- *Expanding sequencing capacity for routine surveillance based on genomic data analysis and outbreak investigation and wastewater surveillance capacities at EU level, while operationalising a global consortium for wastewater and environmental surveillance to ensure the long-term sustainability of these critical public health monitoring activities.*
- *Pioneering new approaches of coupling threat characterisation with MCM innovation through the interdisciplinary and pathogen-agnostic lab network DURABLE.*

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<sup>10</sup> [The Epidemic Intelligence from Open Sources Initiative \(who.int\)](https://www.who.int/epidemic-intelligence)

<sup>11</sup> [Collaboratory \(who.int\)](https://www.who.int/collaboratory)

<sup>12</sup> [EU4S \(europa.eu\)](https://europa.eu/eu4s)

- *Prioritising threats and conducting assessments in relation to MCM, thus informing MCM prioritisation.*
- *Conducting studies to support intelligence gathering on health threats and MCM.*

**ATHINA** is HERA's IT system designed to collect intelligence on health threats requiring MCM and on vulnerabilities in the supply of MCM. It is currently developing a minimum viable product, including a secure surveying module with dashboard on the survey data, and a case management and collaboration module with the first functionalities. ATHINA builds on previous systems like the mapping platform for COVID-19 therapeutics. A comprehensive gap analysis was undertaken, to study which existing systems could be reused or used alongside ATHINA. Future expansion will be based on ongoing assessments of HERA's needs, determining additional modules to be developed from 2025. Due to budgetary constraints, the speed of development and the number of modules planned for ATHINA's initial modular extension will need to be reassessed (these include modules on threat assessment, emergency response, and simulation and analytics). ATHINA's design emphasises interoperability with data sources, where relevant, from DG SANTE, DG ECHO, ECDC and EMA, and with existing commercial data sources, to ensure that the information needed to support HERA's mandate is effectively collected, exchanged and analysed.

Therefore, the next project phase will continue to involve intense collaboration with ECDC, EMA, JRC, DG SANTE and DG ECHO to ensure efficient interoperability and avoid data collection duplication. HERA plans to continue to support the interoperability of Member States' databases with ATHINA through the EU-HIP project (EU interoperability with HERA's IT platform), which started in January 2023 and will continue until mid-2025. This project includes a landscape analysis to map and analyse Member States' digital infrastructures and systems, key actor and stakeholder networks, and relevant legislative aspects to identify best practices and lessons learned. ATHINA will adhere to applicable standards and regulations on data transmission and processing to achieve interoperability, addressing the legal and technical requirements for data sharing between different entities. HERA is working closely with EMA to avoid duplication in data collection efforts and ensure that work under the European Shortages Monitoring Platform (ESMP) and ATHINA complements each other.

**HERA Ontology:** to ensure interoperability on organisational level and on information system level (ATHINA), HERA is developing an ontology. As the HERA ontology includes concepts from the Health domain and cross-sectorial Crisis domain, it is co-developed with JRC and including relevant stakeholders such as SG, DIGIT, DG ECHO, DG SANTE, OP, EMA, ECDC, and WHO. Prioritisation and collaboration between stakeholders are key to obtain the goals according to the set milestones. End 2025 the HERA-JRC co-development activities aim for a first version of the ontology to showcase the facilitation of interoperability between ATHINA and the envisioned ECMP (European Crisis Management Platform) and possible other information systems through a first MVP (minimum viable product).

**Epidemic Intelligence from Open Sources (EIOS)** is an important tool that supports early warning systems. It is used by various Commission departments and agencies, particularly ECDC, for epidemic intelligence. HERA has contributed to the development of EIOS functionalities since 2023 to improve performance and to extend the system to include early warning systems for MCM. The work on EIOS will continue under the new administrative

agreement signed with JRC end of 2024, and a renewed support will be provided to WHO under EU4Health 2025 to ensure further improvements to the system in 2025 and onwards.

HERA scaled up the EU's **sequencing capacities** through the EU4Health 2022 work programme, which included actions to increase Member States' capacity to respond to the COVID-19 pandemic and strengthen Whole Genome Sequencing and RT-PCR capacity beyond SARS-CoV-2 detection. HERA intends to continue to facilitate synergies between Member States, share best practices and provide additional support to those countries that were unable to benefit from previous programmes. In addition, it will continue to support global activities to strengthen pathogen genomic-based sequencing capacities and to promote the establishment of efficient data-sharing mechanisms and laboratory capacities, especially through grants to the Africa Centres for Disease Control and Prevention (Africa CDC) and its Pathogen Genomics Initiative (PGI) as well as Asia PGI.

In 2025, HERA plans to assess the projects launched under EU4Health that support intelligence gathering for MCM (such as Whole Genome Sequence RT-PCR, EU-WISH, EU-HIP and DURABLE) in order to determine the outcomes and ensure that the projects are either maintained or adjusted as needed. The initial outcomes of these projects are helping Member States to align functionality requirements and data-sharing elements so that they can consolidate and enhance their laboratory capacities, thus contributing to the characterisation of pathogens and identification of MCM. Successful completion of the projects will increase the EU's capacity to investigate outbreaks, collect data necessary for MCM update and development and ultimately better respond to future health crises.

**Wastewater surveillance** is a valuable tool for detecting and monitoring health threats in a true One Health approach. Effective collaboration across sectors is essential and this is also ensured within the Commission, particularly with DG SANTE, DG ENV, and the JRC, as well as with key agencies, notably the ECDC. In this context, HERA has funded various actions to support capacity building, establish common tools and institutionalise wastewater surveillance practices. The joint action EU-WISH will continue to support Member States in advancing wastewater surveillance while ensuring synergies with global wastewater surveillance activities led by HERA, in close collaboration with the JRC. This includes conducting tests at airports and on aircraft, as well as maintaining and expanding GLOWACON, the global consortium for wastewater and environmental surveillance for public health.

**DURABLE**, the consortium of first-class laboratories, is funded until 2026 (EUR 25 million for four years). The network will continue to be the EU's insurance against pathogen X and will continue to support Member States and the European Union in addressing MCM characterisation and innovation. Since its inception, DURABLE has supported outbreak investigations in the EU and abroad relevant to MCM deployment, procurement and innovation for high-priority pathogens such as avian influenza and mpox. For instance, the consortium has played a key role in the characterisation of the newly emerging mpox new clade Ib and developing the PCR assay used for surveillance in Burundi after cross-border spread occurred.

It has also carried out immunogenicity studies against the zoonotic influenza vaccines which support HERA and Member States to assess the breadth of the immunity generated by the zoonotic vaccine and create a valuable pool of sera to be tested in the future against new viruses. In 2025, DURABLE will maintain ever-warm facilities for rapid, deep pathogen characterisation of emerging cross-border health threats and innovation of relevant MCM.

## Task 2. Advanced research and development of MCM

HERA aims to focus on advancing MCM by stepping up its horizon scanning and supporting development of vaccines, therapeutics, PPE and diagnostics. HERA intends to update its research and development agenda based on threat assessments and prioritise innovation for MCM addressing pathogens with pandemic potential, climate-related diseases, CBRN and antimicrobial resistance. HERA also aims to support innovative funding mechanisms, contributing to an all-encompassing approach to R&D activities in the field of MCM.

To leverage on all available possibilities to fund MCM related projects, HERA contributes to the Strategic Technologies for Europe Platform (STEP)<sup>13</sup> Regulation<sup>14</sup>, by designing actions that are STEP eligible. In this way STEP seal could be relevant for actions targeting late-stage SME life sciences/biotech companies that bring an innovative cutting-edge element with significant economic potential to the Single Market and/or contribute to reduce or prevent strategic dependencies of the EU. Until now a few actions under the EU4Health 2024 programme have already been identified as STEP eligible. HERA will seek to expand the range of actions which would be STEP eligible in 2025, including HERA Invest, and procurements targeting MCM innovation.

The regularly updated threat assessment drives HERA's support for the development of MCM such as vaccines, treatments, diagnostics and other crisis-related products. A process for pipeline analysis of MCM in the development phase is being established in order to: (i) identify promising candidates in a more structured and efficient way so that they may be prioritised; (ii) decide whether these countermeasures should be supported in the coming years to address unmet needs; and (iii) develop MCM that will be crucial in the next emergency. While several actions are conducted under Horizon Europe, other actions supporting advanced research and development of MCM are funded under EU4Health. Given the reduced budget, HERA's ambitious innovation targets will need to be reassessed.

HERA strives to continue to support innovation in the field of antimicrobial resistance (AMR) MCM to bring to market suitable products that can contribute to the fight against AMR. HERA aims to support research on innovative antimicrobials, helping to bring them closer to the market. Through its support of e.g. translational research, HERA's action is expected to ensure that there are more antibiotics available for clinical development. HERA aims to continue to support the Global Antibiotic Research & Development Partnership (GARDP) and, in addition, a new collaboration with KfW, one of the world's leading promotional banks, and the CARB-X partnership (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) will be established by providing push funding for the clinical development of new MCM and by promoting sustainable access to treatments for drug resistant infections posing the greatest threat to health. This will be done while promoting responsible use and affordability. Furthermore, HERA intends to continue to assist WHO in identifying priority pathogens and performing pipeline analyses for AMR MCM facilitating the establishment of priorities for R&D. Additionally, HERA aims to continue to support WHO and GARDP in their joint effort to ensure access to essential antibiotics.

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<sup>13</sup> [Strategic Technologies for Europe Platform - European Union \(STEP\)](#)

<sup>14</sup> [Regulation - EU - 2024/795 - EN - EUR-Lex](#)



HERA aims to work with DG RTD and DG SANTE on the launch of the Horizon Europe co-funded ‘European Partnership One Health Antimicrobial Resistance’. The partnership should facilitate the coordination and alignment of research and innovation activities and funding among countries in the EU and beyond and help to ensure consistency between the different national services/ministries responsible for the various aspects of AMR and the sectors involved.

HERA intends to further explore the potential of phage therapy, an innovative approach to addressing antibiotic resistance by using bacteriophages, viruses that can target and kill bacteria. HERA aims to work with DG RTD to fund clinical trials for phage therapy, in order to confirm the efficacy of this approach, and work with global partners, including WHO and the members of the Transatlantic Task Force for AMR (TATFAR) to address global challenge in research, development and regulatory pathways for these biological therapeutics.

In close collaboration with DG INTPA, HERA plans to help set up the secretariat for the G7 Development Finance Institutions’ MCM Surge Financing Initiative. The aim of this initiative is to establish a rapidly deployable financing mechanism during health emergencies to enhance the timely procurement, production and distribution of critical MCM, especially in low- and middle-income countries. The initial pilot phase will focus on Africa as well as Latin America and the Caribbean. Working with DG SANTE, HERA aims to contribute to implementing a key commitment made by global leaders in the political declaration of the 79<sup>th</sup> United Nations General Assembly High-Level Meeting on Antimicrobial Resistance. This commitment calls for the establishment of an independent panel to provide evidence for action. The Commission has pledged to fund the creation and operation of this panel through the Quadripartite<sup>15</sup> cooperation on AMR, with EUR 2.5 million allocated in 2025, of which EUR 2 million will be earmarked for HERA actions under the EU4Health programme, supported by other actions (EUR 0.5 million by DG SANTE actions).

As regards MCM and in collaboration with other Commission services, HERA is exploring ways to leverage the power of artificial intelligence (AI) to enhance its capabilities in pandemic preparedness and response by improving the speed and efficiency of its strategies against potential health threats. In addition to a research and innovation call topic in the Horizon Europe work programme for 2025, policy actions to adopt AI-supported technologies will be considered across fields such as early detection of emerging pathogens (in collaboration with DG SANTE and ECDC initiatives on AI for epidemic intelligence), MCM development and decision making, supply and demand monitoring, biosecurity, metagenomics. The studies are being conducted to investigate and evaluate the most promising AI practices and possible measures guiding these initiatives (results to be available by the middle of 2025).

As part of HERA’s efforts to ensure pandemic preparedness, HERA Invest aims to de-risk highly innovative MCM that do not attract private investment, with EUR 110 million allocated to this project since 2023. A budget of EUR 20 million is planned to be earmarked for 2025 to reinforce the action Regulation<sup>16</sup>. This initiative aims to mitigate market failures leading to

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<sup>15</sup> The [Quadripartite](#) cooperation on AMR draws on the core mandates of the Food and Agriculture Organization (FAO), the United Nations Environment Programme (UNEP), the World Health Organization (WHO) and the World Organisation for Animal Health (WOAH) to support the global response to AMR across the One Health spectrum.

<sup>16</sup> [Regulation - EU - 2024/795 - EN - EUR-Lex](#)

sub-optimal investments in MCM by prioritising projects that develop and manufacture preventive, treatment or diagnostic measures for a specific group of pathogens.

HERA plans to continue to support late-stage development and uptake of innovative medical technologies, including bringing improved diagnostic platforms to the EU market, in order to be prepared for or respond to emerging health threats. Supported by the collaboration established with BARDA in 2023, HERA is planning to implement the metagenomics action aimed at developing a respiratory pathogens' agnostic device. Additionally, a workshop on metagenomics and next-generation sequencing is planned for Q2-2025, bringing industry leaders, innovators and regulators together to discuss the future of diagnostics.

HERA plans to support clinical research and innovation by leveraging the newly established HERA Board sub-group on clinical trials coordination (Clinical Trial Coordination Mechanism). The group has been tasked with providing advice/opinions on clinical studies and their funding with a view to prioritising the most promising/appropriate medicinal products and clinical studies so that they may be implemented in the EU for an optimal preparedness and response to public health emergencies. In 2025, HERA, together with DG RTD as co-chair of the group, and in close collaboration with EMA, will work to take the necessary steps to enable the sub-group to meet its objectives. This will include drawing up a roadmap to coordinate its activities. The work of the sub-group is related to non-regulatory aspects, while the ACT-EU<sup>17</sup> initiative is developing options for regulatory flexibilities to support the initiation and authorisation of clinical trials in the context of a public health emergency within the legal framework of the Clinical Trial Regulation<sup>18</sup>. It should be noted that funding for novel MCM, especially in the clinical trials phase, will need to be decreased due to the budget cut and priorities will need to be identified to ensure an adequate level of financing that does not jeopardise investments.

Pathogens with pandemic potential pose a significant threat to global health and security and remain a high priority for HERA. Their rapid evolution, increased risk of emergence and potential for antimicrobial resistance challenge the development of effective MCM. This threat is exacerbated by the potential for rapid transmission through air, water, food and human contact, coupled with the lack of effective vaccines, therapeutics and diagnostics for many diseases. Addressing this requires a coordinated and proactive approach to research, development and deployment of novel MCM. Efforts include improving collaborative surveillance, diagnostics and outbreak response capabilities in MCM, and accelerating the development of vaccines, therapeutics and broad-spectrum antivirals to enhance preparedness for future pandemics.

Climate change also poses significant challenges to public health, notably through the alteration of environments that foster the spread of vector-borne diseases. Rising temperatures, changing precipitation patterns and increased humidity have created more hospitable conditions for the breeding and proliferation of invasive mosquito populations across Europe. These changes have facilitated the northward and upward migration of species such as *Aedes albopictus* and *Aedes aegypti*, known carriers of dengue, Zika and chikungunya viruses. As these invasive species establish themselves more broadly within EU borders, the risk of outbreaks of these diseases increases, necessitating a robust and proactive response. The European Union recognises the urgent need to boost the capabilities of Member States to monitor and control

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<sup>17</sup> Accelerating Clinical Trials in the EU

<sup>18</sup> [Regulation \(EU\) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC](#)

these vector populations effectively. Yet, in most cases, effective MCM to respond to these diseases are scarce or yet to be developed. Through EU4Health, HERA is supporting the development of more specific and sensitive diagnostic methods and aims to enhance the availability of diagnostics as a critical preparedness measure, enabling early detection of these diseases at their onset, as well as supporting the scale up of Member States national vector surveillance and control programs. This joint action will be developed in close collaboration with ECDC and DG SANTE, taking account ongoing or foreseen actions (e.g. vectors assessment and control actions). Finally, HERA is also taking a proactive approach, supporting the development of first antivirals for dengue to prepare for future infectious disease outbreaks.

Ensuring the EU's security in the face of chemical, biological, radiological and nuclear threats is central to HERA's mission. Changes in the geopolitical landscape, especially Russia's war of aggression against Ukraine and disinformation linked to its biolabs, coupled with increased access to online tutorials and materials on producing CBRN agents, highlight the risks in this space. Advances in synthetic biology and AI are outpacing current regulations and safety protocols, heightening the potential for misuse of these technologies. The Niinistö Report<sup>19</sup> underscores the importance of addressing these developments, emphasising that the EU's security framework must evolve rapidly to counter the rising risks associated with hybrid threats and the misuse of emerging technologies. These factors collectively make the EU more vulnerable to CBRN threats. There is a clear need to assess risks, and to develop early warning systems, guardrails for emerging technologies and MCM for better preparedness and response. To address part of those challenges, through EU4Health, HERA intends to support the development of innovative MCM against CBRN threats, focusing on current gaps in MCM development and addressing emerging threats, including those at the intersection of AI and life sciences. HERA also plans to support relevant Horizon Europe projects in enhancing efforts to prevent and prepare for CBRN threats. HERA intends to invest in improving disaster risk management, in tools for first responders and in societal resilience and in enhancing protection against crime and terrorism.

### **Task 3. Addressing market challenges and boosting the EU's open strategic autonomy**

HERA aims to continue its actions to secure access to and ensure equitable distribution of MCM, in cooperation with other Commission services.

The Critical Medicines Alliance, a consultative mechanism established in 2024, includes the Member States, national authorities, industry, civil society representatives and EU agencies. It aims to identify obstacles to and prerequisites for strengthening EU supply chains for critical medicines. As the work on critical medicines is now under the responsibility of DG SANTE, HERA will continue to support the work of DG SANTE on collaborative procurements. On 28 February 2025, the Alliance published its strategic report<sup>20</sup> with recommendations for policymakers and supply chain actors.

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<sup>19</sup> [Safer together: A path towards a fully prepared Union - European Commission](#)

<sup>20</sup> [https://health.ec.europa.eu/document/download/3da9dfc0-c5e0-4583-a0f1-1652c7c18c3c\\_en?filename=hera\\_cma\\_strat-report\\_en.pdf](https://health.ec.europa.eu/document/download/3da9dfc0-c5e0-4583-a0f1-1652c7c18c3c_en?filename=hera_cma_strat-report_en.pdf)

In this context, and as a part of its core mandate, HERA aims to explore the industrial policy aspects of strengthening the existing manufacturing base of MCM, working towards strategic autonomy and resilience. This will include examining conditions for the scaling-up or modernisation of manufacturing facilities and introducing innovations in new industrial practices to improve production and security of supply. HERA aims to also look at the robustness and vulnerabilities of the supply chain of certain MCM, such as personal protective equipment.

Building on the work of the Alliance, HERA aims to also identify manufacturing technologies and vaccine innovations that address identified technology gaps. HERA plans to collaborate and communicate with organisations and stakeholders as part of this technology watch, and projects identified will be considered for potential future funding opportunities.

HERA intends to continue to engage with industry through the Joint Industrial Cooperation Forum, to (i) identify and, where possible, reduce supply chain issues within and outside the EU, including market failures and supply chain bottlenecks that could limit the production of critical MCM and their raw materials, and (ii) ensure that the industrial perspective is considered and included in actions aimed at securing access to critical MCM. In addition, it will foster networking and business relationships through the HERA Industry Days, dedicated to MCM, which will be organised in 2025.

To further strengthen the dialogue with stakeholders, HERA established a stakeholders' platform in 2024. The platform will be fully operational in 2025 and will provide an eco-system for stakeholders to work with HERA on different levels, for example by supporting the creation of new industrial partnerships, providing a confidential space to exchange views with the Commission, including the Joint Industrial Cooperation Forum network. In 2025, HERA plans to organise information webinars to encourage the use of the platform and participation in the matchmaking functionalities offered by the platform.

Finally, based on the lessons learnt from the initiative carried out in 2024, HERA aims to explore the design of a possible multi-country revenue guarantee scheme to improve access to recently authorised antibiotics in the EU.

#### **Task 4. Ensuring the provision of MCM**

Ensuring rapid access to critical products during emergencies will remain a key priority in 2025. Support for the EU FAB network of 'ever-warm' vaccine production facilities helps maintain sufficient manufacturing capabilities for mRNA, viral vector and protein-based vaccines. These capacities can be activated quickly during a public health emergency to speed up the process of manufacturing scale-up. EU FAB framework contracts will continue in 2025 and run until 2027. HERA intends to investigate the potential for expanding the EU FAB concept beyond vaccines to also cover PPE, reagents and possibly medicines. In partnership with EU FAB contractors, HERA also intends to take steps to improve the readiness of the manufacturing network. This will include outreach to EMA, with particular focus on technology transfer and incorporating lessons learned from COVID-19 vaccine development into the EU FAB project.

HERA aims to help Member States, to ensure proper quantification of health-related stockpiles and, in cooperation with DG ECHO, implement a network of regional stockpile and distribution hubs and assist with the development and rollout of new technologies for stockpile management. By making use of mechanisms and tools available, such as strategic reserve ‘rescEU’ under the Union Civil Protection Mechanism and the ReliefEU capacities (former European Humanitarian Response Capacity), HERA aims to support the provision of effective logistics and transport capabilities to ensure that MCM can be promptly delivered to Member States or elsewhere when needed, to meet the needs of an emergency response in full compliance with national and international regulations.

The Commission presented a background paper on the common strategic approach to stockpiling to the HERA Board in September 2024<sup>21</sup> with implementing key actions to improve preparedness through stockpiling for the next three years. In 2025, HERA plans to work closely with Member States and other Commission services to address challenges in stockpiling management, such as product shelf-life, legal status, marketing authorisation, waste and deployment..

The 2024 EU4Health Joint Action on stockpiling (EUR 10 million) will be the main vehicle for implementing the actions outlined in the common strategic approach and will support increased collaboration between Member States.

HERA also plans to continue working with EU Member States to determine the quantities of MCM needed to address cross-border health threats, in particular chemical, biological, radiological and nuclear threats. HERA held an introductory meeting with Member State authorities responsible for deciding the quantities of MCM in February 2024. Based on their recommendations, HERA plans to organise secured, confidential meetings to further discuss selected threats and procurement strategies for MCM, taking into account existing stockpiles under rescEU. The goal is to enhance the EU’s preparedness and to be able to appropriately prioritise and scale MCM. While some funding is available for the MCM development, other funding, such as funding for HERA stockpiling, is currently depleted. If funding does become available, this effort to determine the required MCM quantities should be prioritised. By the end of 2025, HERA aims to have files on 10 different threats, including corresponding pipeline reviews, developed in close collaboration with the Member States.

The EU budget could be implemented by HERA through different mechanisms, including procurement and grants. The use of various procurement possibilities will depend on the circumstances. Notably, while the joint procurement of MCM under Regulation (EU) 2022/2371 is possible during preparedness and response times, central procurement pursuant to Regulation (EU) 2022/2372 will for instance only be possible if the procurement measure has been activated (which can only be done in case of a public health emergency at EU level).

HERA also plans to support the uptake of pathogen-agnostic diagnostic tools in hospitals for sentinel surveillance, in continued cooperation with the US, where several such projects are ongoing (e.g. trials in hospitals of metagenomics sequencing devices). Efforts will continue to promote the use of next-generation PPE in hospitals and other critical settings.

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<sup>21</sup> To be found here: [Register of Commission expert groups and other similar entities \(europa.eu\)](https://ec.europa.eu/eu4health/expert-groups/).

HERA also intends to continue its role on procurements of MCM for countries that participate in the Joint Procurement Agreement. The joint procurement mechanism is designed to ensure preparedness, security of supply and equitable access to MCM, through flexible contracts aiming to achieve favourable contractual conditions. In that context, if a need is identified and countries express their interest, the Commission could launch a joint procurement procedure.

In response to recommendations from the European Court of Auditors, HERA aims to finalise guidelines on crisis procurement in 2025.

HERA also intends to continue its work on a dynamic purchasing system for PPE. Recognising the legal and operational challenges linked to the sharing of MCM, HERA, with the support of Member States, will continue developing a toolbox of policy, legal and operational guidance to facilitate this through mechanisms such as donations, loans, swaps or resales between the Commission, Member States and non-EU countries while taking into consideration existing protocols within the Commission.

## **Task 5. Strengthening knowledge and skills**

HERA's training and exercise programme aims to improve the capacity of public health officials to prepare and respond to cross-border health threats by ensuring the availability and accessibility of MCM. This programme will be built around the entire management cycle of MCM, from development to distribution. The programme will build on established best practices, offering workshops, e-learning, exercises and an exchange programme to strengthen skills, improve coordination and provide policy support for EU Member States.

Training and exercises will also be organised in 2025 following similar activities in 2024, based on the training needs expressed by Member States. In addition, HERA aims to start developing an expert exchange programme, supporting short-term exchanges of staff and experts from different Member States, and country visits, to encourage organisational development and improvement, facilitate mutual understanding and narrow preparedness and response capacity gaps between the Member States.

## **Task 6. International dimension**

HERA intends to continue to engage with international health emergency authorities and partners to implement its mandate more effectively with regard to MCM and contribute to the implementation of the EU's global health strategy and Global Gateway strategy, in close cooperation with other services, in particular DG SANTE, DG INTPA, DG ECHO, DG ENEST and the European External Action Service. In 2025, HERA aims to focus on stepping up its cooperation with like-minded international partners, in a Team Europe approach, and develop new and build on existing administrative arrangements to strengthen collaboration and exchange best practices in the area of MCM, particularly on early threat detection and access to MCM.

HERA, in coordination with other Commission services, aims to reinforce cooperation with EU candidate countries, potential candidate countries and neighbouring countries with regard to MCM. This includes engaging in bilateral cooperation, strengthening supply chains,

increasing wastewater surveillance capacities and supporting these countries in their EU accession talks. HERA intends to also support the Growth Plan for the Western Balkans, the Ukraine Facility and the Growth Plan for the Republic of Moldova by standing ready to assist the implementation of reform priorities related to production and diversification of supply of MCM. The recommendations of the Critical Medicines Alliance with regard to international cooperation will be, where relevant, taken into account, in HERA's work.

Working together with other Commission services, collaboration with international partners will focus on increasing access to and availability of MCM, particularly through existing administrative arrangements with the public health agencies/services in the United States, Japan, Republic of Korea and the Africa CDC.

With the Republic of Korea's Ministry of Health and Welfare, HERA intends to identify collaborative initiatives on threat assessment and stockpile management and ensure that information is regularly exchanged on research and development agendas to coordinate innovation funding. HERA aims to continue working with the Japan Agency for Medical Research and Development (AMED) on advanced research and development for MCM.

HERA plans to continue, where possible, to implement its administrative arrangement with the United States Health and Human Services Department, focusing on strategic cooperation in late-stage development of MCM, and the global availability of MCM. Close collaboration on wastewater surveillance between HERA and the US Centers for Disease Control and Prevention (US CDC) should be maintained, especially through GLOWACON. Additionally, HERA intends to collaborate with US, where possible, on challenges of the African continent, enhancing, wherever possible, the security of supply of critical medicines and access to MCM.

Collaboration with Africa CDC will continue through the administrative working arrangement between Africa CDC and the European Commission focusing on MCM as regards antimicrobial resistance, wastewater surveillance, and technical support on manufacturing and procurement. This partnership also aims to enhance genome sequencing capacities and support logistical operations for MCM in Africa under the AU Pathogens Genomic Initiative (PGI). These efforts will be further strengthened by the Africa PGI-IGS (Integrated Genomic Surveillance) and PGI-DETECT (Integrated Genomic Surveillance for Outbreak Detection) projects, which aim to scale up sequencing-based surveillance and improve laboratory network capacities for outbreak detection and response in 17 African Union countries. These initiatives should be complemented by support for global-level pathogen characterisation. In collaboration with Africa CDC and the African Society of Laboratory Medicines (ASLAM), HERA aims to continue to support Africa's effort in early detection and containment of cross border health threats. Specifically, it will support expanded access to mpox diagnostics and sequencing to enhance epidemiological and genomic interventions in countries in Africa with outbreaks through the PAMTPA initiative (Partnership to Accelerate mpox and Other Outbreaks Testing and Sequencing in Africa). HERA is also expected to take part to the 3rd AU-EU Health partnership High Level steering meeting which will take place in 2025 in an African country. It will be co-chaired by DG INTPA, Africa CDC and Belgium but will be an important milestone in the collaboration with Africa CDC and other African partners.

HERA intends to continue to engage with the European and Developing Countries Clinical Trials Partnership (Global Health EDCTP3 Joint Undertaking) where it represents the Commission jointly with DG RTD, DG SANTE, DG INTPA, DG GROW in the Governing



Board. In 2025, the Global Health EDCTP3 will fund call for proposals worth EUR 214 million on MCM for tuberculosis, malaria, neglected tropical diseases, and strengthening regional networks of excellence for epidemic preparedness between Africa and Europe.

The importance of partnerships with global health security stakeholders such as WHO, UNICEF, and GAVI was highlighted by Commission's response to the 2024 mpox outbreak in Africa, where Team Europe procured, coordinated and delivered vaccine donations, and a new action to support Africa CDC and the Africa Society for Laboratory Medicine was included in the amendment of the 2024 Work Programme (expected to be launched in Q2/2025) launched. Moving forward, HERA plans to continue to share its joint procurement experience and contribute to developing the African Pooled Procurement Mechanism.

Close collaboration with international partners will be essential for establishing an operational global sentinel system based on wastewater surveillance. Through GLOWACON, HERA is expanding its strategic partnerships with countries and stakeholders from Africa, Asia and Latin America. Strengthened collaboration with Africa CDC and Asia PGI on wastewater surveillance and genomics will contribute to expanding capacities for improved early warning systems. Regional events will also be organised in the context of GLOWACON to strengthen links among consortium members, develop synergies and build trust.

HERA aims to continue to work closely with the WHO Berlin Hub, WHO EURO, WHO AFRO and the Pan American Health Organization (PAHO) as regards MCM. Additional funding is planned to be provided to enhance global information exchanges and facilitate rapid response under EU4Health. In 2025, the contribution agreement with WHO will continue to be implemented in the form of the Health Technology Access Pool (HTAP), the successor to the COVID-19 Technology Access Pool (CTAP) in close relation with DG INTPA's work under MAV+. Launched in 2022, this initiative provides a platform for technology developers to voluntarily share intellectual property, knowledge and data, thereby accelerating technological innovation and expanding global production capacity.

Cooperation under HERA's 2022 Administrative Arrangement with the WHO Hub is also expected to be expanded, with collaboration on the development of EIOS, the WHO Collaboratory and the Market Intelligence Platform. The establishment of the Dakar Hub in Africa will further strengthen early warning systems for health threats and ensure the timely deployment of MCM.

In 2025, HERA intends to strengthen its collaboration with public health agencies/services in Latin America and the Caribbean, strengthening ties with PAHO to advance regional health security as regards MCM. This cooperation will aim to support local production capacities for active pharmaceutical ingredients and MCM, helping to address supply chain vulnerabilities. Working with Commission services, HERA also plans to explore opportunities to collaborate with PAHO's initiatives and the newly established G20 Alliance for Local and Regional Production, Innovation and Access, on early threat detection, including expanding wastewater surveillance in the region, and engage in joint efforts with the EU-Community of Latin American and Caribbean States (CELAC) to further align regional priorities on health resilience as regards MCM.



### **III. Strategic orientations for crisis response in 2025**

In the event of a public emergency within the EU, Council Regulation (EU) 2022/2372 provides for an emergency framework to be activated. Specifically, in the event of public health emergency, the Council may, upon the proposal of the Commission, to adopt a regulation activating the emergency framework and one or more of the measures laid down in that Regulation. This framework enhances coordination and allows to implement the measures necessary to ensure the sufficient and prompt availability and supply of critical MCM. In 2025, HERA intends to continue to ensure that it is fully prepared to implement the emergency framework if needed.

The working arrangements signed with EMA and ECDC establish specific methods and procedures for coordinating actions when a public health emergency is recognised within the EU. In accordance with Regulation (EU) 2022/123, which strengthens EMA's role in crisis preparedness and management of medicinal products and medical devices, EMA will routinely share information with HERA on the monitoring of these products, including supply and demand data.

In addition, HERA aims to continue to support ECDC in the assessment of national prevention, preparedness and response planning, focusing on assessing provisions related to identifying critical MCM, estimating the supply and demand of MCM, producing MCM and building strategic stockpiles<sup>22</sup>.

Measures foreseen to respond to emergencies include prioritising clinical research and potentially activating manufacturing facilities such as EU FAB. Depending on the needs and preferences of Member States, the Commission may also launch procurement procedures for MCM under the Joint Procurement Agreement or use ongoing procedures or existing contracts, such as the dynamic purchasing system for PPE. Additionally, the newly established HERA Board sub-group on clinical trials (see Task 2), co-chaired by DG RTD and set up in close collaboration with EMA, will work with EMA/Emergency Task Force (ETF) to provide advice on the most promising/adequate investigational medicinal products, on suitable clinical trials and on their funding in the context of emerging health threats.

Regarding emergency readiness, HERA strives to continue its efforts to boost the EU's and Member States' capacity to respond swiftly and effectively to health emergencies, including but not limited to the Union Civil Protection Mechanism, with appropriate MCM. HERA's emergency response protocol outlines the processes and steps to follow when HERA is responding to an emergency and a case is opened in the Emergency Office. Its goal is to enhance and optimise HERA's response. The first version of this protocol was tested during tabletop exercises with other Commission services in June 2024 and with Member States in October 2024. In 2025, the protocol will be refined based on lessons learned from these exercises and updated to connect HERA processes with the EU health governance in times of crisis, and the wider EU crisis management governance. Dedicated training activities will be organised for HERA staff to ensure a unified approach to emergency response.

The response blueprint complements the emergency response protocol by providing an overview of the measures that HERA may take in any emergency. It details various response

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<sup>22</sup> Article 8 Regulation (EU) 2022/2371

actions and assigns responsibility to specific HERA functions or units under the coordination of the Emergency Office. The response blueprint informs HERA's strategic planning and decision making on MCM during a crisis.

The blueprint consists of a generic response section and a disease-specific section covering several selected threats. Further specific response plans for chemical, biological and nuclear threats will be developed based on HERA's threat prioritisation. As a living document, the blueprint will be updated on a rolling basis.

Following the development of these threat-specific response plans and updates on governance and coordination structures (e.g. the Union prevention, preparedness and response plan set out in Article 5 of Regulation 2022/2371), HERA aims to organise simulation exercises in 2025. These exercises will test HERA's and the EU's crisis response capabilities, improving coordination, the exchange of information and solidarity among EU Member States. All relevant Commission services and agencies will be involved.

In addition, HERA plans to take part in relevant simulation exercises organised by other Commission services, by EU-funded projects and by international organisations, to test and improve preparedness for public health emergencies as part of a multi-sector approach.

## Annex – Total contributions per task in 2025

The following table shows the budget breakdown per task since HERA was set up. Figures are in euro and rounded to the nearest million. HERA's overall budget varies over time and depends on contributions from EU4Health, Horizon Europe and UCPM programmes. The figures below are indicative and including EFTA amounts, and under reservation of the financing decisions on the EU4Health and Horizon Europe covering 2025, still to be adopted. The 2022 work plan showed a total budget of EUR 1.28 billion, the 2023 work plan a total of EUR 1.27 billion, and the 2024 work plan a total of EUR 730 million. In 2025, the contributions from UCPM/rescEU have ceased, but it is expected that HERA will obtain EUR 358 million from EU4Health, and EUR 223 from Horizon Europe, bringing the total expected for the 2025 work plan to EUR 576 million.

Figures: EUR million

Work plan tasks	2022	2023	2024	2025 (provisional figures)
Task 1. Threat assessment and intelligence gathering	139	20	9	27
Task 2. Promoting advanced R&D of MCM and related technologies	306	475	482	369
Task 3. Addressing market challenges and failures, and boosting the EU's strategic autonomy	165	100	187	170
Task 4. Ensuring the provision of MCM	666	658	10	<i>pm</i>
Task 5. Strengthening knowledge and skills with regard to MCM	5	2	3	3
Task 6. International dimension	2	13	40	12