

EN

ANNEX

2024 HERA Work Plan

I. Introduction

The 2024 work plan is the third work plan¹ of the Commission's Health Emergency Preparedness and Response Authority (HERA). HERA was set up in response to the COVID-19 pandemic as the Commission service for addressing health emergencies by strengthening 'the European Union's ability to prevent, detect and respond to serious cross-border health threats by ensuring the development, manufacturing, procurement, and equitable distribution of key medical countermeasures'².

Since its establishment in September 2021, HERA has engaged with Member States and various stakeholders, including industry and civil society³, to develop activities aimed at improving preparedness and response to health threats in the area of medical countermeasures. It has also contributed significantly to strengthening the global health emergency preparedness and response architecture by collaborating with international partners.

In the two years since it was founded, **HERA has delivered the following set of medical countermeasures, structures, and tools to prepare for and respond to health emergencies:**

- Procurement of medical countermeasures: COVID-19 vaccines and mpox vaccines, including vaccines adapted to new COVID-19 variants.
- DURABLE consortium of biomedical and public health laboratories which reinforce the EU's capacity to rapidly characterise emerging pathogens with the aim of adapting and developing effective adequate medical countermeasures and improve EU access to samples and data concerning emerging pathogens in other parts of the world.
- Wastewater surveillance integration which, through the EU-WISH joint action, develops and establishes common EU strategies and capacity-building activities. The EU-level wastewater sentinel system now in development aims to improve intelligence gathering from the surrounding environment and to facilitate the process of testing wastewater samples in centralised partner laboratories to detect serious cross-border health threats.

¹ HERA work plan 2023 is available here: https://health.ec.europa.eu/system/files/2022-11/hera_2003_wp_en.pdf

² Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions 'Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union' (COM (2021) 576 final).

³ Between September 2021 and December 2023 there have been 15 meetings of the HERA Board, 6 meetings of Advisory Forum, 5 meetings of the Civil Society Forum, and 4 meetings of the Joint Industrial Cooperation Forum.

- HERA INVEST mechanism designed to attract and leverage private and public investments in innovative technologies related to medical countermeasures.
- EU FAB⁴ network of European vaccine manufacturing facilities designed to ensure that sufficient and agile manufacturing capacities for vaccines are kept operational and can be activated quickly in the event of a public health emergency.
- Stockpiles of medical countermeasures funded by HERA under the EU's rescEU capacity stockpile reserves, ensuring the EU's preparedness for future health emergencies in cooperation with DG ECHO.

Building on these achievements, HERA intends to concentrate its efforts in 2024 on **further enhancing the EU's preparedness and response capacity to health emergencies**, contributing to the resilient supply of critical medicines as announced in the 24 October 2023 Commission Communication on addressing medicines shortages in the EU.

In terms of **threat assessment and intelligence gathering**, HERA intends to **use the Global Wastewater Sentinel System and continue to develop the ATHINA system (Advance Technology for Health Intelligence and Action)**, ensuring its interoperability with other existing platforms. HERA also intends to **support Member States** in building their intelligence gathering, genome sequencing capacities and efficient biological sampling of aircrafts and airports, in collaboration with the Joint Research Centre (JRC), the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), where appropriate.

Another priority is envisaged to be to **expedite vaccine development, production and distribution** by creating dedicated libraries and accelerators.

HERA will aim to address market challenges and boost the EU's open strategic autonomy by **continuing the EU FAB framework contracts**, and by launching **a pilot action to improve green and efficient manufacturing** of medical countermeasures.

In line with the Communication on addressing medicine shortages in the EU⁵, HERA will continue to coordinate with other relevant Commission services and with EU and Member States efforts to **ensure a resilient supply of critical medicines**, mitigating supply risks and vulnerabilities. This will entail continuous enhanced monitoring of supply and demand, the development of a matchmaking platform, joint procurements and capacity reservation contracts. HERA also intends to promote a comprehensive and coordinated approach with partners and stakeholders at EU and global level to ensure security of supply in the EU, notably through the

⁴ The Network of Ever-warm Production Capacities for Vaccines and Therapeutics manufacturing (EU-FAB) aims to close the gap between manufacturing and scaling up of vaccine production in case of public health emergencies, while ensuring the capacity of the industry to produce life-saving medicines. EU FAB reserves manufacturing capacities for mRNA, vector-based and protein-based vaccines.

⁵ Communication from the Commission to the European Parliament, the Council, The European Economic and Social Committee and the Committee of the Regions - COM (2023) 672 eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023DC0672

Critical Medicines Alliance⁶. HERA will also contribute to the preparatory study paving the way for an impact assessment of the potential future legislative initiative in that area.

The Commission intends to further develop and implement the **next generation vaccines strategy**. It will also strengthen its **strategic approach on stockpiling** through a joint action and a study aiming to develop innovative, sustainable, future-proof strategies for EU stockpiling and deployment.

In terms of emergency readiness, HERA intends to develop **response blueprints and exercises to stress-test the HERA emergency response protocol**. HERA also plans to devise other **training and exercise programmes** to strengthen the knowledge and skills of public health officials with regard to medical countermeasures, thereby contributing to a more robust pharmaceutical response to cross-border health threats. HERA's training and exercise programme will focus exclusively on activities within its mandate while coordinating and pursuing synergies and complementarities with other relevant activities.

HERA will continue strengthening the global health emergency response architecture by **collaborating with EU and international partners** to develop new working arrangements and implement existing ones⁷, focusing on preventing and addressing serious cross-border health threats in the area of medical countermeasures. HERA intends to **deepen its engagement with Ukraine** and sustain its support in two key areas: firstly, in **preparedness**, which includes assessing the health needs of refugees and internally displaced persons; and secondly, in **response**, by collaborating with DG ECHO and utilizing rescEU stockpiles, as well as directly purchasing urgent items.

Finally, HERA intends to consult stakeholders on the **review of its activities** in order to optimise HERA's effectiveness and governance in the field of health crises.

II. Strategic orientations for crisis preparedness in the area of medical countermeasures in 2024

In line with its establishing decision⁸, HERA seeks to mitigate the risks of future health threats in its preparedness phase by pursuing six core tasks:

(1) conducting threat assessments and intelligence gathering relevant to medical countermeasures.

⁶ As announced in Communication COM (2023) 672, Critical Medicines Alliance will be set up by the Commission to allow national authorities, industry, civil society representatives, the Commission and EU agencies to come together to develop coordinated action at the EU level against the shortages of medicines, in compliance with the competition rules and EU's international commitments.

⁷ Administrative arrangement with the US Department of Health and Human Services, administrative arrangement with the Republic of Korea's Ministry of Health and Welfare, working arrangement with Japan's Agency for Medical Research and Development, agreement with the WHO's Pandemic Hub.

⁸ [hera_2021_decision_en_0.pdf \(europa.eu\)](#)

- (2) promoting advanced research and developing medical countermeasures and related technologies.
- (3) addressing market challenges and failures and boosting the EU's open strategic autonomy in medical countermeasures production and on relevant critical medicines under a prioritisation exercise and a vulnerability assessment.
- (4) ensuring the provision of medical countermeasures.
- (5) strengthening knowledge and skills in preparedness and response with regard to medical countermeasures and
- (6) strengthening HERA's international dimension.

Task 1. Threat assessment and intelligence gathering

To respond effectively to health threats, HERA aims to enhance capacities for threat identification and assessment, intelligence gathering, and strategic foresight as regards medical countermeasures. To this end, HERA will further develop a comprehensive intelligence system for early threat identification and effective response coordination: **ATHINA** (**'Advanced Technology for Health Intelligence and Action'**), an IT system that will ensure complementarity and interoperability with existing platforms such as those of the European Medicines Agency (EMA)⁹, the European Centre for Disease Prevention and Control (ECDC), and the Directorate-General for Civil Protection and Humanitarian Aid Operations (DG ECHO)¹⁰.

Moreover, the establishment of a **Global Wastewater Sentinel System** would bolster international surveillance and response capabilities, while foresight and horizon scanning will focus on innovative medical countermeasures technologies and clinical trial advancements. A comprehensive approach to crisis preparedness and response will involve studies analysing various threats relevant to medical countermeasures, including environmental health threats due to climate change, together with chemical, biological, radiological and nuclear (CBRN) threats, in order to devise appropriate medical countermeasures responses.

HERA intends to support Member States' sequencing capacity building and the work of the DURABLE consortium to ensure enhanced intelligence gathering relevant for the development of medical countermeasures, which will result in better preparedness and response to cross-border health threats.

Key elements of the intelligence gathering process intend to ensure that there is no duplication of work and data collection. The intelligence gathering process will build on existing tools managed by the ECDC and DG SANTE. This process will include data collection and analysis, threat

⁹ European Shortages Management Platform (ESMP) and Critical Medical Devices Shortages (CMDS) systems.

¹⁰ Common Emergency Communication and Information System (CECIS).

identification and assessment related to medical countermeasures, along with real-time information sharing among stakeholders on medical countermeasures, including Member States (e.g., through the EU-HIP project¹¹). In accordance with the working arrangements agreed with the ECDC¹², the EMA¹³ and the World Health Organization (WHO)¹⁴, HERA will share all relevant information and coordinate its activities with those organisations and relevant Commission departments in order to monitor emerging risks and inform decision-making.

ATHINA's pilot phase is planned to start in 2024. Designed to be interoperable with other platforms, ATHINA is envisaged to have four different functions making it possible to (i) collect information on health threats and medical countermeasures, (ii) assess and prioritise threats in relation to medical countermeasures, (iii) map and simulate potential scenarios and (iv) allow for an adequate medical countermeasures-related response in the event of an emergency. ATHINA would also include several horizontal features such as administration, collaboration, searching and visualisation and reporting. The first modules and features of ATHINA are expected to be available by the end of 2024, thus supporting decision-making in relation to medical countermeasures.

To allow for a phased development in the coming years, analysis of the requirements for outstanding modules are also planned take place in 2024, including for the 'simulation and analytics module' that would use cutting-edge technology to provide real-time insights into the complex networks of suppliers, distributors and manufacturers. Without mandating data collection from Member States, it would assess their demand for critical medical countermeasures, taking into account data already available from other sources, including the EMA, particularly during public health emergencies. The scope will include active pharmaceutical ingredients and intermediate ingredients/components. HERA intends to propose a structured approach for identifying issues with access, identifying possible gaps, and supporting the management of the supply networks of critical medical countermeasures, thereby facilitating the availability and accessibility of critical medical countermeasures, active pharmaceutical ingredients, intermediate ingredients/components, and raw materials.

Until the ATHINA module on analytics is ready, HERA will rely on analytics as managed services that are expected to be available in early 2024. Additionally, the Epidemic Intelligence from Open Sources (EIOS) initiative is planned to be developed further in collaboration with the JRC, the ECDC and the WHO Hub for Pandemic and Epidemic Intelligence¹⁵.

¹¹ EU-HIP project facilitates integration of national IT systems with the HERA IT platform under development, and complements existing systems for early warning and response, epidemic intelligence, public health surveillance and medical countermeasures. [EU-HIP \(ssi.dk\)](#)

¹² In line with article 3.1.2 of the HERA-ECDC working arrangements on health emergency preparedness and response in the area of medical countermeasures.

¹³ In line with article 3.2 of the HERA-EMA working arrangements on health emergency preparedness and response in the area of medical countermeasures.

¹⁴ In line with article 1.1 of the administrative arrangement between HERA and the WHO Hub for Pandemic and Epidemic Intelligence.

¹⁵ [Early detection, verification, assessment and communication \(who.int\)](#)

Building on the ongoing process to set up a global consortium for wastewater surveillance and the EU sentinel system, HERA, in collaboration with the JRC, intends to take an additional step to create a **Global Wastewater Sentinel System** – an interconnected network of sentinel systems, to facilitate the sharing of information and resources, ultimately enhancing the global capacities to identify and respond to emerging health threats.

HERA will build on its collaborations with national, European, and international partners, including the WHO and the United Nations Environment Programme (UNEP), to enhance international surveillance and response capabilities to various health threats and ensure synergies, complementarities and alignment of priorities at global level.

DURABLE, a consortium of biomedical and public health laboratories in Europe coordinated by Institut Pasteur and the Erasmus Medical Centre, was set-up to conduct experimental work on medical countermeasures development in preparedness and response phases. Building on a range of previous EU-funded research projects¹⁶, the network would continue to work with metagenomic datasets and genomics data to develop novel modelling approaches based on lab-generated data on pathogens. DURABLE complements the EU reference laboratories by leveraging highly interdisciplinary work packages and the pathogen-agnostic approach to be prepared for – and rapidly respond to – Disease X. ECDC’s role as member of the DURABLE steering board allows for clear delineation of tasks and optimal communication with existing and future EU Reference labs, thereby strengthening the European Health Union.

HERA will continue to update **its threat prioritisation and medical countermeasures prioritisation methodology**. This work will be facilitated by studies, including mapping of specific medical countermeasures, focusing on the analysis and mitigation of various threats such as environmental health threats due to climate change, CBRN threats, and novel hazards and their impact on medical countermeasures. The aim will be to identify the need for medical countermeasures preparedness and response to environmental threats.

To enhance security of supply for critical medicines and in addition to the ongoing negotiation of the revision of the pharmaceutical legislation and the regular work of the EMA, the Medicines Shortages Steering Group (MSSG) and the Single Points of Contact (SPOC), the Commission intends to build on the EU list of critical medicines established by the EMA and Member States. This list will be used in 2024 to analyse vulnerabilities in the supply chain of critical medicines, which would provide the basis for decisions on further remedial action.

Robust cooperation with Member States and stakeholders is envisaged to be secured via the establishment of the Critical Medicines Alliance, which would provide a strategic framework to promote structural support for the supply of critical medicines.

Finally, HERA intends to be actively involved in the EU Health Task Force (EUHTF), created as part of the ECDC’s extended mandate, and set to become operational in 2024. Upon request, the

¹⁶ Relevant previously funded projects include [Compare](#), [VEO](#), [MOOD](#) and [ISIDORE](#), among others.

EUHTF provides timely support to EU/EEA Member States, partner countries and international organisations in strengthening countries' emergency preparedness and response to emergencies during outbreaks of infectious diseases of unknown origin and other crises with a cascading risk of infectious disease. HERA intends to be part of the Advisory Group and also play a key role in all medical countermeasures-related activities conducted by the EUHTF.

Task 2. Advanced research and development of medical countermeasures

HERA intends to reinforce its horizon scanning and foresight capacities to proactively identify emerging innovations and technologies within the medical countermeasures field. This will contribute to a rapid adaptation and medical countermeasures response to new health threats as they arise. HERA will also strengthen multinational efforts to develop vaccines, therapeutics, personal protection equipment (PPE) and diagnostics. Additionally, HERA intends to increase financing for high-risk R&D projects through the HERA Invest initiative¹⁷ which would be strengthened with additional funding, mobilising essential resources for innovative medical countermeasures development and production.

Due to its unique position between threat intelligence and support for developing and manufacturing medical countermeasures, HERA is acquiring **a wealth of knowledge in the field of biotechnologies and biomanufacturing**. In this context, HERA will be actively involved in the EU Biotech and Biomanufacturing initiative, announced by President Von der Leyen in the 2023 State of the Union Letter of Intent.¹⁸

Building on the preparatory work conducted in the 2023 mapping and networking exercise, HERA intends to present a **vaccine strategy** in 2024. With this strategy HERA will continue to map gaps in research and manufacturing needs, prioritise funding for the next generation of vaccines, and support manufacturing capacity in the EU. Within the strategy's international dimension, HERA intends to develop a more strategic approach to donations and support manufacturing capacity in low- and middle-income countries.

Through Horizon Europe, HERA intends to support early-stage research aimed at increasing knowledge of viruses with epidemic potential and in particular a better understanding of **pathogen/host interactions** for the development of vaccines and inhibitors for the prevention of viral infection and transmission.

Via the same mechanism, HERA also aims to invest in **multi-country adaptive platform trials** for pandemic preparedness that can rapidly switch to the assessing vaccines and therapeutics for infectious diseases in the event of epidemic or pandemic health threats.

HERA will continue to be involved in the preparatory work on creation, under Horizon Europe, of the **European Partnership on Pandemic Preparedness**. This partnership is designed to

¹⁷ [HERA Invest \(europa.eu\)](https://europa.eu/HERA-Invest)

¹⁸ [State of the Union 2023 \(europa.eu\)](https://europa.eu/State-of-the-Union-2023)

enable Member States, associated countries and the Commission to rapidly and jointly support transnational research and innovation in pandemic preparedness, as well as an EU ‘ever-warm’ clinical trial site network, ready to switch rapidly to sustain clinical trials in response to a health emergency. This trial site network will enable the medical countermeasures development activities outlined below.

Close coordination will continue with the ongoing Innovative Health Initiative Joint Undertaking (IHI-JU) and the Global Health European and Developing Countries Clinical Trials Partnership 3 Joint Undertaking (GH-EDCTP3 JU), which may also contribute to, for instance, **advancement of research and innovation relevant to pandemic preparedness and response of medical countermeasures**.

Through EU4Health, HERA intends to create **the European Vaccine Development Hub** with a view to expediting the development, production, and distribution of vaccines by fostering collaboration and innovation. This decentralised hub would involve different development centres of excellence which will bundle critical knowledge and link it with ever-warm capacities for clinical trials to be created within the partnership on pandemic preparedness, in collaboration with the EU clinical trial networks. By preparing libraries of vaccines and monoclonal antibodies for priority pathogens, HERA will aim to establish a readily available arsenal of tools that can be quickly deployed during a health crisis.

Based on the list of critical medical countermeasures established in 2023 in collaboration with Member States, HERA will continue to **support the development of and access to a wide range of medical countermeasures** necessary to improve preparedness and response to serious cross-border health threats, including by supporting late-stage clinical trials, clinical investigations, and performance assessments or similar studies.

The focus will be on innovative and ‘one size fits all’ personal protective equipment (PPE), notably next-generation respiratory PPE, to ensure an adequate level of protection in the event of emergencies. HERA intends to ensure that its innovation funding makes medical countermeasures accessible by all population groups, including children.

In addition, HERA intends to contribute to the broader aim of achieving effective pandemic preparedness within a 100-day timeframe by supporting the development of rapid diagnostic tests and access to appropriate diagnostic testing in the right settings to enable rapid detection of pandemic-prone pathogens and a swift response to outbreaks.

HERA will also support the development and characterisation of broad-spectrum antivirals and relevant drug combinations.

Following on from its launch and initial investments in 2023, HERA will expand **HERA Invest**, a funding mechanism to support the development of innovative medical countermeasures. With the support of the EIB and through InvestEU, ERA Invest facilitates investments in innovative and strategic projects to develop and produce, where appropriate, medical countermeasures (e.g., diagnostics, therapeutics, vaccines and other preventive interventions) against priority cross-border health threats (i.e., pathogens with high pandemic potential, antimicrobial resistance

(AMR) and CBRN threats). In 2024, HERA intends to focus on concluding co-investment arrangements with international NGOs and other interested third-party investors to expand HERA Invest.

In 2024, building on the studies on ‘bringing more AMR medical countermeasures to the market’¹⁹ and ‘stockpiling antimicrobials and active pharmaceutical ingredients’²⁰, HERA will continue supporting the development and availability of and access to preventive, diagnostic and therapeutic **medical countermeasures for AMR**, notably through pull incentives. This would include (but would not be limited to) reserving capacities for producing or accessing targeted medical countermeasures for products with an EU-wide marketing licence and for products under development. In addition, further pull incentives will be explored, e.g., market entry rewards funded by the EU to incentivise R&D in new antibiotics.

In terms of push incentives, HERA will continue to contribute to the clinical development of **AMR** medical countermeasures by providing financial support to international bodies, notably the Global Antibiotic Research and Development Partnership (GARDP), a not-for-profit organisation that develops new treatments for drug-resistant infections posing the greatest threat to health.

In addition, HERA will collaborate with the Directorate-General for Research and Innovation (DG RTD) on the work to prepare the Horizon Europe co-fund Partnership ‘**One Health Anti-Microbial Resistance**’, to be launched in 2025. The partnership should facilitate the coordination and alignment of activities and funding among countries in the EU and beyond, as well as consistency between the different national services/ministries responsible for the various aspects of AMR and the sectors involved.

Task 3. Addressing market challenges and boosting the EU’s open strategic autonomy

HERA has several ongoing actions to secure access to and equitable distribution of medical countermeasures and improve the resilience of supply chains in the EU, including the management of COVID-19 vaccines contracts and preparing, negotiating and implementing joint procurement contracts through the Joint Procurement Agreement instrument.

With a view to improving EU’s preparedness for future pandemics, in June 2023 HERA published a **study on flexible manufacturing**²¹ to assess what action could be taken at EU level to support the agile production of medical countermeasures in the EU.

¹⁹ [Study on bringing AMR medical countermeasures to the market - Publications Office of the EU \(europa.eu\)](#)

²⁰ [HERA AMR feasibility study on stockpiling - Publications Office of the EU \(europa.eu\)](#) (phase 1) and [HERA AMR feasibility study on stockpiling - Publications Office of the EU \(europa.eu\)](#) (phase 2)

²¹ [A study assessing scientific, engineering, legal and economic considerations of flexible EU manufacturing and innovation of medical countermeasures for serious cross-border threats to health - Publications Office of the EU \(europa.eu\)](#)

Through funding from EU4Health, in June 2023 HERA signed the framework contracts for EU FAB, a network of ever-warm vaccines production facilities aimed at bolstering the EU's capacity to respond to public health emergencies. **EU FAB** helps maintain sufficient EEA 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. The framework contracts will continue in 2024 and run until 2027.

In addition, HERA will build on the flexible manufacturing study by launching a pilot action under EU4Health aimed at supporting innovation to **improve manufacturing technologies and processes for pharmaceuticals** and active pharmaceutical ingredients. The overall aim here is to enhance the EU's open strategic autonomy through improved capabilities for greener and more efficient manufacturing of medical countermeasures.

Additionally, in response to the recommendations of the European Court of Auditors in its special report on the procurement of COVID 19 vaccines published in 2022, HERA intends to produce **pandemic procurement guidelines** by the end of 2024.

HERA will also continue to **engage with industry**, including through the Critical Medicines Alliance and the twice-yearly meetings of the Joint Industrial Cooperation Forum, to discuss supply chain challenges and bottlenecks, and ensure that the industrial perspective is considered and included in actions aimed at securing access to critical medical countermeasures.

HERA also intends to establish a **matchmaking platform** in 2024, where economic operators and developers, in line with EU competition law, would be able to flag their capabilities and collaboration needs.

Furthermore, the Commission will foster networking and business relationships through the HERA Industry Days, dedicated to medical countermeasures. Finally, HERA will launch and follow up on a study of whether legislation could help offer long-term structural support to critical medicines supply.

Task 4. Ensuring the provision of medical countermeasures

Ensuring quick access to critical products in case of emergency will remain a key priority in 2024. In full cooperation with Member States, HERA will continue to build on the Communication on Addressing medicine shortages in the EU and the related **strategic approach to EU-level stockpiling of medical countermeasures** for health emergencies, including the establishment of stockpiles in coordination with the Union Civil Protection Mechanism. The strategic approach aims to coordinate and bridge gaps in EU medical countermeasures stockpiles, addressing their geographical positioning, distribution, sustainability, and market impact.

The 2022 and 2023 grant agreements involving rescEU medical and CBRN stockpiles, with a combined value of EUR 1.2 billion funded by the HERA budget, increased the EU's capacity to ensure access to medical supplies and devices for timely and efficient responses to serious cross

border health crises. rescEU stockpiles are last resort stockpiles under the EU's Civil Protection Mechanism managed by DG ECHO. The stocks also cover the three priority threats identified by HERA (pathogens with pandemic potential, AMR, and CBRN) and are hosted across several Member States to ensure appropriate geographical coverage.

To further support rescEU stockpiles, the Commission – including through HERA and with its governing bodies and the Member States – has devised a strategic approach for the EU on stockpiling medical countermeasures. Recommendations on establishing and managing national stockpiles have been developed, informing the management and sustainability of the HERA-funded rescEU medical countermeasures stockpiles and providing guidance for future EU stockpiling policy and activities.

To facilitate the implementation of the Communication on addressing medicine shortages in the EU, the Commission will develop a common strategic approach with Member States on stockpiling. In addition, HERA intends to launch a joint action in 2024 under the EU4Health programme (through direct grants to Member States) with the aim of enabling Member States to continue developing sustainable, forward-looking **national and EU stockpiling strategies**. The financing would aim to foster the sharing of best practices on innovative stockpiling solutions, evidence-based strategies, and risk-based approaches, as well as to promote networking and collaboration among Member States, enabling them to trial innovative stockpiling methods, such as virtual stockpiling arrangements and IT solutions.

By offering support for Member States to try out innovative ideas, HERA aims to enhance the overall effectiveness and resilience of the EU's health preparedness infrastructure, benefiting the health and well-being of citizens across the region. The expected results and impact of this initiative include better preparedness, more sustainable stockpiles, faster distribution, and deployment of medical countermeasures, improved collaboration among Member States, and a stronger evidence base for future stockpiling proposals.

In 2024, HERA will continue its **coordination role on procurements** of medical countermeasures for participating countries. This procurement mechanism is designed to ensure preparedness, security of supply, equitable access, flexibility and more favourable contractual conditions. In that context, if a need is identified and countries express their interest, the Commission could launch a joint procurement procedure.

HERA will also continue its work on the dynamic purchasing system for personal protective equipment. Together with DG SANTE, HERA will **consider the findings of the** evaluation report of **the Joint Procurement Agreement** and identify whether changes might be needed.

Task 5. Strengthening knowledge and skills

Building on the best practice workshops on procurement and stockpiling and other activities implemented throughout 2023, **HERA's training and exercise programme** will be fully developed and operational in 2024. In close cooperation with Member States and relevant

Commission services, HERA's training programme will contribute to ensuring that public health officials develop the necessary capacity to prepare for and respond to cross border health threats through medical countermeasures and to ensure medical countermeasures supply-chain security.

While the programme aims to focus on all aspects related to managing medical countermeasures, from development through to distribution, in 2024 priority will be given to **training related to stockpiling, response management and incentivising production** in support of current policy goals and needs. The programme is envisaged to include thematic seminars and workshops, essentially building on best practices and experience gathered by Member States and main international stakeholders. To further enhance capacity building, it would also include eLearning and train-the-trainer modules. Training initiatives will also take into account HERA's own actions, such as HERA Invest, ensuring that participants are fully aware of how it works, and its value added.

In addition, ensuring timely and equitable medical countermeasures access for all Member States and achieving solidarity among Member States is essential to save the lives of those at risk in any public health crisis. Therefore, it is essential to continuously strengthen coordination at EU level, ensure clear and swift decision-making procedures, and streamline communication processes and information sharing. This will be achieved through tabletop and simulation exercises, as described below under 'Emergency readiness'.

HERA's training programme will thus aim to enhance coordination and strengthen Member States' knowledge and skills on preparedness and crisis response related to medical countermeasures. It would also contribute to policy development and support HERA's international cooperation activities, contributing to European and global health security.

Task 6. International dimension

HERA will seek to engage with international health emergency authorities to fulfil its mandate more effectively with regard to medical countermeasures and contribute to the implementation of the EU global health strategy, in close cooperation with DG SANTE, DG INTPA, other Commission departments and the European External Action Service. In 2024, HERA will focus on enhancing cooperation with like-minded international partners, and on developing new and implementing existing administrative arrangements to further strengthen collaboration and exchange of best practices in the area of medical countermeasures, with a particular focus on the early detection of threats and on medical countermeasures availability.

HERA, in coordination with other Commission services, will also work together with the **WHO** under the agreements signed in 2022 and 2023, in particular in the area of clinical trials with WHO R&D Blueprint, AMR, including collaboration with GARDP (Global Antibiotic Research and Development Partnership) and SECURE (a new global initiative to provide access to essential antibiotics, as well as prepare and respond to pandemics), sequencing and environmental surveillance capacities with WHO AFRO (the WHO Regional Office for Africa), and enhanced data collection and exchange with the WHO AFRO Dakar Hub, the market

intelligence platform and the COVID-19 technology platform. In addition, HERA will support the WHO Operations Support and Logistics to support the expansion of the stockpiling of critical medical countermeasures in the Dakar Hub in order to ensure timely response in Africa.

In the context of the Team Europe initiative on manufacturing of and access to vaccines, medicines and other health technologies in Africa (MAV+), and of the Team Europe Initiative with Africa on sustainable Health security using a One Health approach, HERA will strengthen its collaboration with the Africa Centres for Disease Control and Prevention (**Africa CDC**) to reinforce genome sequencing capacities and will support the logistical operations for medical countermeasures in Africa. HERA will also identify areas for further collaboration in the field of intelligence gathering and access to medical countermeasures.

HERA intends to strengthen cooperation with **candidate countries, potential candidates and neighbouring countries**, continuing to engage bilaterally, increasing wastewater surveillance capacities in collaboration with DG NEAR, offering support as these countries proceed with accession talks, and supporting the New Growth Plan for the Western Balkans²² by developing strategic partnerships to enhance the security of supply of critical medicines.

Close cooperation will continue as well with **African partners**, while possible cooperation with other regions will be further explored. Key objectives in the preparedness phase are to improve surveillance/sequencing capacity, facilitate data exchange, and support sustainable production and distribution capacities for relevant medical countermeasures, so that in times of crisis African partners can rapidly identify and characterise pathogens of concern and enjoy extensive and fast medical countermeasures access. This includes work through international partnerships such as the Global Health European and Developing Countries Clinical Trials Partnership 3 Joint Undertaking²³ to advance the development of medical countermeasures for infectious diseases affecting Africa. EU4Health will provide funding support for global, regional and national initiatives in pandemic preparedness, including late-stage clinical trials of vaccines and treatments against priority health threats and enhancing sequencing capacities.

To **address medicine shortages in the EU**, HERA – in collaboration with other Commission departments - will establish a network of international partners and companies to boost the exchange of information on supply issues. It will support Team Europe initiatives to enhance production capacity and access in low- and middle-income countries (MAV+ in Africa and its sister initiative in the Latin and Caribbean region) and reinforce cooperation on prevention and preparedness. HERA will also help develop strategic partnerships with non-EU countries for the production of critical medicines, reflecting both local demand and needs at the EU and global level. This will be done in coordination with existing Team Europe Initiatives.

At **international multilateral level**, HERA will contribute to the Commission's external representation at global forums, and the Commission's collaboration with key international stakeholders, and the Commission's role as the EU's negotiator in discussions on an international

²² [Q&A Growth Plan for the Western Balkans \(europa.eu\)](#)

²³ [Global Health - EDCTP3](#)

legal instrument on pandemic prevention, preparedness and response, and as a main donor and board member of the Pandemic Fund.

III. Strategic orientations for crisis response in 2024

In the event of a public emergency at EU level, Council Regulation (EU) 2022/2372²⁴ allows for the activation of an emergency framework, enhancing coordination and empowering the Commission to implement necessary measures to ensure sufficient and prompt availability and supply of critical medical countermeasures. To ensure effective functioning during public health emergencies, work continues on the implementation of the Regulation (EU) 2022/2372.

The working arrangements signed with the EMA and the ECDC provide for specific working methods and procedures for the coordination of actions in the event of a public health emergency being recognised at EU level. In line with Regulation (EU) 2022/123 on its strengthened role in crisis preparedness and management of medicinal products and medical devices, the EMA will routinely share information on the monitoring of medicinal products and medical devices, including supply and demand data.

In line with Regulation (EU) 2022/2371 on serious cross-border threats to health, in the case of biological threats the ECDC will offer risk assessments and details on epidemiological surveillance results and countries' healthcare system capacities, while other EU agencies will be consulted individually and contribute to be a lead agency depending on the nature of the threat (ECHA for chemical threats, EEA for environmental risks, all agencies for unknown risks). In parallel, the Health Security Committee will coordinate crisis response in EU/EE countries.

Using the data collected, HERA intends to generate a comprehensive overview of required crisis-relevant medical countermeasures and the EU's ability to fulfil those needs. Together with the EMA, HERA will be responsible for monitoring the supply and demand of specific medical countermeasures during public health emergencies.

Close coordination is essential to avoid duplication and ensure swift decision-making at EU level in times of crisis, even though the focus of HERA and the EMA will differ based on their respective mandates and expertise.

While the EMA will concentrate on monitoring the supply and demand of selected authorised critical medicines and medical devices, HERA will monitor a wide range of crisis-relevant medical countermeasures, including both authorised and unauthorised medicinal products and certified and uncertified medical devices, as well as raw materials, diagnostics, and personal protective equipment. Using the information it collects, HERA plans to assess, together with other Commission departments, whether to recommend activating and implementing emergency research and innovation plans and access to emergency funding.

²⁴ Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, 6.12.2022, p. 64, ELI: <http://data.europa.eu/eli/reg/2022/2372/oj>).

Clinical research will be prioritised through the clinical research and funding coordination committee, established as part of a collaboration between the Commission and the EMA.²⁵ On the basis of the vaccine purchases, whenever applicable it will be assessed whether the Commission should activate EU FAB facilities. Depending on the needs and wishes of Member States, the Commission could also launch procurement procedures under the Joint Procurement Agreement, or use ongoing procedures or existing contracts, e.g., the dynamic purchasing system for personal protective equipment.

With regards to **emergency readiness**, HERA will continue its activities aimed at improving the EU's and Member States' ability to respond quickly and effectively to health emergencies through relevant medical countermeasures. An emergency response protocol was developed in 2023 setting out the internal steps to be taken by HERA when responding to emergencies. In addition to the HERA emergency response protocol, HERA has taken preparatory measures in order to be ready to implement the measures that could be activated under the emergency framework for medical countermeasures²⁶.

In 2024, work on the emergency response protocol will integrate how the HERA response can be articulated to take into account Member States responses to crisis and the contents of the EU Prevention, preparedness and response plan that is envisaged to be drafted in the first half of 2024. As the EU plan is complementary to national plans and is expected to promote effective synergies between Member States and the Commission, it is necessary to assess the interlinkage between the EU and national plans and then integrate the Protocol in such a way that would allow for the best possible interplay and would yield best possible results.

HERA intends to develop response blueprints to test the HERA emergency response protocol. Based on the work on scenario planning for smallpox in 2023, several scenarios will be developed addressing the main priority threats identified by HERA. These scenarios and response plans, prepared together with other Commission services, will form the basis for adapted preparedness and readiness activities to respond to health crises through targeted measures. They will also enable identification of the key stakeholders for every type of situation.

As part of these efforts and to ensure full readiness, HERA will carry out various tests. The best way to enhance coordination and capacity building between crisis-relevant bodies involved at EU and Member State level in the management of medical countermeasures and the public health response to cross border crises, is through simulations and exercises aimed at testing and improving existing preparedness and response frameworks related to medical countermeasures.

In 2024, HERA will implement at least three exercises, either internally or with other Commission departments, the EMA, the ECDC, Member States, the WHO and other potential

²⁵ [Coordinated clinical trials in public health emergencies in the EU | European Medicines Agency \(europa.eu\)](#)

²⁶ Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

international partners, in support of these objectives and in compliance with the recommendation from the Court of Auditors on testing the EU's pandemic procurement system²⁷.

IV. Addressing medicine shortages in the EU

In line with the Communication on addressing medicine shortages, adopted on 24 October 2023 and as already explained above, HERA will focus on addressing medicine shortages in the EU through a series of coordinated actions with partners and stakeholders at EU and global level, as well as developing an industrial policy agenda with all relevant stakeholders under Critical Medicines Alliance, complementing the ongoing negotiations of the revision of the pharmaceutical legislation and the work of the EMA, the MSSG and the SPOC.

These include the continuous enhanced monitoring of supply and demand, the development of a matchmaking platform, joint procurements or capacity reservation contracts. HERA will also contribute to the preparatory study paving the way for an impact assessment in the potential future legislative initiative in that area.

Building on the Union list of critical medicines, established by the EMA and Member States, HERA will analyse supply chain vulnerabilities in 2024 to guide remedial actions, including procurement with stringent delivery obligations.

HERA will further enhance Europe's capacity for producing and innovating in the field of critical medicines, including the development of broad-spectrum antivirals. Industry engagement through the Critical Medicines Alliance and the Joint Industrial Cooperation Forum will focus on identifying supply chain challenges and providing strategic recommendations on possible actions and initiatives moving forward. A matchmaking platform to facilitate collaborations in line with the EU competition law will be established in 2024, while the Commission will promote networking through annual HERA Industry Days.

The Commission will develop a common strategic approach to medicines stockpiling with Member States. A joint action under the EU4Health programme (through a direct grant to Member States) will allow Member States to continue developing sustainable, forward-looking national and EU stockpiling strategies.

Finally, HERA will establish a network of international partners to enhance information exchange on supply issues, support production in low- and middle-income countries, and develop strategic partnerships for producing critical medicines, considering both local and global needs.

Appendix I provides an overview of the planned 2024 contributions from EU4Health and Horizon Europe programmes for the implementation of HERA's activities.

Appendix II provides a detailed breakdown of activities planned for 2024.

²⁷ www.eca.europa.eu/Lists/ECADocuments/SR22_19/SR_EU_COVID_vaccine_procurement_EN.pdf

Appendix I.

Total contributions per task in 2024

A total contribution of EUR 730.55 million from the EU budget is provisionally allocated to HERA in 2024 for preparedness activities. HERA's 2024 budget provides for contributions from EU4Health (EUR 470.80 million) and Horizon Europe (EUR 259.75 million) programmes. Budget figures included in Appendices I and II are indicative only, pending the completion of negotiations and adoption of the relevant EU4Health work programme.

Work plan tasks	2022 work plan	2023 work plan	2024 provisional figures*
Task 1. Threat assessments and intelligence gathering	139.5	20	8.5
Task 2. Promoting advanced R&D of medical countermeasures and related technologies	306.08	474.75	481.75
Task 3. Addressing market challenges and failures, boosting EU strategic autonomy	165.3	100	187
Task 4. Ensuring the provision of medical countermeasures	666.5	658	10
Task 5. Strengthening knowledge and skills with regard to medical countermeasures	5	2	3.4
Task 6. International dimension	2	13	39.9

** Figures in EUR million. HERA's overall budget varies over time and depends on contributions from the EU4Health, Horizon Europe and UCPM programmes. The 2022 work plan had a total budget of EUR 1.28 billion, and the 2023 work plan a total budget of EUR 1.27 billion. In 2024, the contributions from UCPM/rescEU will cease, but there will be increased contributions from the two remaining programmes, EU4Health and Horizon Europe. According to HERA's financial statement, the best estimate for budget figures beyond 2024 is EUR 707 million in 2025, EUR 722 million in 2026, and EUR 1.06 billion in 2027.*

Appendix II.

Activities per task in 2024

Task 1. Threat assessments and intelligence gathering (EUR 8.5 million)

Objective: drawing up a list of high-impact threats requiring medical countermeasures preparedness, early detection of health events that may require a medical countermeasures response, rapid evaluation of those health events in order to identify the relevant medical countermeasures response, and continuous collection and analysis of intelligence on medical countermeasures required for rapid response

Activities funded in 2024		Budget (EUR million)
1.1	Support for the Commission in identifying priority threats and medical countermeasures	0.5 (EU4Health)
1.2	Establishment of a global wastewater sentinel system	8 (EU4Health)

Task 2. Promoting advanced R&D of medical countermeasures and related technologies (EUR 481.75 million)

Objective: promoting research and innovation to develop effective, safe and affordable medical countermeasures.

Activities funded in 2024		Budget (EUR million)
2.1	<u>Actions under Part 4. ‘Health of Horizon Europe’ of the 2023-2024 Horizon Europe work programme.</u> - Adaptive platform trials for pandemic preparedness - Maintaining a European partnership for pandemic preparedness - Host-pathogen interactions of infectious diseases with epidemic potential - European Partnership: One Health Anti-Microbial Resistance (OH AMR) - Emergency funds	103 (Horizon Europe)
2.2	<u>Actions under Part 6. ‘Civil Security for Society’ of the 2023-2024 Horizon Europe work programme</u> - Cost-effective sustainable technologies and crisis management strategies for radiological/nuclear large-scale protection of populations and infrastructures after a nuclear blast or nuclear facility incident	6 (Horizon Europe)

2.3	<u>Provisional contributions from institutionalised partnerships.</u> - Innovative Health initiative: supporting pre-competitive research and innovation for medical countermeasures for cross-border health threats - European and Developing Countries Clinical Trials Partnership (EDCTP3): support for clinical research into poverty-related infectious diseases in sub-Saharan Africa	80.75 (Horizon Europe)
2.4	Provisional European Innovation Council Accelerator Challenge on mAbs-based therapeutics for emerging pathogens	70 (Horizon Europe) Subject to EISMEA Work Programme decision)
2.5	Call for proposals to create the European vaccine development hub	102 (EU4Health)
2.6	Call for proposals for next-generation respiratory protection	20 (EU4Health)
2.7	Support to speed up the development of, access to and uptake of medical countermeasures including critical medicines	40 (EU4Health)
2.8	Support for innovation and access to antimicrobials and critical medicines	50 (EU4Health)
2.9	Purchase, innovation and deployment of medical countermeasures in emergency situations	(EU4Health) Budget will be mobilised in case of emergency
2.10	Support for the development of novel antivirals	10 (EU4Health)

Task 3. Addressing market challenges and failures and boosting the EU's open strategic autonomy (EUR 187 million)

Objective: identifying and ensuring the availability of critical technologies and production sites for medical countermeasures in the EU that can increase their production in times of need, including through support for breakthrough innovation.

Activities funded in 2024		Budget (EUR million)
3.1	Continuous support for ever-warm facilities (EU FAB) for vaccines	160 (EU4Health)
3.2	Support for innovative medical countermeasures manufacturing technologies and processes in the EU for medicines production	17 (EU4Health)
3.3	Top up for the InvestEU guarantee through a blending operation –HERA INVEST	10 (EU4Health)

**Task 4. Ensuring the provision of medical countermeasures
(EUR 10 million)**

Objective: using stockpiling and EU procurement to ensure provision of medical countermeasures

Activities funded in 2024		Budget (EUR million)
4.1	Direct grants to authorities in Member States: support for the development of sustainable, forward-looking national and EU stockpiling strategies	10 (EU4Health)
4.2	Support for purchase, innovation and deployment of medical countermeasures in emergencies	(EU4Health) Budget will be allocated in the light of emerging needs

Task 5. Strengthening knowledge and skills

(EUR 3.4 million)

Objective: improving Member States' capacities in preparedness and response related to medical countermeasures.

Activities funded in 2024		Budget (EUR million)
5.1	HERA's training and exercise programme for management of medical countermeasures	3.4 (EU4Health)

Task 6. International dimension

(EUR 39.9 million)

Objective: coordination and cooperation within and beyond Europe are necessary to build up resilience and to provide timely and appropriate responses to potential health crises in the future

Activities funded in 2024		Budget (EUR million)
6.1	Support for strategies, capacity and data for global wastewater and environmental surveillance	6.8 (EU4Health)
6.2	Support for the development of antibiotics to strengthen global preparedness and response	20 (EU4Health)
6.3	Support for implementing the diagnostics component of the 100 Days Mission ²⁸	11.6 (EU4Health)
6.4	Support for logistical operations for medical countermeasures in Africa	1.5 (EU4Health)

²⁸ The goal of the 100 Days Mission, agreed by G7 leaders in June 2021, is to prepare as much as possible for future outbreaks, so that within the first 100 days that a pandemic threat is identified, safe, effective, and affordable vaccines, diagnostics and therapeutics can be made available.