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ANNEX

2023 Annual Work Plan of the Health Emergency, Preparedness and Response
Authority (HERA)

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This document outlines HERA’s strategic orientations for 2023. Budgetary figures and related actions presented in this document remain indicative, pending the outcomes of the parallel negotiations for the 2023 work programmes of Horizon Europe, EU4Health and the Union Civil Protection Mechanism.

1. Introduction

The Health Emergency, Preparedness and Response Authority (HERA) was established on 16 September 2021 “to strengthen Europe’s ability to prevent, detect, and rapidly respond to cross-border health emergencies, by ensuring the development, manufacturing, procurement, and equitable distribution of key medical countermeasures”¹.

A first work plan, adopted in early 2022, described the actions that would contribute to HERA’s objectives throughout 2022. Important efforts were dedicated to the recruitment of staff, as well as establishing working methods and links with a broad range of stakeholders.

In 2023, building on these early achievements, HERA will be able to bring, via the relevant instruments and where relevant in cooperation with other Commission services, further Union’s support to Member States’ preparedness for pandemics and other large-scale health crisis, with focus on the availability and accessibility of medical countermeasures (MCMs). This work will in particular include five **flagship initiatives**:

- establishment of a **state-of-art IT system** for intelligence gathering, threat assessment, mapping medical countermeasures², supply chain risk management and management systems for stockpiling (**HERA MCMI platform**)³;
- ensuring the further development of medical countermeasures for epidemic and pandemic preparedness, such as **innovative vaccines**, therapeutics and diagnostics, including for COVID-19 -the **vaccine 2.0 strategy**, aiming for investments worth at least EUR 80 million-, and access to innovative medical countermeasures against antimicrobial resistance (**AMR**);
- reservation of manufacturing capabilities for vaccines in case of a new public health emergency (**EU FAB**);
- establishment of a financing mechanism⁴ referred to as the “**HERA INVEST**” for an amount of EUR 100 million, to leverage private investment for the development and production, where relevant, of a wide range of medical countermeasures;
- development of a **strategy on EU-level stockpiling** of medical countermeasures, including stockpiling of chemical, biological, radiological and nuclear (CBRN) relevant medical countermeasures and other medical items.

More specifically, in the area of **threat assessment and intelligence gathering**, HERA in collaboration with the European Centre for Disease Prevention and Control (ECDC) has initiated several projects mainly funded under the EU4Health programme to detect health threats soon after their emergence, evaluating their impacts and identifying the critical medical countermeasures needed to respond. In 2022, HERA produced a list of three preliminary threat categories (namely pathogens with high pandemic potential, CBRN threats and AMR)⁵, based on which a list of specific cross-border health threat agents and related medical countermeasure gaps will be established. This process is also reflected in the **State of Preparedness Report**⁶, scheduled for publication on 30 November 2022, which should drive a large part of HERA’s strategic agenda in 2023 and beyond.

¹ 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).

² Including authorized and unauthorized medicines, APIs, raw materials, diagnostics, devices, PPE

³ The Intelligence Gathering and Threat Assessment Medical Countermeasures Intelligence Platform (HERA MCMI platform)

⁴ Details on the pilot action will be available in the relevant action fiche within the 2023 EU4Health AWP

⁵ https://ec.europa.eu/commission/presscorner/detail/en/IP_22_4474

⁶ 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 “State of Health Preparedness Report” planned for adoption on 30 November 2022

First calls have been launched under the EU4Health programme in 2022 for the establishment of an **IT platform for intelligence gathering, threat assessment, mapping medical countermeasures and management systems for stockpiling**. An important task of 2023 will be its first deployment and operationalisation. Particular effort will go into ensuring interoperability between the HERA MCMI platform and other existing IT platforms, such as those of ECDC and the European Medicines Agency (EMA), ensuring full complementarity.

Building on the work started in 2022, also in 2023 HERA in cooperation with DG RTD will continue supporting **research and innovation** primarily within the framework of the Horizon Europe programme to develop effective, safe and affordable medical countermeasures for pathogens with high pandemic potential.

While the Union has built the most complete portfolio of COVID-19 vaccines, it is now time to address some of the existing limitations (i.e. insufficient duration of immunity, limited protection against transmission, short shelf-life etc) and look for a **new generation of vaccines** and other relevant medical countermeasures. The EU is ready to engage with developers of such promising new vaccines and additional funds will be earmarked in 2023 primarily under the Horizon Europe programme⁷ to support these developments in collaboration with international stakeholders. Moreover, following the Letter of Intent signed on 18 October 2022, HERA intends to continue supporting the **Coalition for Epidemics Preparedness Initiative (CEPI)**, from the Horizon Europe programme in close cooperation with DG RTD, focusing on late-stage development of vaccines against pathogens such as Chikungunya, Lassa fever, MERS, Nipah and Rift Valley fever. In addition, HERA will support with EU4Health funds global, regional or national initiatives on pandemic preparedness, including late-stage clinical trials for vaccines and/or treatments against priority health threats, such as Ebola.

In addition, support will be given to the development of other medical countermeasures, such as **in-vitro diagnostics** for detection and characterisation of pathogens with pandemic potential. Other actions will aim at advancing a broad-spectrum **anti-viral compounds** targeting viruses with high epidemic or pandemic potential.

HERA, in cooperation with other Commission services, will also support R&I projects on **CBRN threats**, focusing both on prevention and response.

On **AMR**, following-up on the 2022 studies, HERA will work on the priority list of resistant pathogens and a pipeline analysis for AMR medical countermeasures. Working closely with Member States, HERA aims to improve the continuity of supply by stockpiling and early identification of demand surges or supply issues. HERA will work on establishing a comprehensive EU approach, in coherence with the upcoming Council Recommendation on AMR, to incentivise development and availability of countermeasures, both at regional and international⁸ levels, in line with the initiatives on AMR under the Pharmaceutical strategy for Europe⁹. Funding will also be made available through Horizon Europe for the development of improved AMR medical countermeasures including through the One Health AMR Partnership.

The availability and accessibility of safe and effective medical countermeasures (MCM) dealing with those threats requires not only public, but also private investment. Yet, private investors hesitate to invest into assets which are highly risky and with returns that are highly uncertain (e.g. in the area of AMR or infectious diseases). In 2023 HERA intends to develop a financing mechanism referred to as the **“HERA INVEST”**, which will effectively top up the InvestEU guarantee through a blending operation

⁷https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en

⁸Such as via WHO, the Global Antibiotic Research and Development Partnership (GARDP), Expanding Sustainable Access to Antibiotics (SECURE).

⁹ 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, Pharmaceutical strategy for Europe, (COM(2020) 761 final)

in order to leverage high-risk private investment in the development and production of medical countermeasures.

The specific contracts for the reservation of manufacturing capacity in case of a future public health emergency through the **EU FAB** launched in 2022 will be signed in 2023.

Building on the experience of the call published in 2022 under rescEU¹⁰ to procure and stockpile medical countermeasures to respond to large-scale **CBRN threats** and other emergencies, in cooperation with DG ECHO, a second rescEU call will be launched in 2023. HERA will also work with relevant Commission services and Member States on the development of a strategy on EU-level stockpiling of medical countermeasures, addressing complementarity between national and EU-level stockpiles.

Finally in 2023, HERA, in cooperation with other Commission services and Union agencies (e.g. ECDC and EMA), or other organisations such as WHO, where needed, will develop a **training strategy** to strengthen Member States' knowledge and skills in preparedness and response related to medical countermeasures.

Beside actions focused on preparedness, HERA will also continue to implement response actions, supporting Member States. The establishment of HERA was a direct response to the ongoing **COVID-19** pandemic, for which HERA will continue the response and delivery of medical countermeasures. HERA's emergency response capacities have been also tested in 2022 by Russia's war of aggression against **Ukraine**, for which HERA is contributing to activities led by DG ECHO aiming to ensure access to medicines for Ukrainian refugees, including for chronic diseases and vaccines, as well as activities to monitor the spread of infectious diseases, including COVID-19, through coordination with the Joint Research Centre (JRC) on wastewater surveillance. These activities will continue as long as the emergency remains. HERA is also coordinating some actions to purchase medical countermeasures (e.g. vaccines and antivirals) in response to the **Monkeypox** outbreak.

2. Preparedness for serious cross-border threats in the area of medical countermeasures

Task 1. Threat assessments and intelligence gathering¹¹

HERA's work on threat assessments and intelligence gathering lays the foundations for the implementation of all its other tasks and is intended to complement national policies and provide support to Member States' actions. In 2022, HERA has established a list of three threats categories, (1) pathogens with high pandemic potential, (2) chemical, biological, radiological and nuclear threats originating from accidental or deliberate release, and (3) threats related to antimicrobial (multi-)drug resistance, which will be periodically updated (task 1.2, Annex II)

Building on this, in 2023 HERA's work will focus on **building intelligence on the accessibility and availability of critical medical countermeasures** related to the three health threats categories identified, while **enhancing capacity for real-time threat detection**. The planned HERA MCMI platform will aim at making use and complementing existing epidemic intelligence resources by combining intelligence on health threats (including threats other than communicable diseases, such as chemical, environmental and other threats) and on medical countermeasures. This involves considerable collaboration and interaction with ECDC (in particular regarding health threats) and EMA (regarding medical countermeasures) and other Commission services when relevant.

¹⁰ Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision N° 1313/2013/EU on a Union Civil Protection Mechanism

¹¹ In line with tasks identified in COM(2021) 576 final

The identification of health threats and of the relevant medical countermeasures requires access to large sets of data together with the capacity to interpret such data¹². Acknowledging the importance of intelligence gathering, EUR 73.5 million have been earmarked in 2022 in order to initiate the work to build the HERA MCMI platform for intelligence gathering, threat assessment, mapping medical countermeasures and management systems for stockpiling¹³.

In 2023, HERA intends to **operationalise this IT platform** and ensure that **data collected** is continuously updated, providing the capacity to anticipate the occurrence of health threats that require medical countermeasures response, as well as to assess the needs for the corresponding medical countermeasures and to manage supply chain risks. These activities will be implemented in close cooperation with other Commission services, ECDC and EMA as well as Member States and where relevant international partners, to ensure complementarity and avoid duplications. The platform will use data sources by leveraging existing IT platforms and monitoring tools of the Commission and EU agencies in several areas, such as: early detection and assessment of health threats that may require medical countermeasure response; rapid assessment of health events in order to identify the relevant medical countermeasure response; intelligence gathering on medical countermeasures, understood as the collection of relevant data and information; data comparability and alignment (e.g. data processed by the IT platform, be it health threats related (epi data) or MCMs related data); exchange of data at local, regional and international levels on serious cross-border threats to health.

The intention is to link different existing IT tools to HERA MCMI platform, based on the outcomes of the landscape review of existing platforms in the area of intelligence gathering, medical countermeasures and threat assessment. HERA intends to use data collected following the implementation of direct grants provided to Member States (via 'Strengthening Member States' IT systems ensuring interoperability with HERA MCMI platform').

In addition, HERA MCMI platform is expected to exchange with existing IT platforms, such as those of ECDC, EMA, the Union Civil Protection Mechanism (UCPM) and the Emergency Response Coordination Centre (ERCC) and other relevant stakeholders, including the WHO, ensuring complementarity and interoperability¹⁴. Aspects related to data protection will be duly taken into account. HERA intends to use only non-personal data, including non-personal electronic health data for secondary use purposes, i.e. exclusively the use of anonymised electronic health data which is devoid of any personal data. Specifically on data protection, any processing of personal data, such as when relevant for technical support or user access to the IT platform purposes, by HERA will comply with Regulation (EU) 2018/1725.

As input to **data collection** for **pathogens with high pandemic potential that require MCM response**, HERA intends to further finance projects to **strengthen surveillance infrastructures** for example by supporting national wastewater-based surveillance activities (tasks 1.3 and 1.4, annex II)¹⁵, as well as by strengthening sequencing capacities in Member States, technological development of EIOS

¹² This is both at EU and international levels, for which, for example, specific collaborations with Member States as well as the WHO Hub for Pandemic and Epidemic Preparedness have been initiated. The "One Health approach" will be duly taken into account.

¹³ These actions refer to the implementation of the planned IT tool as described in the HERA 2022 annual work plan. A call for tender under the EU4Health programme (EUR 24.5 million) is currently under preparation and will be launched in Q1 2023. The action is also listed under task 1.1, annex II of the current workplan

¹⁴ This will be achieved among others through the initial meticulous assessment of the landscape of existing EU and global systems for early warning, public health (epidemic) intelligence, surveillance and medical countermeasures in order to ensure complementarity and avoid any duplications with existing systems.

¹⁵ This includes a joint action to strengthen national capacities for pathogen prioritisation, sampling and integration of wastewater data in surveillance for public health decision making. HERA will also support an EU level sentinel system and enhance coordination with JRC. Surveillance activities are shared with other Commission services and Union agencies, such as DG SANTE and ECDC respectively, complementing for example activities carried out in the framework of the implementation of the Serious cross-border health treats Regulation. For 2023 HERA plans to expand the activities of the HERA incubator to wastewater surveillance as it was the case in 2022 for sequencing.

Platform or development of diagnostics (task 1.5, Annex II), carried out by the Joint Research Centre (JRC).

Among various actors active in the field of event-based surveillance at Union and global levels, of particular importance for HERA's work is a close cooperation with ECDC, the WHO Hub for Pandemic and Epidemic Intelligence, and EMA¹⁶.

Also, HERA, in coordination with DG SANTE and the ECDC, will establish a **network of laboratories** by the end of 2022 that can be mobilised swiftly for the **rapid detection and characterisation** of emerging pathogens. This network will have a global outreach and work in synergy with existing structures, to address emerging pathogens¹⁷

HERA will collaborate on a permanent basis with other relevant Commission services, ECDC, Member States as well as with international partners and organisations to gather information on **CBRN** threats and the related medical countermeasures. For instance, HERA will support the JRC in the technical development of the system for Epidemic Intelligence from Open Sources (EIOS) and will represent the Commission in the EIOS coordination group. Finally, HERA will gather **intelligence on AMR medical countermeasures** to promote their development and accessibility in One Health collaboration where relevant¹⁸.

Task 2. Promoting advanced R&D of medical countermeasures and related technologies

HERA will finance **R&D for the development of innovative medical countermeasures for epidemic and pandemic preparedness and response, and fostering the development of next generation vaccines (Vaccines 2.0 strategy)**. For the COVID-19 pandemic¹⁹, more than a dozen of vaccines were developed in record time, relying on different technologies. This was a major achievement and it allowed to get the COVID-19 pandemic partially under control. Under the EU Vaccine Strategy launched in July 2020, the EU built the world largest portfolio of vaccines. As the virus is constantly evolving and mutating, the EU's contracts include the possibility for the supply of safe and effective adapted vaccines. However, we should continue to look for new vaccines which can offer advantages over those currently available: for example, longer duration of protection; broader spectrums of protection against variants; efficacy against transmission; better storage and handling conditions. In December 2022, HERA will bring together experts, scientists, industry, authorities and international partners to discuss a new generation of vaccines for COVID-19, and more broadly for respiratory viruses. The event will allow to review on-going developments and assess possible actions to support and accelerate the research and development of promising candidates for new vaccines and other medical countermeasures, **through the actions described below** [aiming for investments worth at least EUR 80 million].

¹⁶ HERA is in the process of signing administrative arrangements with both ECDC, EMA and the WHO Hub for Pandemic and Epidemic intelligence, which will define working arrangements between HERA and these organisations.

¹⁷ The relevant call for proposals has been included in the amended 2021 EU4Health annual work programme ([Funding & tenders \(europa.eu\)](https://ec.europa.eu/info/life-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en)). This network will be complementary to the future EU Reference Laboratories as defined in the serious cross-border health threats Regulation. More specifically, the HERA Labs network will address emerging pathogens that may not be covered by current networks, which are dedicated to a given disease/group of diseases. The network will have a stronger global reach, and carry out emergency characterisation studies, to provide HERA with information on the severity and transmissibility of emerging pathogens, and on the efficiency of available diagnostics, vaccines and therapeutics. Importantly, the network will develop procedures to ensure it does not overlap with the work of existing or future networks. HERA and ECDC will be in their governance structures.

¹⁸ See also Task 4 of this work plan.

¹⁹ https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en

Regarding early-stage research, HERA through the Horizon Europe programme will support projects aiming to increase knowledge on **immunity induced by vaccines** against viruses with a high epidemic or pandemic potential as well as to define **optimal vaccine design** for pathogens, where information on host-pathogen interaction and viral surface structures is available²⁰ (task 2.1, Annex II).

HERA will support **rapid and efficient clinical development** and early access to critical medical countermeasures through the establishment and coordination of networks with the required expertise along the development lifecycle. Building on existing adaptive platform trials and cohort studies, HERA, in cooperation with DG RTD, will also facilitate strategic coordination mechanisms in the Union and beyond to enable the conduct of **perpetual platform trials and perpetual strategic cohorts** in order to pivot to emerging diseases if an epidemic strikes and generate scientific evidence on different possible medical countermeasures²¹.

Moreover, other research actions for MCMs will focus on **advancing broad-spectrum anti-viral compounds** targeting viruses with high epidemic or pandemic potential. HERA will also support the development of and access to **in-vitro diagnostics** for the detection and characterisation of pathogens with pandemic potential (task 2.1, Annex II) as well as access to medical devices and in vitro diagnostic medical devices for cross-border health threats (task 2.7, Annex II).

On late-stage development of innovative MCMs, HERA will work in cooperation with international stakeholders, in particular the US BARDA, to identify MCMs that can be a priority at global level and therefore maximise the efficiency of investments to bring those to the market (action 2.5, Annex II).

Via Horizon Europe, HERA will also promote the development and commercialisation of **technological solutions for pandemic management**, including for example advanced systems for aerosol capture, pathogen deactivation and air circulation optimisation, next generation face masks, and rapid surface decontamination devices (task 2.4, Annex II).

Moreover, HERA, together with other Commission's services and in cooperation with Member States, will be involved in the preparatory phase of the **EU Partnership on Pandemic Preparedness**, which intends to develop a Strategic Research and Innovation Agenda (SRIA) for pandemic preparedness by 2024.

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)** will also contribute to supporting R&D for pandemic preparedness (task 2.3, Annex II).

In addition to these activities, other actions include for example research aimed at **preventing CBRN incidents and improving European crisis management**. To this end, HERA will support the expansion of international networks of training centres for the validation and testing of CBRN tools and technologies as well as the development of tools and procedures to manage and minimise the effects of an attack with biological toxins (task 2.2, Annex II).

HERA, in close cooperation with DG SANTE and DG RTD, intends to work on push-and-pull funding to support research and development of **AMR medical countermeasures**. More specifically, HERA will work on establishing a comprehensive EU approach tailored to this need as well as to incentivising development and availability of countermeasures, both at regional and international²² levels, in line with the initiatives on AMR under the Pharmaceutical Strategy for Europe.

²⁰ A direct contribution to the Coalition for Epidemics Preparedness Initiative (CEPI) will support later-stage development phases.

²¹ This action refers to the topic HORIZON-HLTH-2023-DISEASE-03-05: Pandemic preparedness and response: Sustaining established coordination mechanisms for European adaptive platform trials and/or for cohort networks.

²² Such as via WHO, GARDP and SECURE.

HERA will also follow-up on **its two studies on AMR**²³ and use their deliverables²⁴ to design and implement actions for the development and access to AMR medical countermeasures. Actions considered include:

- (i) maintaining, updating and sharing with MS the mapping of existing AMR medical countermeasures and those in development, the supply chain vulnerabilities analysis, and the priorities identified
- (ii) the implementation of an EU multi-country pull incentives to improve access to newly authorised and old antimicrobials (e.g. based on the EU-JAMRAI proposal)
- (iii) targeted stockpiling actions to address supply chain disruptions.

More specifically, HERA intends to organise a call under the 2023 EU4Health Work Programme to establish a group of tenderers of public bodies to support the design and implementation of the above listed actions.

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

One of the key lessons learned from the COVID-19 pandemic was that while effective vaccines could be quickly developed and authorised, manufacturing capacities were insufficient in the early stages to rapidly meet demand both at Union and global levels. The pandemic has exposed important gaps in the capacity of the Union and Member States to provide quick and effective solutions to address sudden surges in demand.

In 2023 HERA will **continue with the implementation of the EU FAB** tender launched in April 2022, a network of vaccine manufacturing facilities in the EEA, to reserve manufacturing capacity and secure early availability of vaccines in case of a future public health emergency. EU FAB will complement capacity reserved by Member States at national level. The first contracts are expected to be signed in spring 2023 (task 3.1, Annex II).

The high-risk nature of investments into the development and production of innovative medical countermeasures against cross-border health threats (in particular the three prioritised by HERA, i.e. AMR, CBRN or pathogen threats), which are hard to predict, leads to a lack, or at the very least insufficient private investment. In collaboration with other Commission services and European Investment Bank (EIB), HERA will explore how Invest EU financing, topped up with EU4Health funds, could de-risk such investments. The investments through the so-called “**HERA INVEST**” could constitute a form of “insurance policy” for the future serious cross-border health threats (task 3.2, Annex II).

Currently, a market failure in the development of such interventions exists since there is no private investment due to the high-risk nature of such investments (i.e. low probability of success, low expected revenue). HERA intends to develop an action that would de-risk such investments by topping up a thematic financial product, thereby incentivising private investment, and filling the R&D pipeline against cross-border health threats.

Concretely, HERA intends to contribute to the Research, Innovation and Digitalisation policy window (RIDW) financial product implemented by the European Investment Bank (EIB) under the InvestEU Fund. The aim is to establish a platform or blending operation, the “**HERA INVEST**”, topping up the policy area ‘Health innovation investment’ of the RIDW Thematic Innovation financial product. HERA will cooperate with EIB to establish the structure.

²³ HERA currently carries out two actions, (1) [A Study on bringing AMR Medical Countermeasures to the Market](#), and (2) [Feasibility Study on Stockpiling of Medical Countermeasures in the Area of AMR](#). For both studies, contracts were signed in February 2022, and will run until Q3/4.

²⁴ The ongoing [Feasibility Study on Stockpiling of Medical Countermeasures in the Area of AMR](#) includes a supply chain vulnerability analysis, as well as an analysis of potential demand surge scenarios. The result of this analysis will help identifying options for antimicrobial stockpiling. The findings will also help HERA establishing a system for early identification of antimicrobial demand surges or supply issues, to be included in HERA MCM IT Platform for intelligence gathering and threat assessment.

Through this mechanism a restricted number of priority health threats and medical countermeasures will be targeted on the basis of its prioritisation activities. Therefore, in order to ensure a better understanding of the extent to which market failures of suboptimal investments into MCMs can be mitigated, investments will focus on projects targeting the development of preventative, treatment or diagnostics MCMs for a specific group of pathogens. In addition, the investment could also be made into early to late-stage SME life sciences companies tackling other targets that are commercially attractive. This will allow for higher chances of repayment and economic success.

In 2022, HERA commissioned a study on flexible manufacturing capacity for therapeutics²⁵ to identify scientific, engineering, legal and economic considerations of flexible EU manufacturing and innovation of medical countermeasures for serious cross-border threats to health. The study will propose areas where EU action may be necessary to better prepare for future health crises, in particular to facilitate surge manufacturing capacity and improve the Union access to medical countermeasures in case of health emergencies. The final report will be presented towards the end of Q1 2023. Building on it, follow-up actions will be pursued in 2023 to bolster the EU's flexible manufacturing capacity and address possible supply chain vulnerabilities. HERA will identify and prioritise actions following discussion of the results of the study with the Member States in the HERA Board and the industry in the Joint Industrial Cooperation Forum. Discussions with the Joint Industrial Cooperation Forum will also look into options to contribute to boosting EU open strategic autonomy including for the supply of **raw materials** relevant for medical countermeasures, as well as identifying and addressing supply chain vulnerabilities for the production of critical medical countermeasures.

In 2023, HERA will also build on the current work of DG GROW's Task Force for Industrial Scale-up (TFIS) with regard to the monitoring scheme for **trade flows of critical components for vaccines and therapeutics**, and explore how to extend this approach to other components for other critical medical counter measures.

HERA will continue to follow the preparatory work by Member States for potential **Important Projects of Common European Interest on Health** which encourage cross-border innovations in areas such as AMR and emerging health threats.

HERA will also facilitate **industrial partnerships** for the production of critical medical countermeasures, including through matchmaking events where relevant.

Task 4. Ensuring the provision of medical countermeasures

The need to ensure quick access to critical products at a time of emergency is a key priority for HERA. In close cooperation with HERA, DG ECHO launched in 2022, a call under rescEU to **procure and stockpile medical countermeasures to support responding to large-scale CBRN emergencies** that risk overwhelming national response mechanisms including health care systems.

To further support the rescEU stockpiling and deployment of medical countermeasures, HERA, together with DG ECHO and other Commission services as relevant²⁶, will work with Member States to **assess the availability of medical countermeasures national stockpiles** in response to the three threat categories identified in 2022. More specifically, a working group including representatives of the Member States will be set up to define priorities of the EU stockpile strategy and its interlink with national strategies. This will allow the identification of gaps and definition of a strategy and decision making for future stockpiling or provision of relevant medical countermeasures at EU level. This work will be carried out in cooperation with EMA, and will ensure coherence with provisions under the pharma strategy for critical medicines and critical shortages in peace time.

In case of urgent needs, HERA will mobilise resources to ensure quick access to medical countermeasures targeting potential outbreaks.

²⁵ Medicines

²⁶This include for example seeking complementarity with actions developed under other programmes, such as EDF, which under its 2021 calls earmarked EUR 68.5 million for the detection and identification of CBRN threats and medical countermeasures.

This work will also help identify priorities for a **second rescEU call** to procure and stockpile CBRN medical countermeasures and other medical items to be launched in 2023 to further strengthen HERA capacities to address cross border health threats through rescEU/UCPM (task 4.1, Annex II).

For **AMR**, HERA will also mobilise funds to purchase or reserve access to medical countermeasures (task 4.3, Annex II).

Task 5. Strengthening knowledge and skills

In 2023, HERA will develop a **training strategy** to address stakeholders (e.g. Member States as well as industries, associations, international organisations) learning needs in the field of medical countermeasures in cooperation with all relevant stakeholders (task 5.1, Annex II). Based on this strategy, HERA will promote in the following years training programmes to improve knowledge and skills related to all aspects of access to medical countermeasure based on identified gaps and areas where specific knowledge needs arise. The strategy will also take into account lessons learned from crises, such as the COVID-19 pandemic and recommendations from 2022 national/regional assessment process of public procurement practices²⁷. Activities such as best practice exchange, **twinning partnership, exchanges of experts, capacity building workshops, or table-top exercise** to ensure the deployment/availability of medical countermeasures in the event of a cross border health emergency will be organized in collaboration with other Commission services and Union agencies (e.g. ECDC and EMA) concerned. In the implementation of these training activities, HERA will coordinate with other Commission services and agencies (e.g. with training activities that will be carried out through the implementation of the new Serious Cross-border Health Treats Regulation) and rely on existing training organisations and agencies²⁸.

Task 6. International Dimension

Taking into account the new Global Health Strategy along with the State of Preparedness report, HERA will **contribute to Commission's exercise of the external representation in global fora, and via administrative arrangements with key international stakeholders**, such as **WHO**, to build up resilience and to provide timely and appropriate response to potential health crises in the future, particularly regarding availability and access to medical countermeasures.

Specifically, HERA and DG SANTE, in cooperation with other Commission services as relevant, will continue implementing the administrative arrangement it concluded in 2022, with the US Department of Health and Human Services, linking as well with the work of the EU-U.S. COVID-19 Manufacturing and Supply Chain Taskforce. HERA will also enhance cooperation with regulatory authorities, agencies active in the field of health emergency preparedness and response and with health ministries of other third countries (e.g. Republic of Korea, Japan) and with relevant bodies within international organisations (e.g. WHO).

HERA will also continue to support the Commission's efforts as Union negotiator²⁹ in the negotiations on a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, in particular with regard to framing obligations for the provision of medical countermeasures and to the **inclusion of AMR and "One Health" provisions in a pandemic treaty**. In addition, HERA will also support Commission's ambition to increasing funding for pandemic

²⁷ ongoing call under EU4Health: https://hadea.ec.europa.eu/news/eu4health-call-proposals-support-public-procurement-health-sector-and-crises-preparedness-2022-09-15_en

²⁸ Such as the WHO, and more specifically the WHO Academy, the European Centre for Disease Prevention and Control or the UCPM training and exercise programme.

²⁹ COUNCIL DECISION (EU) 2022/451 of 3 March 2022 authorising the opening of negotiations on behalf of the European Union for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005)

preparedness response (PPR) globally, in particular through the new Financial Intermediary Fund (FIF) for Pandemic, Prevention, Preparedness and Response (PPR).

HERA, in close cooperation with other responsible Commission services will continue to support the **international roll-out of COVID-19 vaccines**, notably via donations of medical countermeasures to Low and Middle Income Countries (LMIC) countries through COVAX or other relevant organisations.

In addition, HERA will continue supporting global, regional and national initiatives, to **ensure the availability and accessibility of medical countermeasures** and **strengthen the capacities of LMIC to carry out surveillance and whole genome sequencing activities**³⁰, in synergy with the activities the Global Health EDCTP3 could ultimately implement in genomic epidemiology for surveillance and control of emerging and re-emerging infections in sub-Saharan Africa in collaboration with the Bill and Melinda Gates Foundation. HERA will also support initiatives to develop **manufacturing potential in LMIC**. HERA will also continue to contribute to the Team Europe's initiative on health security with a "One Health" approach.

HERA will also continue to work closely with candidate countries, potential candidates, and neighbourhood countries.

Furthermore, via international partnerships, such as the GH-EDCTP3 JU, HERA, in close cooperation with the responsible Commission services, will engage with African countries to boost the development of medical countermeasures for infectious diseases affecting Africa, including those with epidemic or pandemic potential.

HERA will continue its collaboration with the WHO Pandemic Hub and the WHO Regional Office for Africa (AFRO) to support the intelligence gathering and threat assessment functions of HERA, specifically addressing the threat of emerging infections on the African continent. For example, HERA will support initiatives aiming at increasing the transparency of the critical supply chains.

In terms of AMR, HERA will monitor an activity launched in 2022 on **priority signalling** regarding resistant bacteria and fungi, pipeline analysis for antibacterial and antifungal agents, diagnostics and vaccines against resistant pathogens, as well as support WHO-GARDP-SECURE for late-stage development of antimicrobials and the implementation of pull incentives.

An overall budget of EUR 13 million from EU4Health has been provisionally set aside as possible contribution to global, regional or national initiatives in the field of pandemic preparedness, including late-stage clinical trials of vaccines and/or treatments against priority health threats (e.g. Ebola), and more specifically to support the enhancement of sequencing capacities in Africa, in collaboration with the African Centre for Disease Control (CDC), through the African Union Commission, and to support the data collection on emerging pathogens in Africa in collaboration with the WHO pandemic Hub and WHO AFRO (task 6.1, Annex II).

3. Crisis response to serious cross-border health threats through relevant medical countermeasures

COVID-19 pandemic

HERA will continue to play an important role in the **implementation of the COVID-19 vaccines and therapeutics contracts**. HERA will implement existing contracts for COVID-19 in conjunction with Member States via the Vaccines Steering Board. HERA will also work with relevant stakeholders³¹ to identify promising vaccines or therapeutics in development which may prove valuable in the EU's ongoing efforts to manage the COVID-19 pandemic. Given the volatile epidemiological situation related to SARS CoV-2 variants, HERA will continue to host the **EU's Expert Group on Variants**, to provide independent expert advice on the epidemiological evolution of the COVID-19 pandemic. HERA

³⁰ For COVID-19 and other threats including AMR.

³¹ HERA Advisory Forum, the Vaccines Steering Board, the Expert Group on SARS-CoV-2 and leading researchers from major research institutions in the Union.

will ensure that the advice of the expert group is available to partner DGs and agencies as well as Member States to help inform their policy development.

In addition to these horizon-scanning activities, HERA will continue to work with Member States to **determine their priorities and carry out future joint procurement** of diagnostics, therapeutics and vaccines against COVID-19 and carry out such joint procurement .

Ukraine

As the humanitarian situation in Ukraine and neighbouring countries has systematically worsened over the last months, the European Commission is working on all fronts to provide assistance to Ukraine, its population and to Member States hosting Ukrainian refugees. The provision of medical items (drugs, medicines, equipment) is one of the highest priorities. HERA contributes to the Commission's efforts coordinated by the ERCC in DG ECHO and will continue to do so in 2023 as needed, be it on preparedness side such as working with DG ECHO and DG SANTE on **anticipating and assessing health needs of Ukrainian refugees**³² or on response side such as working with DG ECHO on **ensuring the procurement of the most urgently needed items**³³.

Emergency readiness

In 2023, HERA's Emergency Office will continue the implementation of its strategic framework enabling HERA to prepare for and coordinate actions aiming at improving Member States ability to respond quickly and effectively to health emergencies with the relevant medical countermeasures.

HERA's Emergency Office will develop all of the **capabilities necessary for a robust response to cross-border health emergencies with focus on medical countermeasures**, such as strengthening stakeholder relations, in particular with industries and international organisations, develop credible scenarios plans and protocols to ensure maximum effectiveness in response and build a multi-disciplinary team to lead and manage an effective coordinated response. In addition, it will **prepare and roll-out the tools needed to implement the Council Regulation 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**³⁴. More specifically, HERA has already initiated internal work for the establishment of *ad hoc* procedures for the **activation, prolongation and expiration of the framework**. This work will be further developed in the coming months, including by involving relevant Commission services and additional stakeholders as relevant.

Annex I provides an overview of the overall 2023 contributions from the Horizon Europe, the EU4Health and the rescEU programmes for the implementation of HERA's activities.

Annex II provides the detailed breakdown of actions planned for 2023

³² On paediatric vaccines and treatment for tuberculosis and HIV.

³³ Such as the potassium iodide tablets purchased in 2022.

³⁴ Council Regulation 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, adopted on 24 October 2022.

Annex I. Total 2023 Contributions per tasks

A **total contribution of EUR 1.267,75 billion** from the Union budget is provisionally allocated to HERA in 2023 for preparedness activities. The budget of HERA for 2023 provides for contributions from **EU4Health (EUR 242,75 million), Horizon Europe (EUR 389 million) and UCPM/resceEU (EUR 636 million) Programmes.**

Budget figures included in Annexes I and II are indicative only, pending the completion of the negotiation and adoption of the relevant Horizon Europe and EU4Health work programmes.

Total for preparedness phase in 2023	Total per Task (in million EUR)	EU4Health (in million EUR)	Horizon Europe (in million EUR)	UCPM (in million EUR)
Task 1. Threat assessments and intelligence gathering with regard to medical countermeasures	20,0	20,0		
Task 2. Promoting advanced R&D of medical countermeasures and related technologies	474,75	85,75	389	
Task 3. Addressing market challenges and failures and boosting the Union's open strategic autonomy	100	100		
Task 4. Ensuring the provision of medical countermeasures	658	22		636
Task 5. Strengthening knowledge and skills with regard to medical countermeasures	2	2		
Task 6. International dimension ³⁵	13	13		
Total	1.267,75	242,75	389	636

³⁵ This does not cover the external dimension of actions presented under other tasks

Annex II. 2023 Activities per tasks

Task 1. Threat assessments and intelligence gathering (EUR 20 million)

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

2023 Funded activities		Budget (million EUR)
1.1	IT platform for intelligence gathering, threat assessment, mapping medical countermeasures and management systems for stockpiling (HERA MCM platform)	[24.5(EU4Health)]³⁶
1.2	Study on the identification of high impact threats for health and their periodic update in order to develop, produce and deploy MCM	1 (EU4Health)
1.3	Support to MS to enhance alignment and consolidation of wastewater surveillance	15 (EU4Health)
1.4	Wastewater monitoring at Union level - Sentinel system	2.5 (EU4Health)
1.5	Support to Epidemic intelligence from open sources (EIOS) initiative. This action is related to the technical development of the EIOS system, which is carried out by the JRC	1.5 (EU4Health)

³⁶Included in the HERA 2022 annual work plan. The call for tender under the EU4Health programme is currently under preparation and will be launched in Q4 2022 or Q1 2023.

Task 2. Promoting advanced R&D of medical countermeasures and related technologies

(EUR 474,75 million)

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

2023 Funded activities		Budget (million EUR) ³⁷
2.1	<p><u>Provisional actions under Part 4. 'Health of Horizon Europe' of Horizon Europe Work Programme 2023-2024.</u></p> <ul style="list-style-type: none"> - Pandemic preparedness and response: <ul style="list-style-type: none"> o Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential o Sustaining established coordination mechanisms for European adaptive platform trial network and cohort network o Understanding vaccine induced-immunity o Immunogenicity of viral proteins of viruses with epidemic potential o In vitro diagnostic devices to tackle cross-border health threats - Direct contribution to CEPI³⁸ - Emergency funds 	234 (Horizon Europe)
2.2	<p><u>Provisional actions under Part 6. 'Civil Security for Society' of Horizon Europe Work Programme 2023-2024.</u></p> <ul style="list-style-type: none"> o Operability and standardisation in response to biological toxin incidents o Internationally coordinated networking of training centres for the validation and testing of CBRN-E tools and technologies in case of incidents, with consideration of human factors 	10 (Horizon Europe)
2.3	<p><u>Contributions from institutionalised partnerships.</u></p> <ul style="list-style-type: none"> - Innovative Health Initiative: support to pre-competitive research and innovation for medical countermeasures for cross-border health threats - European and Developing Countries Clinical Trials Partnership (EDCTP3): support to clinical research for poverty-related infectious diseases in sub-Saharan Africa 	70 (Horizon Europe)
2.4	EIC Accelerator Challenge on circumventing the need for social distancing in the context of pandemic management.	75 (Horizon Europe) Subject to EISMEA Work Programme decision)

³⁷ For the determination of the contribution of the Horizon Europe Work Programme to the HERA Work Plan 2023 in an ex post assessment, other projects promoting research and innovation to develop effective, safe and affordable medical countermeasures will be taken into account irrespective whether the corresponding topics have been identified ex ante.

³⁸ Composed of an additional EUR 35 million that will be awarded to CEPI from the Horizon Europe Work Programme 2022, and EUR 35 million allocated to CEPI in the Horizon Europe Work Programme 2023.

2.5	Support to speed up of development, access and/or uptake of innovative technologies <i>medical countermeasures for epidemic and pandemic preparedness, including for a new generation of COVID-19 vaccines</i> . Actions to be implemented in cooperation with international stakeholders, such as BARDA	84 (EU4Health)
2.6	Support to clinical trials, clinical investigations, performance studies for MCMs needed in case of emergencies	(EU4Health) Budget will be allocated in the light of emerging needs
2.7	Support access to medical devices and in vitro diagnostic medical devices for cross-border health threats ³⁹	1.75 (EU4Health)

Task 3. Addressing market challenges and failures and boosting the Union’s open strategic autonomy (EUR 100 million)

Objective: Identifying and ensuring the availability of critical technologies and production sites for medical countermeasures in the Union capable of increasing their production in times of need, including through support of breakthrough innovation.

2023 Funded activities		Budget
3.1	Continuous support to Ever-warm facilities (EU FAB) for vaccines	[160(EU4Health)⁴⁰]
3.2	Top-up of the InvestEU guarantee through a blending operation – the HERA INVEST	100 (EU4Health)

Task 4. Ensuring the provision of medical countermeasures (EUR 658 million)

Objective: Using stockpiling and Union procurement to ensure provision of medical countermeasures

2023 Funded activities		Budget (million EUR)
4.1	Calls on medical stockpiles and CBRN	636(rescEU/UCPM)
4.2	Procurement of medical countermeasures as an emergency response	(EU4health) Budget will be allocated in the light of emerging needs
4.3	Support to innovation and access to AMR countermeasures through the coordination of a network and reservation contracts for specific products	22 (EU4Health)

³⁹ The action will facilitate the development, production, and distribution of devices relevant for serious cross-border health threats, by providing for example services and advice on: intellectual property, prototyping, engineering, laboratory and animal testing, grant-writing, and clinical investigation design.

⁴⁰ 2023 activities to be funded with EU4Health budget 2022.

Task 5. Strengthening knowledge and skills (EUR 2 million)

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

2023 Funded activities		Budget (million EUR)
5.1	Training and simulation exercise on medical countermeasure management in the event of cross border health threats based on a gap analysis on Member States preparedness in the field of medical countermeasures (strategy and preliminary training activities).	2 (EU4Health)

Task 6. International Dimension (EUR 13 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.

2023 Funded activities		Budget (million EUR)
6.1	Support to external action at global, regional and national levels initiatives in the field of MCM ⁴¹	13 (EU4Health)

⁴¹ e.g. initiative of the African CDC (through the African Union Commission), WHO, or others to be identified