



# Annual Activity Report 2024

Health Emergency Preparedness and  
Response Authority

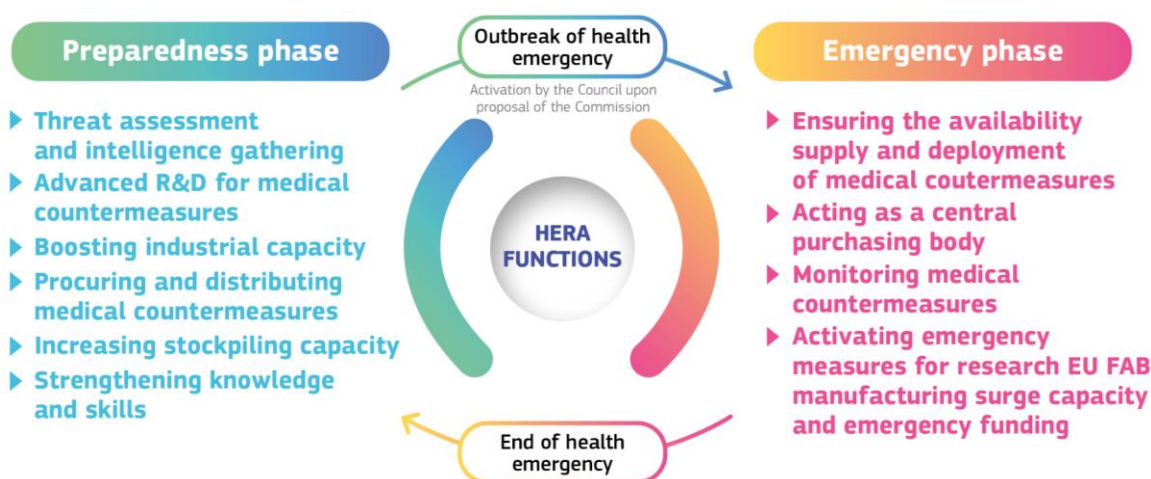
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## HERA IN BRIEF

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 distribution of key medical countermeasures (MCMs)** <sup>(1)</sup>. HERA's activities are shaped by the Treaty on the Functioning of the European Union (TFEU) and principally linked to Articles 168 (public health) and 122 (legal basis for adopting temporary measures in a crisis situation).

HERA functions in two modes: one for 'peace' time and one for crisis. In recognition that preparedness is essential to mitigate the risks of future health threats, HERA **works first and foremost in preparedness mode**.



HERA **complements** the work done by other Commission services, and by the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA) and other relevant Union agencies in both preparedness and crisis times and ensures a coordinated approach in terms of medical countermeasures against future health threats.

HERA draws funding from a number of sources: the EU4Health programme, Horizon Europe programme, the Union Civil Protection Mechanism (UCPM). HaDEA implements for HERA most of the actions under the annual EU4Health work programmes and Horizon Europe, with the latter managed by DG RTG. The UCPM transactions are under the responsibility of DG ECHO authorizing officer. Partner DGs have set their own control activities, part of their internal control systems, to ensure compliance with the corresponding internal control principles in the area.

HERA is a Commission service under the leadership of Commissioner Hadja Lahbib and Acting Director-General Laurent Muschel. Starting from the 1<sup>st</sup> of April 2025, Dr. Florika Fink-Hooijer will act as a Director-General.

<sup>(1)</sup> Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority 2021/C 393 I/02

## EXECUTIVE SUMMARY

This Annual Activity Report is a management report of the acting Head of HERA to the College of Commissioners. Annual activity reports are the main instrument of management accountability within the Commission and constitute the basis on which the College takes political responsibility for the decisions it takes as well as for the coordinating, executive and management functions it exercises, as laid down in the treaties <sup>(2)</sup>.

### A. Key results and progress towards achieving the Commission's general objectives and department's specific objectives

In 2024, HERA continued to work with Member States, other Commission services and relevant stakeholders to strengthen health security coordination within the Union during preparedness and crisis response times. Work has been carried out on all fronts to ensure the development, manufacturing, procurement and stockpiling of key medical countermeasures.

#### General Objective 4: Promoting our European way of life

##### *Specific objective 1: Preparedness for health emergencies*

In recognition that preparedness is essential to mitigate the risks of future health threats, HERA worked throughout 2024 first and foremost in preparedness mode. Throughout 2024, HERA has strengthened its activities on **intelligence gathering** and analysis. Thanks to projects such as EIOS <sup>(3)</sup>, EU-WISH, GLOWACON, Whole Genome Sequencing grants, HERA allowed for increased and up-to-date knowledge on health threats and gathering intelligence pertinent to medical countermeasures. Several steps forward were made as regards the IT system 'ATHINA' to collect intelligence and assess threats, along with improving the readiness of adequate databases and ensuring their interoperability for the exchange of data through EU-HIP <sup>(4)</sup>.

In 2024, HERA continued to consolidate R&D efforts in the field of pandemic preparedness and supported research and development of **innovative medical countermeasures**, including antimicrobials and critical medicines. Through Horizon Europe, efforts focused on advancing knowledge of epidemic-prone viruses, particularly pathogen/host interactions, to develop vaccines and treatments for preventing viral infections and transmission. This has been done alongside investments in adaptive trials for pandemic preparedness. HERA contributed to the European Partnership on Pandemic Preparedness and global health initiatives such as GH-EDCTP3. Under EU4Health, HERA launched a call to create the European

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<sup>(2)</sup> Article 17(1) of the Treaty on European Union

<sup>(3)</sup> Epidemic Intelligence from open source

<sup>(4)</sup> EU interoperability with HERA's IT platform

Vaccine Development Hub with a view to expediting the development, production, and distribution of vaccines by fostering collaboration and innovation. To further support investment in R&D for promising MCMs, HERA designed and started establishing **HERA INVEST** under the InvestEU fund. In 2024, two agreements were signed supporting research and development activities against cross-border health threats <sup>(5)</sup>. With the support of HaDEA, HERA launched a call to support innovative manufacturing technologies, contributing to strengthening the supply chains of critical medicines and medical countermeasures.

**Shortages of medical countermeasures** can occur due to a variety of factors, including surge of demand or vulnerabilities in global supply chains. On 24 October 2023 <sup>(6)</sup>, the Commission adopted a Communication on medicines shortages which sets out actions to better prevent and mitigate critical medicine shortages in the EU. This included the establishment of the **Critical Medicines Alliance**, for which HERA has provided secretariat functions and the carrying out of a **vulnerability analysis** to identify **industrial and market bottlenecks**, as well as **the development of a common strategic approach** to medicines stockpiling to prevent and mitigate shortages in cooperation with Member States.

In 2024, HERA continued to support the preparedness of the Member States and other participating countries (the 37 signatories of the Joint Procurement Agreement) against health threats by conducting several **joint procurements**: launching a call for tenders for mRNA COVID-19 vaccines, a call for protein-based COVID-19 vaccines, renewing the contract for the COVID-19 therapeutic Remdesivir, signing a contract for the pre-pandemic zoonotic influenza vaccine, signing a contract for diphtheria antitoxin, launching a call for RSV vaccines and starting the preparation for a new contract to access mpox vaccines. HERA also started the work to pilot demand signalling of antibiotics through joint procurement at EU level.

HERA's work in health preparedness and emergency response to health emergencies involving medical countermeasures has an impact on several sectors, such as health, research, innovation, and industry. HERA continued operationalising **in 2024** the **governance and coordination mechanisms** with Member States, other Commission Services and Agencies as well as specific groups of stakeholders. In 2024, 10 meetings took place with the HERA Board and the various consultative bodies of HERA (Advisory Forum, Civil Society Forum and the Joint industrial Cooperation Forum). In addition, HERA organised 13 policy and ad-hoc workshops to ensure EU MS are fully engaged in strategic and policy development and exchanges of best practices.

### ***Specific objective 2: Crisis response readiness for health emergencies***

HERA continued during 2024 to carry out preparatory work for the implementation of Council Regulation (EU) 2022/2372 on a framework of measures for ensuring the supply of crisis-

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<sup>(5)</sup> [First HERA Invest agreement signed to support research and development in cross-border health threats - European Commission](#)

<sup>(6)</sup> [Communication on addressing shortages in the EU](#)

relevant medical countermeasures in the event of a public health emergency at Union level <sup>(7)</sup>. More specifically, HERA established procedures for the **activation, prolongation and expiration of the framework**. This entailed primarily preparation of personal data protection implementing acts and other drafts of implementing acts. HERA has also operationalised its emergency response protocol by publishing an enhanced version. The protocol is complemented by the Response blueprints, which identify the relevant response measures.

In August 2024, HERA, through the use of an existing joint procurement contract, swiftly mobilised emergency funding under the EU4Health programme to support Africa CDC's response to the escalating mpox outbreak in Africa, by donating and shipping 215,000 mpox vaccine doses to the affected countries. Additionally, since the start of Russia's invasion of Ukraine, HERA has been involved in the provision of the necessary medical countermeasures.

### ***Specific objective 3: International resilience and appropriate response readiness for health emergencies***

Collaboration with global partners is a crucial aspect of ensuring worldwide access to vaccines and addressing deficiencies in global pandemic preparedness, prevention, and early detection of health emergencies. Since its creation, HERA has successfully established strategic relationships and finalised agreements with key non-EU countries and organisations (USA, Japan, Republic of Korea, WHO Hub); such as the Working Arrangement with Africa Centres for Disease Prevention and Control (Africa CDC) signed in March 2024. These agreements aim to enhance global intelligence capacities, intelligence gathering, and promote collaboration on countermeasures for preventing, preparing, detecting, and swiftly responding to serious cross-border health threats. Furthermore, HERA strengthened existing relationships through its engagement in trilateral and multilateral formats (US-Japan Health Security Committee Meeting, B5 Partnership with the Republic of Korea, Japan, USA and India).

In 2024, HERA continued to play a significant role in the European Commission's external representation in global forums (e.g. Team Europe Ministerial Mission on AU-EU partnership on Global health, BIO International Convention).

In 2024, HERA also established new contacts with non-EU countries (contact with the Indian Ministry of Commerce through the EU-India Trade and Technology Council Working Group 3 on resilient supply chains).

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<sup>(7)</sup> Regulation (EU) 2022/2371 of the European Parliament and the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU

## B. Key performance indicators

Since HERA was established in September 2021, it has not participated in the 2020-2024 strategic plan, and therefore this part is not applicable.

## C. Key conclusions on internal control and financial management

HERA has systematically examined the available control results and indicators, as well as the observations and recommendations issued by the internal auditor and the European Court of Auditors. These elements have been assessed to determine their impact on management's assurance about the achievement of the control objectives. Please refer to Section 2 for further details.

In conclusion, management has reasonable assurance that, overall, suitable controls are in place and working as intended; risks are being appropriately monitored and mitigated. Minor improvements are necessary concerning the completion rates of the mandatory training under Principle 8 <sup>(8)</sup>. This minor deficiency is mainly due to the lack of courses programmed on fraud in 2024. Once courses will be again available, reminders will be sent to the staff concerned.

The Acting Director-General, in his capacity as Authorising Officer by Delegation, has signed the Declaration of Assurance.

## D. Provision of information to the Commissioner(s)

In the context of the regular meetings during the year between HERA and the Commissioner(s) on management matters, the main elements of this report and assurance declaration, have been brought to the attention of **Commissioner Stella Kyriakides** that served in 2024, responsible for Health and Food Safety and **Commissioner Hadja Lahbib** appointed for the period 2024-2029, responsible for Equality; Preparedness and Crisis Management.

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<sup>(8)</sup> Principle 8 of the European Commission's Internal Control Framework covers the potential for fraud in assessing risks to the achievement of objectives.

# 1. KEY RESULTS AND PROGRESS TOWARDS ACHIEVING THE COMMISSION'S GENERAL OBJECTIVES AND SPECIFIC OBJECTIVES OF THE DEPARTMENT

## General Objective 4: Promoting our European way of life

HERA contributes to the Commission's headline ambitions. In health, this means a continued focus on building a strong **European Health Union**, borne out of the lessons learned from the COVID-19 pandemic and strengthening the "**European way of life**" for 2020-2024.

The strategic and coordinated approach to preparedness at the EU-level should help to avoid, or, at the very least, significantly decrease the adverse effects of health crises in terms of human lives, impacts on health services, negative economic growth, unemployment, threats to security of energy supply or market disruptions.

Ultimately, increased capacities to prevent, detect and rapidly respond to future health emergencies should allow to safeguard the economic and social stability of the EU and of its Member States.

As a central pillar of the European Health Union, HERA is strengthening the EU preparedness and response capabilities in the field of medical countermeasures.

The EU is building and reinforcing preparedness capabilities for the development, manufacturing, procurement and distribution of medical countermeasures, underpinned by reinforced surveillance capacity.

## Specific objective 1: Preparedness for health emergencies

Future serious cross-border threats to health <sup>(9)</sup> are likely to arise: the outbreaks of infectious diseases have been occurring with increasing frequency, driven by factors such as global population growth, climate change and pressures on land use, food production and animal health. The intentional releases of biological or chemical agents also remain a persistent threat with a potential for significant impact. To address these risks, HERA intends to focus on activities to operationalise the five **preparedness tasks** outlined in the Communication introducing HERA, cooperating with Member States and relevant stakeholders via the established **governance and coordination structures** such as the HERA Board and the HERA Advisory Forum.

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<sup>(9)</sup> This includes threats of chemical, biological, radiological, nuclear or environmental origin, as well as threats of unknown origin – whether of natural or deliberate origin.

**Threat assessments and intelligence gathering.** The availability of relevant and high-quality data, evaluation of this data as well as that of potential threats and their impacts is essential in order to define preparedness strategies for critical medical countermeasures. In 2024, HERA updated its annual Threat Prioritisation exercise and continued monitoring the identified priority health threats and thus building on the categories identified, namely pathogens with high pandemic potential; CBRN threats originating from accidental or deliberate release, and antimicrobial resistance, with additional focus areas being environmental threats due to climate change, and threats associated with emerging technologies.

This threat prioritisation exercise has been complemented by the development of lists of critical medical countermeasures relevant for crisis preparedness and response, and the assessment of potential gaps in terms of availability and accessibility, including research and development needs. In 2024, HERA further refined the identification of threats and their analysis, in close cooperation with the European Centre of Disease and Control, as well as the mapping and assessment of availability and accessibility to medical countermeasures.

In 2024, HERA advanced the development and operationalisation of a comprehensive intelligence system for early threat identification and effective response coordination: ATHINA, the Advanced Technology for Health Intelligence and Action IT system. Additional assessment of business needs was carried out in 2024 which will include complementarity and interoperability with existing platforms, like the European Shortages Monitoring Platform.

In 2024, HERA strengthened sequencing capacities and established new activities on wastewater surveillance in collaboration with the JRC, such as GLOWACON, the global consortium for wastewater and environmental surveillance for public health. In particular, HERA further strengthened wastewater monitoring capacities in the EU through knowledge exchange and sharing of best practices between Member States' authorities, and started to set up a network of testing hubs in the EU and in Africa. In addition, HERA expanded its collaboration with WHO <sup>(10)</sup> and UNEP <sup>(11)</sup> to support strategies, capacity and data for global wastewater and environmental surveillance. Further, HERA continued to follow the implementation of the action CP-g-22-01.04 initiated under EU4Health 2022 providing direct grants to Member States' authorities to enhance whole genome sequencing (WGS) and/or reverse transcription polymerase chain reaction (RT-PCR) national infrastructures and capacities to respond to the COVID-19 pandemic and future health threats. HERA strengthened its collaboration with Africa CDC <sup>(12)</sup> to reinforce sequencing capacities and will identify areas for further collaboration in the field of intelligence gathering and access to medical countermeasures.

In 2024, HERA continued to support, in collaboration with the World Health Organization and the Joint Research Centre (JRC), the technological development of the EIOS Platform

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<sup>(10)</sup> World Health Organisation

<sup>(11)</sup> United Nations Environment Programme

<sup>(12)</sup> Africa Centre for Disease Control and Prevention

(Epidemic Intelligence from open source) and contribute to its governance. This financial and operational support will strengthen the features of this platform to gather intelligence from open sources on medical countermeasures.

HERA continued to work with DURABLE, a network of public health and research laboratories in Europe coordinated by Institute Pasteur and Erasmus Medical Centre, that has been set-up to perform research and MCM development in preparedness and response phases.

### **Promotion of advanced R&D of medical countermeasures and related technologies.**

In 2024, HERA reinforced its horizon scanning and foresight capacities to proactively identify emerging innovations and technologies within the MCMs field.

Through EU4Health, HERA launched a call to create the **European Vaccine Development Hub** with a view to expedite the development, production, and distribution of vaccines fostering collaboration and innovation. Complementing this, support was given to drive innovation in next-generation respiratory protection, addressing critical needs for enhanced personal protective equipment during health crises. Furthermore, plans for supporting initiatives to speed up the development, access, and uptake of medical countermeasures were developed and will be further expanded in 2025. Based on the list of critical MCMs established in 2023 in collaboration with Member States as well as through a dedicated workshop organised with several stakeholders, including industry, HERA continued to support the development and access to a wide range of MCMs necessary to improve preparedness and response to serious cross-border health threats, including by supporting late-stage clinical trials, clinical investigations, performance evaluation or similar studies.

The COVID-19 pandemic showcased the shortcomings of existing masks and respirators, which do not offer adequate protection or comfortable multi-hour use. Through a dedicated EU4Health grant, HERA fostered innovation in the field of personal protective equipment, ensuring the development and uptake of improved respiratory protection.

One of the key lessons learned from the COVID-19 pandemic was the lack of a coordinated clinical trial infrastructure across the Union that could be pivoted in the case of emergency. To address this gap, HERA created, in cooperation with DG RTD and EMA <sup>(13)</sup>, a coordination mechanism at the EU level that aligns funding strategies, prepares for a swift and coordinated clinical trial response in the EU during a health emergency, and streamlines the identification and prioritization of pipeline products and clinical trials.

Through Horizon Europe, HERA continued to support basic research aimed at increasing knowledge on 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. HERA also invested in multi-country adaptive platform trials for pandemic preparedness able to rapidly pivot to the assessment of vaccines and therapeutics for infectious diseases in the case of epidemic or pandemic health threats.

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<sup>(13)</sup> European Medicines Agency

HERA continued to be involved in the preparatory work for the creation of the Horizon Europe European Partnership on Pandemic Preparedness, which should enable Member States, Associated Countries and the Commission to rapidly and jointly support transnational research and innovation in pandemic preparedness, as well as an ever-warm clinical trial site network in the EU.

Close coordination continued 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).

In Europe, more than 35,000 people die from antibiotic-resistant infections every year. Without action, annual deaths could rise to 390,000 by 2050.

**For AMR**, HERA continued promoting the development and availability of relevant medical countermeasures, including old and new antimicrobials, rapid diagnostics, and vaccine against priority pathogens. In 2024, building on the studies on ‘Bringing AMR MCM to the market <sup>(14)</sup>’ and on ‘Stockpiling of antimicrobials against AMR <sup>(15)</sup>’, HERA continued supporting the development, availability and access to preventive, diagnostic and therapeutic MCM for AMR.

On the side of pull incentives, HERA continued exploring with Member States the implementation of procurement-based pull incentives, in articulation with other types of pull incentives proposed by the Commission. HERA notably focused on the design of EU multi-country revenue guarantee to improve access to new antibiotics, with the support of service contracts to be passed under EU4Health action CP-p-23-16 Support innovation and access to antimicrobials.

As a result, in cooperation with HERA, the Health and Digital Executive Agency (HaDEA) launched two different negotiated procedures under EU4Health action CP-p-23-16 Support innovation and access to antimicrobials for a multi-country revenue guarantee pull incentive pilot for the procurement of availability and accessibility services of two different antibiotics in the European Union for the Member States interested. Due to different reasons and in different stages of the process, none of the procedures concluded with the signature of a contract. The latter procedure launched for Varborem (9399-2025 - Result - TED <sup>(16)</sup>), reached the award notice phase, but the company Menarini decided not to sign a contract. On this basis, HERA will launch a lesson learned exercise with Member States in 2025.

On the side of push incentives, this year, HERA has awarded push funding to two projects addressing tuberculosis. HERA has provided EUR 12.5 million to support the new tuberculosis vaccine and EUR 5 million to support the development of antituberculosis medicines for children to ensure age-appropriate first-line treatments. HERA continued to contribute to clinical development of AMR MCM by providing a financial support to international

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<sup>(14)</sup> [Bringing AMR MCM to the market](#)

<sup>(15)</sup> [Stockpiling of antimicrobials against AMR](#)

<sup>(16)</sup> [9399-2025 - Result - TED](#)

organisations, especially the Global Antibiotic Research and Development Partnership (GARDP), a non-profit organisation that develops new treatments for drug-resistant infections that pose the greatest threat to health. HERA also continued to support WHO for maintaining and implementing both bacterial and fungal priority pathogen lists and to be able to continue to focus on the appropriate AMR MCMs. In addition, HERA is collaborating with DG RTD in the work of the Horizon Europe co-funded European Partnership 'One Health Anti-Microbial Resistance', to be launched in 2025, which should allow coordinating, aligning of activities and funding among countries in the EU and beyond, as well as facilitating national coherence between different services/ministries with responsibility for the various aspects of AMR and sectors involved.

As regards the availability of antibiotics, in 2024, HERA started exploring how the Joint procurement mechanism could improve availability and demand signalling of antibiotics. Early 2025, participating countries will make a decision on the way forward.

**Ensuring access to medical countermeasures and boosting the Union's open strategic autonomy.** Shortages of medical countermeasures as well as critical medicines can be a result of a lack of manufacturing and supply capacities due to surge of demand, vulnerabilities in global supply chains and dependencies on third countries. In 2024, HERA has the **Critical Medicines Alliance** as a consultative mechanism bringing together relevant stakeholders from EU Member States, key industries, the civil society. The Critical Medicines Alliance was formally launched in April 2024, and during 2024 over 300 stakeholders joined its membership. The Alliance has an overall objective to identify key areas and priorities for action, proposing solutions to strengthen the supply of critical medicines in the EU, ultimately enhancing efforts to prevent and address shortages effectively. HERA provided Secretariat to the Alliance, its Steering Board and its Working Groups, through organising several physical and virtual meetings, as well as by inviting representatives of various Commission services to help discussions. The first meeting of the Forum set the agenda of the work ahead to address supply chain vulnerabilities. Two working groups, on strengthening manufacturing capacity in the EU and on international partnerships and diversification were developing their recommendations.

By the end of the year, the Steering Board of the Alliance adopted draft recommendations on strengthening EU manufacturing capabilities through financial incentives, on procurement, contingency stocks, ensuring a level playing field for EU manufacturers, international partnerships and solidarity. The work of the Alliance provides important contribution to the preparations of the Critical Medicines Act announced by the President in her political guidelines.

To support the work of the Alliance and achieve a better understanding on the supply chains, in 2024, HERA, together with DG GROW, conducted a pilot exercise to assess the vulnerability of 11 molecules from the Union list of Critical Medicines. The primary objectives of the pilot exercise were to identify vulnerabilities in the supply chains of the selected critical medicines, evaluate potential disruptions and dependencies, and stir the discussion within the Critical Medicines Alliance on identifying industrial interventions to enhance the resilience of the

supply chain of critical medicines. The process, methodology, and main findings of the pilot exercise were published in a comprehensive technical report in July 2024 <sup>(17)</sup>. The Strategic Report of the Alliance, encompassing all recommendations developed within the Alliance, will be finalised in February 2025, following a consultation of the Forum of the Alliance.

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. In 2024, HERA continued to monitor the implementation of **EU FAB** <sup>(18)</sup> and visited each physical manufacturing sites to deepen discussions with the contractors and ensure activation of the contract and manufacturing can be done without unnecessary delays and difficulties. EU FAB contractors will implement optimisations based on feedback and secure early availability of vaccines in the event of a future public health emergency. EU FAB complements capacity reserved by Member States at national level. In 2024, HERA started examining the possibilities of an expansion of the EU FAB framework beyond vaccines to include additional capacity reservation contracts for access to medical countermeasures, including antibiotics. Consultation with the Member States, industry, academia and civil society within the Critical Medicines Alliance have contributed to the medical countermeasure capacity reservation strategies for future implementation.

To support **preparedness through Joint Procurement**, HERA continued to collect information from the participating countries and industry stakeholders on products that could be candidate for joint procurement. In 2024, HERA launched calls for COVID-19 vaccines to ensure security of supply and access to a diversified portfolio: a call for tenders for mRNA COVID-19 vaccines and a call for tenders for protein-based COVID-19 vaccines, HERA negotiated contract terms to allow signature of the contracts in early 2025. HERA also launched a call for vaccines against Respiratory syncytial virus (RSV), following announcement of the Commission Communication on addressing medicine shortages in the EU, as tackling RSV can lower the use of antibiotics and hence contribute to shortage prevention. Regarding antibiotics, HERA also started exploring how joint procurement at EU level could improve availability and demand signalling by aggregating the demand of all participating countries. HERA designed several options to pilot a JP that could contribute to that goal, which participating countries will be able to choose from early 2025. In addition, HERA has signed a contract to purchase 665,000 doses of pre-pandemic zoonotic influenza vaccines and reserved more than 40 million doses of this vaccine for 15 participating countries. In August 2024, HERA also signed a contract for diphtheria antitoxin to allow access to the product to 8 participating countries. HERA also renewed the contract for the COVID-19 therapeutic Remdesivir to secure more than 2 million treatments for 14 participating countries. Given the outbreak in Africa and the end of the mpox joint procurement contract, HERA also started the preparation for a new contract to access mpox vaccines (call to be launched early 2025). The work on the renewal of pandemic influenza vaccines contract has

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<sup>(17)</sup> [Assessment of the supply chain vulnerabilities for the first tranche of the Union list of critical medicines: Technical report - European Commission](#)

<sup>(18)</sup> Network of Ever-warm Production Capacities for Vaccines and Therapeutics manufacturing

also started and HERA is committed to ensure timely signature as these reservation contracts largely contribute to the preparedness of Member States. All this work was done in close collaboration with the participating countries through different online meetings as well as one in-person workshop that took place in March 2024 with all the members of the Joint Procurement Steering Committee.

In November 2024, HERA launched the HERA Stakeholders Hub <sup>(19)</sup>, a secure and multifunctional platform designed to enhance collaboration across the EU pharmaceutical sector. This Hub facilitates direct communication between participants, as well as with HERA, on medical countermeasures and pharmaceuticals, including critical medicines. Its mission is to enhance cooperation, address supply chain vulnerabilities, and tackle medicine shortages, with the ultimate goal of contributing to a stable and reliable supply of strategic resources in the EU. The platform features a matchmaking tool, a cutting-edge feature connecting companies with potential partners for supply chain collaboration and research projects. HERA also started preparatory works to organise its first Industry Days in June 2025 with the objective of bringing together actors of the MCM supply chains.

In the framework of HERAInvest, in 2024, the European Investment Bank implemented the first two venture loans to selected small and medium enterprises in the EU working on innovative development of medical countermeasures. The funded projects address priority threats identified by HERA: CBRN threats and AMR. HERA continued to follow the implementation of HERA Invest by bringing an additional EUR 10 million top-up to the guarantee. HERA will continue to follow the preparatory work by Member States for potential **Important Projects of Common European Interest on Health (IPCEI)** which encourage cross-border innovations in areas such as critical medicines, AMR and emerging health threats such as CURE4Health and TECH4Health. HERA also ran a grant call on innovation in manufacturing to support the development of more efficient, greener and lower cost manufacturing processes to ensure that the supply of critical medicines and MCMs is robust and resilient and prepared in the event of future Public Health Emergencies.

In cooperation with DG BUDG, HERA will promote the goal of the proposed Strategic Technologies for Europe Platform (STEP) to support investments in companies that contribute to preserving a European edge on critical biotechnologies. For example, the creation of a European hub for vaccine development and the top-up to HERA Invest support European innovation in strategic technologies. Reaping the full benefits of biotechnology can help the EU economy grow in respect of priorities such as sustainable development, public health, and environmental protection.

**Strengthened knowledge and skills.** Building on the success of 2023 training events on stockpiling and procurement, HERA has delivered four capacity-building activities targeting public health authorities at EU Member States and EU4Health associated countries in the context of its 2024 training programme on management of MCM for preparedness and response to cross border health threats. The training events focussed on different topics

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<sup>(19)</sup> [Home | HERA Stakeholders Hub](#)

along the life cycle of MCM, including the Emergency Framework Regulation on measures to ensure access to crisis relevant MCM, management of stockpiles, the EUFAB initiative and on Pull incentives. The events were supported by experts from different EU Member States, partner organisations like the World Health Organisation or the Biomedical Advanced Research and Development Authority (BARDA) as well as the private sector. Overall, satisfaction rate from participants was over 80%.

In parallel, the report on the training needs and gap analysis carried out in late 2023 and in 2024 was finalised, allowing HERA to draft its training and exercise strategy and design a comprehensive training programme to be implemented in the upcoming years.

In 2024, HERA also organised two simulation exercises to test its readiness to respond to a non-intentional biological threat. The first exercise targeted different Commission services and Agencies, while the second exercise also targeted EU Member States, with the participation of NATO and WHO as observers. Both exercises aimed at testing coordination and information exchange processes at EU and EU-EU MS level. The feedback from both exercises on the 2024 exercise was overall positive although the exercise demonstrated that the current EU Health crisis framework needs to be streamlined, EU MS also called on HERA to provide guidance and recommendations, notably on estimation of needs and stockpiling. HERA also took part in the EU Integrated Resolve (PACE) 2024 exercise. A list of lessons learned, and recommendations have been made from these exercises.

## Specific objective 2: Crisis response readiness for health emergencies

### Crisis mode – response protocol.

In 2024, HERA has further operationalised its emergency response protocol by publishing an enhanced version which includes the first elements of the Emergency Framework Regulation (EFR) response governance. The emergency response protocol has also been used and tested by HERA staff on two occasions. The first exercise took place in June 2024, and it included a tabletop exercise with other EC services and agencies while the second exercise, in October, involved European Economic area (EU/EEA) Member States on testing coordination, and information exchange when needing to ensure access and availability of MCM in case of a serious cross border threat to health.

The Protocol is complemented by **Response blueprints** identifying the response measures to be taken when responding to a serious threat to health, in accordance with HERA prioritisation exercise. In 2024, HERA has kept updated a set of 10 Response blueprints covering threats ranging from pathogens with high pandemic potential to Chemical, Biological, Radiological and Nuclear (CBRN) ones. HERA continued to carry out a preparatory work for the implementation of Council Regulation (EU) 2022/2372 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, **in order to prepare for** a possible declaration of

health emergency<sup>(20)</sup> at Union level, and to be able to adopt swiftly the necessary implementing measures. More specifically, HERA continued working on the establishment of procedures for the **activation, prolongation and expiration of the framework**. This entailed primarily preparation of personal data protection implementing acts and other drafts of implementing acts.

**Response to outbreaks.** In 2024, HERA further improved its ability to help EU countries with outbreaks of emerging or existing diseases. HERA built on the lessons learned from the MPOX outbreak in 2023 and continued to follow up the implementation of the actions related to the detection of cross border health threats extending the activities, such as whole genome sequencing, testing capacity and wastewater monitoring. These intelligence gathering activities on potential threats will contribute to these readiness efforts. Possible response measures now include the activation of EU FAB, the deployment of stocks constituted under rescEU and the deployment of vaccines and therapeutics purchased via HERA's own procurement tools, such as for instance for avian influenza.

In August 2024, Africa CDC and the WHO declared public health emergencies due to a significant mpox outbreak in Democratic Republic of Congo (DRC) and other African countries. This situation highlighted the urgent need for a coordinated global response to contain the virus and protect public health.

HERA swiftly donated and shipped 215,000 mpox vaccine doses to affected countries in Africa in response to the public health emergency, which were purchased under the FWC in place through the Joint procurement Agreement. In addition, HERA coordinated a Team Europe initiative, mobilising over 566,000 mpox vaccine doses donated by 12 EU Member States, including the logistics and transport with DG ECHO and UNICEF which was 100% funded by the Commission. HERA also supported diagnostic and genetic sequencing with a €9.4 million grant. HERA continued to collaborate with Africa CDC on mpox vaccine donations, enhance access to mpox diagnostics and genetic sequencing to save lives and prevent mpox from becoming endemic.

**Provision of medical countermeasures in times of crisis.** Immediate access to needed medical countermeasures is essential in order to respond to health emergencies. Ensuring such access can be enabled by rapid public procurements and distribution of stockpiles. Through EU4Health, HERA ensured rapid mobilisation of funds in case of emergency. In 2024, the provision was activated to support Africa CDC's response against mpox. In addition, stockpiles of CBRN and other medical countermeasures of a value of EUR 1.2 billion have now been constituted under rescEU. In 2024, HERA worked on operationalising the management and deployment of the stocks in the most efficient way. In 2024, HERA coordinated the work on the development of a **common strategic approach to medicines stockpiling**, which was presented to the HERA Board in September 2024. To support the implementation of such a strategic approach, HERA launched a Joint Action on stockpiling in 2024 led by Finland. The technical work will start in June 2025.

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(20) Regulation (EU) 2022/2371 of the European Parliament and the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU

**COVID-19 vaccines/therapeutics and response to variants.** In 2024, HERA provided ongoing support to Member States in the implementation of the sole existing contract, particularly in ensuring the deliveries of the latest adapted vaccine targeting the newest variants. In 2025, HERA will continue supporting Member States, as well as, assisting interested contracting authorities in procuring jointly COVID-19 vaccines to ensure security of supply and a diversified portfolio. HERA will also continue supporting the development, manufacturing, and availability of improved vaccines against COVID-19. That strategy will incorporate a longer-term view, beyond the immediate threat of COVID-19 vaccines, to develop the EU's capacity to manage emerging health threats. In 2024, HERA also renewed the FWC for the therapeutic Remdesivir from Gilead under the Joint procurement Agreement.

Since the outbreak of COVID-19, several SARS-CoV-2 variants of concern have been detected, reported and monitored. These variants can pose a significant challenge to overcoming COVID-19, notably as they can undermine current vaccine strategies. On the proposal of HERA, the Commission extended the mandate of the European expert group on SARS CoV-2 variants to advise on the need to develop new or adapted vaccines in view of new emerging variants.

**Response to Russia's invasion of Ukraine.** Since the start of Russia's invasion of Ukraine, HERA has worked closely together with DG ECHO's Emergency Response Coordination Centre to help channel medical countermeasures to Ukraine and neighbouring countries in need. Ukraine became an EU Civil Protection Mechanism (UCPM) participating country, so the strategic stocks of essential therapeutics and equipment for responding to cross-border health threats could be deployed to Ukraine too. HERA worked with EMA to monitor whether the invasion had an impact on the availability of medicinal products in Europe. HERA monitors the epidemiological and humanitarian situation as well as the chemical, biological, radiological and nuclear risks affecting both Ukraine and the EU. Together with DG ENER, JRC and other services, HERA followed the work of the International Atomic Energy Agency in Ukraine and Russia, closely follows the situation at Ukrainian nuclear power plants, including in Zaporizhzhia. HERA stood ready to support the timely provision of medical countermeasures for any cross-border health threat, including radiological and nuclear incidents - in liaison with UCPM and the ERCC - and intends to continue doing so for as long as it will be required. HERA has worked with Ukraine to address critical medicine shortages and to improve access to vital medical countermeasures. Ukraine has joined the Critical Medicines Alliance, together with six Ukrainian pharmaceutical companies. This was launched in January 2024, as a consultative mechanism aiming to identify key areas and priorities for action, proposing solutions to strengthen the supply of critical medicines. Furthermore, HERA will continue exploring opportunities to strengthen manufacturing capacity, supply chains and resources in Ukraine. In 2024, HERA has launched a study that will provide a detailed inventory and analysis of pharmaceutical manufacturers, production facilities, supply chains, and resources in Ukraine, with a view to enhancing the resilience and security of supply of critical medicines and active pharmaceutical ingredients.

Moreover, HERA will continue supporting medical needs far beyond the humanitarian and war-zone related situation, such as the provision of paediatric vaccines. Continued

coordination with international actors like WHO and UNICEF will be of paramount importance in that regard in 2025 too.

**HERA Review:** Article 8 of the Commission Decision C(2021)6712 of 16 September establishing HERA foresees an in-depth review of the implementation of the operations of HERA, including its structure and governance, as well as assessing in particular any need to modify the mandate of HERA and the financial implications of any such modification.

With the Secretariat-General being the responsible service for the review report, HERA assists the assessment by the means of a study launched with an external contractor. The study was launched in October 2023 with the main objective of assessing the extent to which HERA's mandate and tools (legal basis, structure, governance, funding) has allowed it to effectively and efficiently contribute to strengthen the EU's health emergency preparedness and response and fulfil the tasks as laid down in Commission Decision C(2021) 6712, based on qualitative and quantitative evidence. It also looks at the complementarity with work carried out by other EU bodies. This analysis further supports the Commission's assessment of the need to establish HERA as a distinct entity, considering relevant agencies or authorities active in the field of health preparedness and response. The report also analyses to what extent the HERA mandate fits the current health challenges and if any changes to this mandate are needed. The study takes into account the results of an open public consultation launched in the "Have Your Say" portal on 27 November 2023, as well as feedback to the Call for Evidence and extensive targeted consultation activities comprising surveys and interviews with stakeholders.

### Specific objective 3: International resilience and appropriate response readiness for health emergencies

The COVID-19 crisis has clearly illustrated the need to ensure equitable global access to vaccines and other medical countermeasures. At the same time, COVID-19 has also clearly shown deficiencies in global preparedness, prevention and detection of health emergencies. HERA has therefore continued to pursue several activities at an international level throughout 2024: collaboration with global partners to address international supply chain bottlenecks, expanding global production, reinforcing global surveillance, facilitating cooperation and support with global actors to ensure availability and accessibility for medical countermeasures for the Union and third countries, focusing in particular on Africa in collaboration with DG INTPA. Building expertise to develop local manufacturing and distribution capacities and supporting access to EU funded or EU procured medical countermeasures.

Furthermore, HERA supported the Africa Centres for Disease Control and Prevention to counteract the Mpox epidemic by reinforcing testing and sequencing capacities, while also increasing its ability to share data and cross-reference important variants characterisations.

In addition, HERA will continue to actively contribute to Commission's exercise of the external representation in global fora, such as G7 and G20, where such issues are also discussed.

HERA will continue to participate in the WHO-led interim MCM network. HERA also continued supporting the Commission's ambition to increase the availability for funding for pandemic preparedness and response (PPR) globally, in particular through the Pandemic Fund and other global health institutions.

Finally, in 2024, HERA has concluded two contribution agreements, with WHO and UNEP respectively, support strategies, capacity and data for global wastewater and environmental surveillance. An additional contribution agreement with WHO Logistics Hub Dakar was also signed in 2024 to support the expansion of the stockpiling of critical medical countermeasures in regional hubs, in particular in the Dakar Hub, allowing for significant cost savings and reduction of lead times for critical supplies during emergencies in West and Central Africa.

### Global health security and access to medical countermeasures

In 2024, HERA has continued supporting global, regional and national initiatives, **to ensure the availability and accessibility of medical countermeasures and strengthen the capacities of Low-and Middle-income Countries (LMIC) to carry out surveillance and whole genome sequencing activities.** In this context, HERA responded to the call of Africa CDC to support its efforts in tackling the ongoing multi-country mpox outbreak by procuring and donating 215,00 doses of the MVA-BN® vaccine to the affected African countries. HERA is also coordinating the donation of additional 367,500 doses pledged by the EU Member States in a Team Europe approach. Additional support to the African continent includes a EUR 9.4 million pledged action to support the Africa CDC's "Partnership to Accelerate Mpox Testing and Sequencing in Africa" project, expected to significantly boost diagnostics and sequencing efforts.

Importantly, HERA is responsible for implementing **Joint Procurement at EU level for medical countermeasures against serious cross-border threats to health.** Participation in the Joint Procurement Agreement now totals 37 signatories, covering around 470 million people, including all EU and EEA population and almost all Candidate and Potential Candidate Countries.

### Collaboration with global partners

Throughout 2024, HERA continued its active collaboration with international partners by developing new and implementing existing working arrangements, focusing on preventing and addressing serious cross-border health threats in the area of medical countermeasures.

HERA has ongoing active collaboration with the United States, Japan, Republic of Korea, Canada, the World Health Organization, United Nations Environment Programme, philanthropic foundations, such as the Bill & Melinda Gates foundation and the Africa Centres for Disease control and Prevention (Africa CDC). With some key partners, such as the U.S. Department of Health & Human services, the Ministry of Health and Welfare of the Republic of Korea, the Japan Agency for Medical Research and Development, or the WHO Hub for

Pandemic and Epidemic Intelligence, the cooperation was formalised through **administrative or working arrangements** <sup>(21)</sup>. Furthermore, HERA has strengthened cooperation with relevant international organisations (e.g., WHO, UNICEF, Gavi, CEPI, BMGF <sup>(22)</sup>, UNEP <sup>(23)</sup>, etc.), including via i-MCM-Net and the Mpox Access and Allocation Mechanism. The European Commission (HERA, DG INTPA, DG SANTE, DG RTD) signed a Working Arrangement with Africa CDC, in the margins of the High-level conference on the EU-AU health partnership on March 20, 2024. Further cooperation arrangements are anticipated in 2025 with other key partners.

HERA is also contributing to the creation of the African Pooled Procurement Mechanism by Africa CDC, by sharing its experience and expertise on Joint Procurement at EU level.

HERA supported the WHO-implemented Health Technology Access Program (HTAP) as the successor of the COVID-19 Technology Access Program (C-TAP), with the aim to ensure equitable and affordable access to essential health products globally. HTAP maintains its focus on pandemic preparedness and response and aims at facilitating access to health products through the voluntary sharing of intellectual property, knowledge, and data among technology developers with a focus on LMICs.

HERA has also continued to work closely with EU candidate countries, potential candidates, and neighbourhood countries.

**Governance and coordination.** HERA's work on medical countermeasures necessary for health preparedness and emergency response to health emergencies has an impact on several sectors, such as health, research, innovation and industry. HERA's Governance can be regarded as a **vibrant hub of expertise**, bringing together nearly 225 specialists from Member States, the EMA, ECDC, various key stakeholders, and civil society. This diverse and dynamic collaboration is **unique to HERA**, setting it apart as a Commission service that thrives on regular, meaningful interactions with the broader community.

The continuous engagement and interaction with the HERA Advisory Forum as well with the Joint Industrial Cooperation Forum and the Civil Society Forum has further enabled effective communication channels with crucial stakeholders. In response to interest in mapping HERA-like structures in the field of medical countermeasures, HERA presented in 2024 the results of a dedicated study it had funded on existing structures with relevant mandates, tasks and functions to HERA within **Member States** and **globally**. The study's primary goal was to provide a comprehensive overview of organisations with missions and functions similar to HERA's.

This knowledge will inform the Commission's ongoing work to further develop its networks and international cooperation. HERA has built close links with different Commission services. A HERA Inter-service steering group (HERA ISSG) has been set-up, which is systematically consulted.

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<sup>(21)</sup> or Letter of Intent, in the case of CEPI.

<sup>(22)</sup> Bill & Melinda Gates Foundation

<sup>(23)</sup> UN Environment Programme

HERA has examined a possible contribution to the objective of simplification and rationalisation of reporting obligations. Since there are no legally binding acts under the responsibility of HERA that provide for reporting obligations creating burden on businesses and national administration, HERA will not contribute to this objective this year. However, should binding legal acts introduce reporting obligations, especially following the activation of measures related to public health emergencies outlined in Regulation (EU) 2022/2372, HERA intends to minimize such obligations to only essential requirements for obtaining meaningful information from businesses and public administration. HERA has formulated a plan to assess the proportionality and the necessity of any requests, in case the relevant public health emergency measures are activated, concerning the production, availability and supply of crisis-relevant medical countermeasures, including the establishment of an inventory of crisis-relevant medical countermeasures production and production facilities, and, as appropriate, of crisis-relevant raw materials, consumables, medical devices, equipment and infrastructure, and including measures aimed at increasing their production in the Union.

**Communication.** HERA has implemented several actions in 2024, with the aim of raising awareness of its initiatives and main strands of work towards both external and internal audiences.

To enhance HERA's strategic role within the EU, a campaign targeting selected EU countries was launched in April 2024, called the HERA Info Days. The series of events aims to present to a wide portfolio of stakeholders (national authorities, industry, academia, universities, CSOs and NGOs) HERA's mission and policy priorities, including actions under EU4Health and Horizon Europe. Considering these overarching objectives, the series of events also seeks to inform about funding and matchmaking opportunities. The series targets 10 countries over a period of 24 months. In 2024, countries selected were: France, Germany, Hungary and Poland. In 2024 the events have been organised in collaboration with HaDEA and EU4Health national focal points (NFPs), and the same scheme will be replicated for 2025.

In order to promote HERA's pivotal role in fostering collaboration across the European health preparedness landscape, emphasis is being put on increasing the visibility and reach of the recently launched HERA Stakeholders Hub. To raise awareness and drive adoption of this key deliverable, a series of targeted communication activities is being prepared. These include the production of a brief promotional video to highlight the Hub's features, an in-depth online tutorial to guide users through its functionalities, and the development of a multilingual brochure to ensure accessibility across the EU.

The communication activities of DG HERA also extend to outreach towards the general public. In May 2024, HERA has participated for the first time in the EU Open Day. The objective of this corporate event, gathering different European institutions, is bringing the EU closer to its citizens and residents. For 2024 edition, HERA was associated to two different villages, and proposed two different activities: an engagement one, specially conceived for the younger public, and a quiz. The first edition was a success for HERA, and this is why the communication team is currently active member of the interservice group for the organisation of 2025 EU Open Day.

With a focus on visibility, stakeholder engagement, and collaboration, HERA has implemented a dynamic communication strategy through diverse social media channels, such as LinkedIn and X (formerly Twitter). At the same time, the HERA website continues to play a critical role as an external information hub, offering the public and stakeholders' easy access to the latest updates, initiatives, and resources. Webpage content (corporate department page and policy pages) is actively maintained and updated, to ensure external audiences are informed about key initiatives and achievements. Regularly published news articles and refreshed content, including on dedicated pages like the Critical Medicines Alliance, serve to highlight HERA's ongoing work and successes. By monitoring website traffic and user engagement trends, the communication team ensures that HERA's digital presence remains dynamic, accessible, and aligned with stakeholders' informational needs. This approach not only enhances transparency, but also strengthens HERA's role as a trusted source in health preparedness and response.

Moreover, an external newsletter has been launched in February 2024, to regularly engage with external audiences and keep them updated about the most recent and relevant activities. The newsletter, produced on a quarterly basis, features a wide array of formats, for example a feature interview, a highlights section, or a thematic segment called "Discover HERA's activities". In 2024, HERA released four issues (February, May, July, and October).

In an effort towards branding and with the goal of positioning HERA in a field that may appear crowded and confusing to those who are not familiar with EU and global health security entities, the communication team has also worked in synergy with an external agency to produce a series of promotional brochures and audiovisual outputs. The promotional brochures detail the main areas of activity of HERA and have been used by the staff at different promotional occasions. The audiovisual outputs, on the other hand, replicate the storyline adopted for the brochures, but in a visually appealing and catchy fashion. Such products have been used at different dissemination occasions, too.

Internally, the communication team also regularly publishes articles on the HERA Intranet, to maintain employees and Commission staff updated on key achievements, upcoming events, and organisational news. This internal communication helps promote transparency and increase awareness of HERA's work.

## 2. INTERNAL CONTROL AND FINANCIAL MANAGEMENT

Management monitors the functioning of the internal control systems on a continuous basis and carries out an objective assessment of their efficiency and effectiveness. In annex 7, there is a list and details of the reports that have been considered. The results of the above assessment are explicitly documented and reported to the Director-General.

### 2.1. Control results

Management uses control results to support its assurance and reach a conclusion about the cost-effectiveness of those controls, meaning whether the right balance between the following elements is achieved:

- **Effectiveness** – The level of error found, based on the controls carried out.
- **Efficiency** – The average time taken to inform or pay.
- **Economy** – The proportionality between the costs of controls and the funds managed.

#### 2.1.1. Overview of the budget and relevant control systems (RCS)

This section presents an overview of HERA's activities and related amounts of payments during the year. Since DG SANTE carries out financial initiation and verification for all HERA financial transactions, the relevant control systems (RCS) with the main indicators used to measure the level of compliance with legality and regularity could be found in DG SANTE's AAR.

HERA's assurance building, and materiality criteria are outlined in the annual activity report annex 5.

In 2024, HERA had payments of EUR 44.2 million under the EU4Health programme. Approximately half of it (45% of the total payments), EUR 19.9 million, were paid as pre-financings.

Under indirect management, HERA paid EUR 19.8 million as pre-financings to the WHO, GARDP and UNEP; EUR 15.8 million represented first pre-financing for 4 contribution agreements signed in 2024 – with GARDP on supporting the development of antibiotics to strengthen global preparedness and response, with WHO to support the logistical operations for medical countermeasures in Africa, and one with UNEP and one with WHO to support the strategies, capacity and data for global wastewater and environmental surveillance. The remaining EUR 4 million of pre-financings under indirect management represented second pre-financings for 3 contribution agreements signed in 2022 with WHO to support the activities of the WHO Hub for pandemic and epidemic preparedness, to support the member states of the African Union to build genomics capacity to detect and characterize SARS-COV-2, and for development of medical countermeasures relevant against antimicrobial resistance.

Under direct management, for procurement, HERA paid EUR 0.09 million of pre-financing to a contractor to initiate a study mapping the pharmaceutical facilities, supply chains and resources in accession countries.

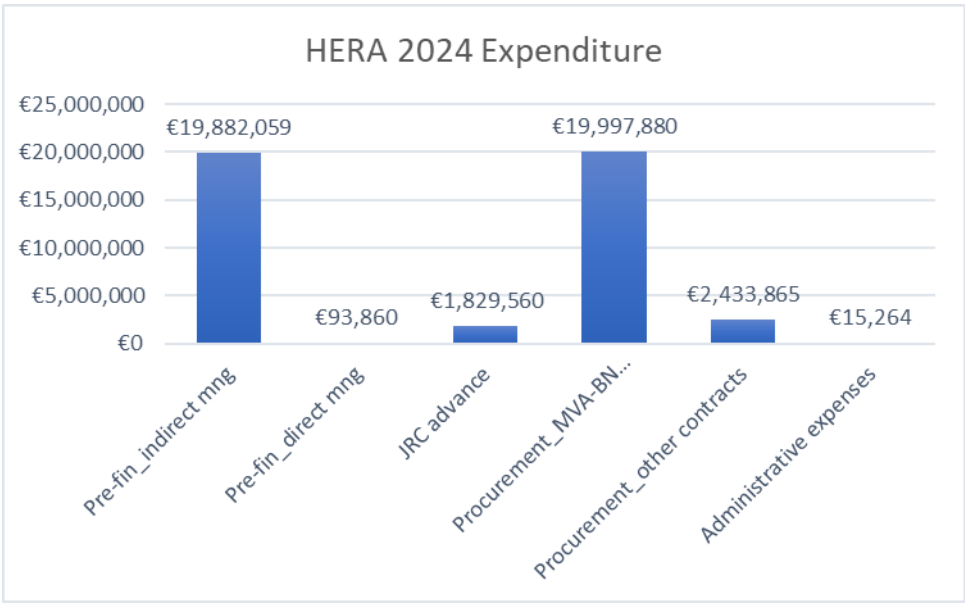
Thus, excluding the pre-financings, the amount that represents relevant expenditure for HERA’s assurance in 2024 comes up to EUR 24.2 million, and it covers payments on procurement contracts and an advance to JRC executed in direct management mode.

In 2024, EUR 1.2 million were advanced to JRC on the basis of an administrative agreement signed in 2024 to support the epidemic intelligence from open sources.

EUR 19.9 million or 90% of the relevant expenditure is attributed to the purchase of 175,420 doses of Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN®) against smallpox disease donated to Africa Centre for Disease Control and Prevention. The purchase was carried out through an existing framework contract.

The remaining EUR 2.5 million were spent on procurement contracts, mostly IT services to support the ATHINA project, communication services to raise awareness and understanding of HERA purpose and actions, and legal advice.

HERA spent EUR 0.02 million on administrative expenditure.



All HERA 2024 payments were executed by DG SANTE on the basis of a Memorandum of understanding, in compliance with DG SANTE control strategy. DG SANTE has confirmed that there were no issues to report concerning the HERA files verified by DG SANTE in 2024.

Besides the ex-ante control on the financial aspects of the operations carried out by DG SANTE, HERA has established robust ex ante controls relating to the operational aspects of the operations. For operational credits, a detailed annual work programme is adopted by the Commission specifying the areas for which requests for proposals and calls for tenders will

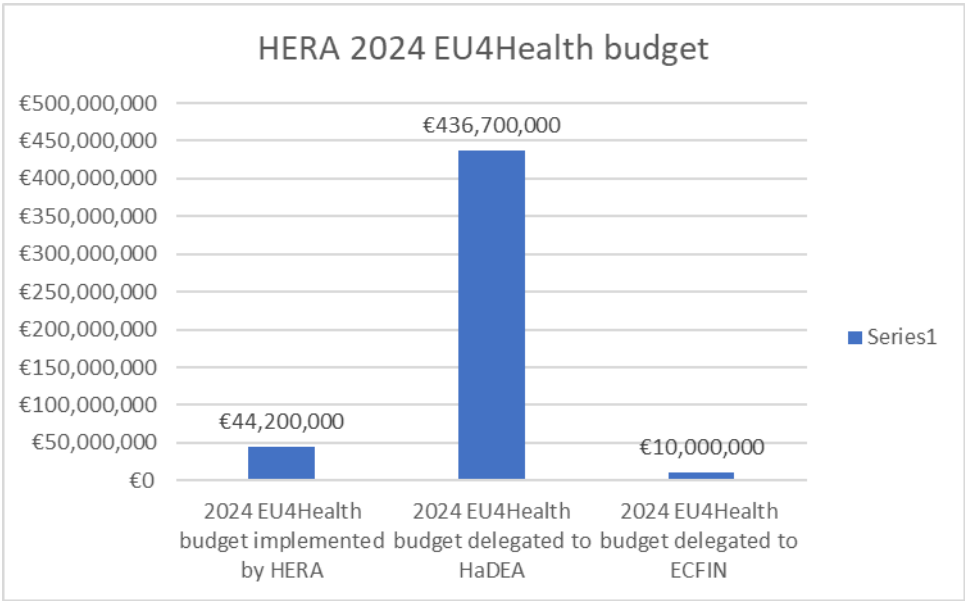
be organised. For administrative budget, all actions are pre-approved by management. Tender specifications (in the case of procurement) and descriptions of the actions (in the case of contribution agreements) are validated by the Authorising Officer. Timing is monitored and planning updated through budget implementation reports prepared on a regular basis.

HERA uses templates for terms of reference, exclusion and selection criteria that follow the Commission guidelines. The Authorising Officer validates the evaluation results and takes the award decision. Contract provisions and special and general conditions for contribution agreements follow the models of the Commission.

**HERA delegated budget in 2024:**

In 2024, HERA delegated through a type II co-delegation EUR 436.7 million to the Health and Digital Executive Agency (HaDEA) in order to implement actions envisaged with the 2024 EU4Health work programme in the area of crisis preparedness.

Further, in line with the 2024 EU4Health work programme, HERA delegated through a type II co-delegation EUR 10 million to DG ECFIN to support investments into R&D of medical countermeasures for pandemic preparedness. HERA Invest contributed to the Thematic Innovation - Research, Innovation and Digitalisation Window (RIDW) financial product implemented by the European Investment Bank (EIB) under the Invest EU programme.



Also, in 2024, and with regard to the 2024 Horizon Europe work programme, there were projects for a total budget of EUR 82 million earmarked for HERA, and in addition, there are projects for approximately EUR 73 million still in the pipeline, expected to be earmarked for HERA in the coming months.

HERA has entrusted partner DGs with the implementation of internal control processes to ensure the adequate management of the risks related to the legality and regularity of the underlying transactions they are responsible for, taking into account the multiannual

character of programmes and the nature of the payments concerned. The partner DGs bear the responsibility for the delegated appropriations and report on them in their own AAR.

For the 2024 reporting year, the executive agency HaDEA has itself reported reasonable assurance on the delegated EU4Health budget. HaDEA has signalled no serious control issues, and no reservation has been made in the implementation of the EU4Health Programme. As DG SANTE is the lead parent DG for HaDEA, DG SANTE has developed control strategy for HaDEA which encompasses both the delegated EU funds and the subsidy payments to the executive agency's operating budget. DG SANTE control strategy for HaDEA is detailed in DG SANTE 2024 AAR.

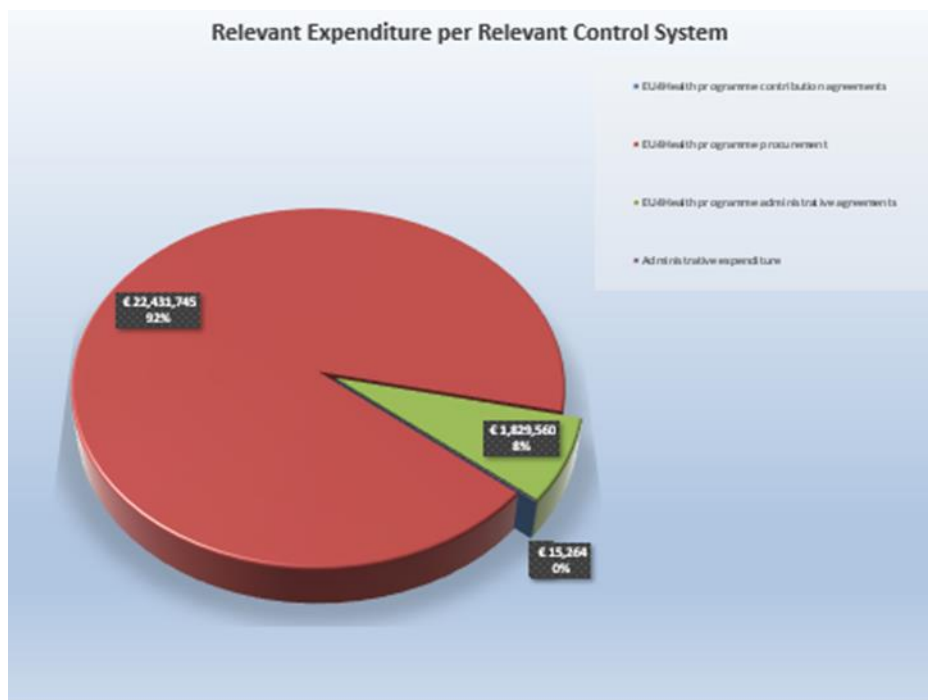
In 2024, the authorizing officer of DG ECFIN did not communicate any events, control results or issues which could have a material impact on assurance with regard to the HERA Invest funds HERA co-delegated to DG ECFIN.

HERA recorded 2 exceptions to the standard procedures in financial management in 2024. HERA AOD did not receive any binding instructions which he considered to be irregular or contrary to the principle of sound financial management, and therefore no cases of 'confirmation of instructions', in the sense of Article 92(3) FR, are reported.

## 2.1.2. Effectiveness of controls

### ***a) Assessment of control results per RCS for expenditure***

In 2024, all HERA payments were initiated and verified by DG SANTE on the basis of a Memorandum of understanding. HERA has entrusted the adequate management of the risks relating to the legality and regularity of the underlying transactions to DG SANTE, and all HERA payments were carried out in compliance with DG SANTE control strategy. The coverage of the Internal Control Objectives and their related main indicators are thus described in detail in DG SANTE 2024 AAR.

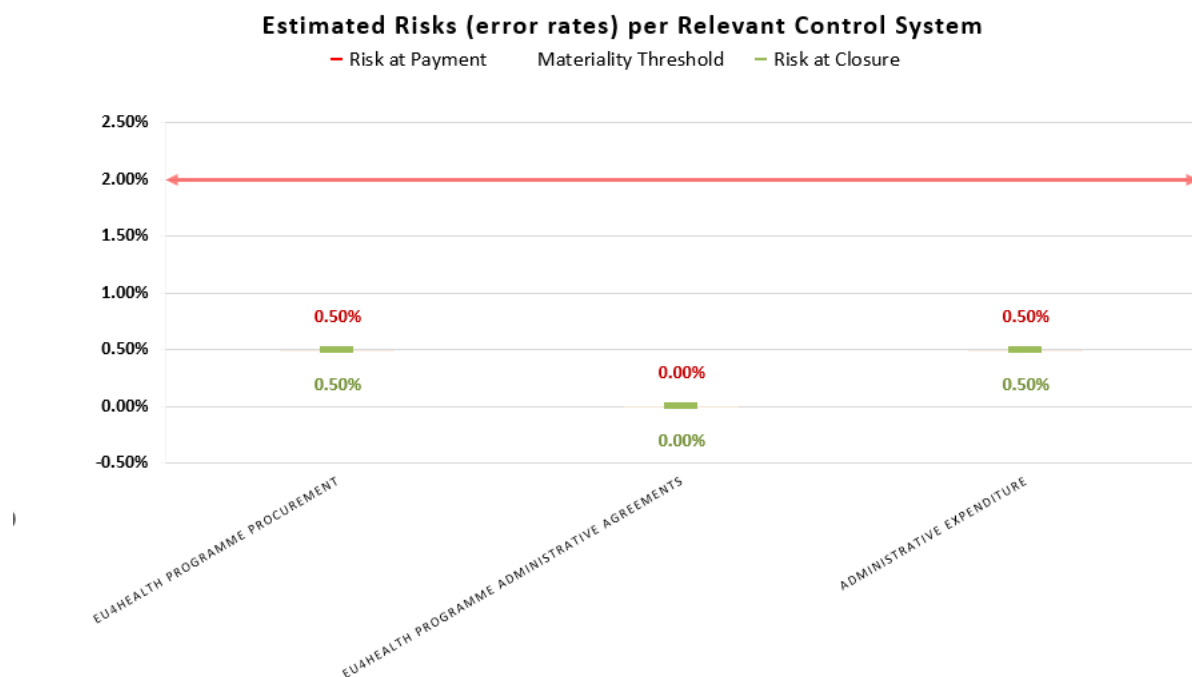


In 2024, HERA's portfolio consisted of relatively low-risk type of expenditure related to payments on procurement contracts (EUR 22.5 million). The purchase of smallpox vaccines was carried out on the basis of an existing framework contract and the remaining payments were primarily low and middle-value procurement contracts. In accordance with DG SANTE control strategy, no ex-post audits took place on the procurement contracts, and an error rate of 0.5% is set for these low-risk types of expenditure, the future corrections are estimated at 0%.

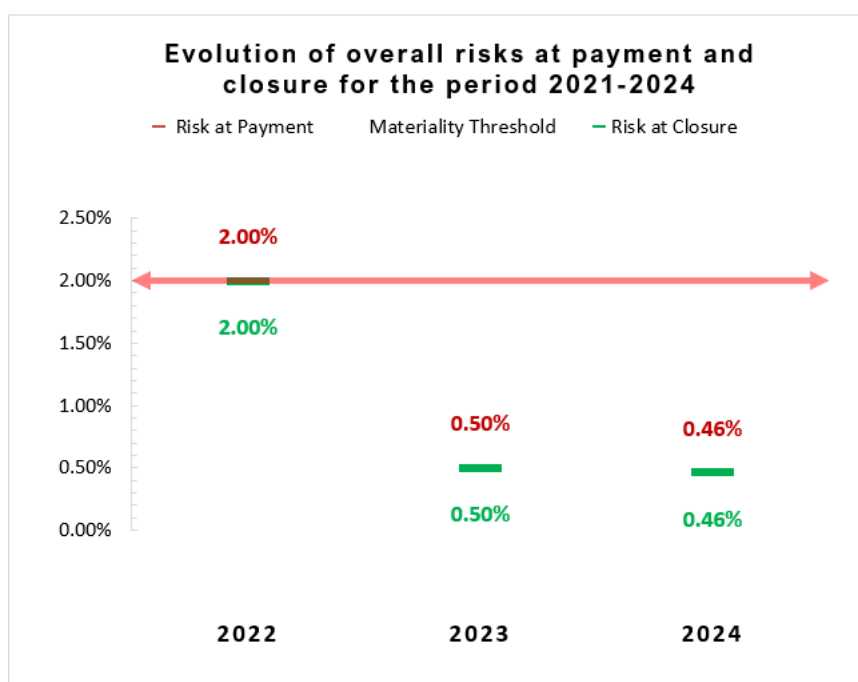
In 2024, HERA advanced EUR 1.8 million to DG JRC as stipulated with the signature of an administrative arrangement; however, no error rate is applied. This represents internal transfer for the Commission, and the advance will be cleared at the end of the project.

On the negligible amount of administrative expenditure incurred in 2024, HERA applies the standard for this segment 0.5% error rate.

For the 2024 reporting year, DG SANTE has not raised any significant issues which could have a material impact as regards the legality and regularity of HERA financial operations. Thus, HERA concludes that the control objectives as regards legality and regularity have been achieved.



***b) Estimation of the overall risk at payment and risk at closure***



The estimated overall risk at payment for 2024 expenditure is the AOD's best conservative estimate of the amount of relevant expenditure during the year, not in conformity with the contractual and regulatory provisions applicable at the time the payment was made. As DG SANTE carries out only ex ante controls for HERA, in compliance with their control strategy, consequently for the risk at payment and risk at closure, HERA is using the Commissions' flat rate of 0,5% as a conservative estimate for low-risk type of expenditure.

There is a decreasing trend since 2022 as in 2022, HERA had payments on grants with higher risk at payment and closure in accordance with DG SANTE control strategy whereas in 2023 and 2024, HERA payments were mostly carried out on procurement contracts.

For an overview at Commission level, the departments' estimated overall risk at payment, estimated future corrections and risk at closure are consolidated in the AMPR.

### ***c) Quantitative benefits of controls: Preventive and corrective measures***

With its ex-ante controls, performed by DG SANTE, HERA has an effective mechanism in place for detecting and correcting errors, reaching in total EUR 0.0003 million of corrections for 2024. Please see details in annex 3 table 8.

This is similar to last year with EUR 0.01 million.

### ***d) Fraud: prevention, detection, and correction***

HERA developed in 2023 its first anti-fraud strategy as well as an action plan with a duration of three years. The strategy was developed based on the methodology provided by OLAF. Its implementation is being monitored and reported to the management through a yearly risk assessment exercise. All necessary actions from the HERA's anti-fraud strategy including those that are implemented on a continuous basis were taken in 2024 except the launch of a staff survey on the level of awareness of how to report fraud. The launch is scheduled to take place after a critical mass of staff will have participated in the fraud prevention training 'Fraud – Staying vigilant'. In addition, the staff was also encouraged to take part in the training on ethics. HERA has been pursuing the other actions included in the action plan of its anti-fraud strategy: the Intranet page on anti-fraud is kept up to date, an informatory note from DG is sent to all staff and HERA participates in and disseminates the relevant information from the Fraud Prevention and Detection network (FPDNet).

HERA's anti-fraud strategy is in line with the objectives of the Commission's Anti-Fraud Strategy <sup>(24)</sup> and the related 2023 action plan <sup>(25)</sup>. HERA did not receive any financial recommendations from OLAF.

On the basis of the available information, HERA has reasonable assurance that the anti-fraud measures in place are effective. However, the additional measures such as promotion of available trainings will be taken in order to further improve awareness in this area.

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<sup>(24)</sup> [Communication from the Commission on Commission Anti-Fraud Strategy: enhanced action to protect the EU budget](#)

<sup>(25)</sup> [Commission Staff Working Document – Action Plan](#) accompanying [Communication from the Commission on Commission Anti-Fraud Strategy: enhanced action to protect the EU budget](#)

### 2.1.3. Efficiency of controls

In 2024, DG SANTE carried out financial initiation and verification for all HERA financial transactions, based on a Memorandum of Understanding. Thus, the efficiency of controls depended on the systems and controls set up by DG SANTE.

The only efficiency indicator relevant for HERA is the time-to-pay, and for 2024, 100% of the amounts due were paid on time. In 2024, 11 payments out of a total of 76 payments were delayed; however, they concerned very low amounts, and therefore, do not affect the excellent score.

### 2.1.4. Economy of controls

In 2024, DG SANTE carried out financial initiation and verification for all HERA financial transactions, based on a Memorandum of Understanding. Thus, the cost of controls depended on the systems and controls set up by DG SANTE.

### 2.1.5. Conclusion on the cost-effectiveness of controls

Based on the most relevant key indicators and control results reported above, HERA has assessed the effectiveness, efficiency and economy of its control systems and reached a positive conclusion on the cost-effectiveness of the controls for which it is responsible.

## 2.2. Audit observations and recommendations

In 2024, there were no audits carried out by the Internal Audit service (IAS) or the European Court of Auditors that resulted in recommendations/ findings for HERA that were related to financial management and internal control or affected HERA's control systems.

### 2.2.1. Internal Audit Service (IAS)

In its contribution to the 2024 Annual Activity Report process, the Internal Audit Service concluded that HERA internal control systems in place for the audited processes are effective.

## 2.3. Assessment of the effectiveness of internal control systems

The Commission has adopted an Internal Control Framework based on the highest international standards. <sup>(26)</sup>

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<sup>(26)</sup> The Committee of Sponsoring Organizations of the Treadway Commission Internal Control Integrated Framework, the golden standard for internal control systems.

HERA has adapted the Internal Control Framework to their specific characteristics and organisational structure. The internal control systems are suited to achieving its policy and internal control objectives in accordance with the internal control principles, having due regard to the risks associated with the environment in which it operates.

HERA has assessed its internal control system during the reporting year and has concluded that it is effective, and the components and principles are present and functioning well overall, but some improvements are needed as minor deficiencies were identified related to the completion of the mandatory training under principle 8.

The Commission has adopted an Internal Control Framework based on international good practice, to ensure the achievement of its policy and management objectives. Compliance with the internal control framework is a compulsory requirement.

HERA uses the organisational structure and the internal control systems suited to achieving its policy and internal control objectives in accordance with the internal control principles and has due regard to the risks associated with the environment in which it operates.

For the assessment of the effectiveness of the internal control systems, HERA followed the methodology established in the 'Implementation Guide of the Internal Control Framework of the Commission'. In order to detect possible control deficiencies HERA used the following information sources:

- The results from the review of the internal control monitoring criteria set out in HERA Internal Control Framework;
- HERA risk assessment exercise at DG level;
- Exceptions to rules and procedures, including non-compliance events or cases of "confirmation of instructions";
- Issues raised by the authorising officers by delegation;
- Audit observations of the IAS and the Court of Auditors.

In 2024, there were 2 recorded exceptions and no cases of confirmation of instructions (art 93.2 FR). There were no weaknesses reported by staff and no issues were raised by the authorising officers by delegation. There were no recommendations reported by the IAS and the European Court of Auditors on HERA internal control framework.

As HERA's financial management is fully delegated to other entities, the internal control in the context of the AAR mainly refers to the implementation of the internal control framework and its 17 principles for its non-financial operations.

No significant risks were identified which could have a material impact on the achievement of the internal control objectives and therefore on assurance.

The self-assessment of the implementation of HERA internal control framework was finalized in time for the completion of the AAR 2024.

The self-assessment conducted by HERA concluded that in 2024, HERA had 16 internal control principles that were present and functioning well and 1 internal control principle, namely principle 8, that was partially present with minor improvements required.

Visible improvements can be noted in comparison to 2023 where only 12 internal control principles were present and functioning well, 1 was partially present with major improvements required and 3 with minor improvements.

In 2024, HERA staff participated to the first HR Staff Survey since its creation. The results of this staff survey allowed to reinforce the assessment of many monitoring criteria. In addition, the average time to reply to access to documents requests has been improved in order to respect the deadline envisaged by the Regulation 1049/2001 on public access to documents.

These major improvements are the result of the consistent efforts HERA has put in the area of building institutionally and growing out of its infant phase as a solid and fully operational organization with well-developed internal processes.

However, the risk assessment has identified that in order to be able to fully achieve its objectives, HERA would require more staff in particular on financial related issues, between 2025 and 2027 as assessed in the context of the annual budgetary process.

In line with the Commission's Internal Control Framework, HERA has assessed its internal control system during the reporting year and has concluded that it is effective, and the components and principles are present and functioning well overall, but minor improvements are needed as a minor deficiency was identified related to the percentage of staff having attended the course on "Fraud – staying vigilant" in 2024. This deficiency is mainly due to the lack of courses programmed on fraud. A lot of staff has expressed interest to attend but no availabilities were offered in 2024.

## **2.4. Conclusions on the assurance**

This section presents the conclusion on the assurance of the assessments made in sections 2.1, 2.2 and 2.3.

The information reported in section 2.1 is comprehensive, complete (as regards the coverage of the budget delegated to HERA AOD) and reliable. Adequate control indicators exist, and the results indicate that all expenditure represents a true and fair view, resources are used for the intended purpose, there is sound financial management, transactions are legal and regular, and there is no omission of significant information.

In conclusion, based on the elements reported above, management has reasonable assurance that, overall, suitable controls are in place and working as intended; risks are being appropriately monitored and mitigated; and necessary improvements and reinforcements are being implemented. The Director-General, in his capacity as Authorising Officer by Delegation has signed the Declaration of Assurance.

## 2.5. Declaration of Assurance

*Declaration of Assurance*

*I, the undersigned, Laurent Muschel*

*Acting Director-General of HERA until the 31<sup>st</sup> of March 2025*

*In my capacity as authorising officer by delegation*

*Declare that the information contained in this report gives a true and fair view <sup>(27)</sup>.*

*State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.*

*This reasonable assurance is based on my own judgement and on the information at my disposal, such as the results of the self-assessment, ex-post controls, [the work of the Internal Audit Service - delete this if not applicable] [and the lessons learnt from the reports of the Court of Auditors - delete this if not applicable] for years prior to the year of this declaration.*

*Confirm that I am not aware of anything not reported here which could harm the interests of the institution].*

*Brussels, 31.03.2025*

*(signed)*

*Laurent Muschel*

*(Acting) Director-General*

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<sup>(27)</sup> True and fair in this context means a reliable, complete and correct view on the state of affairs in the DG/Executive Agency.

## 3. MODERNISING THE ADMINISTRATION

### 3.1. Human resource management

In 2024, HERA's expansion persisted, reaching a staff of 107 staff by the end of the year. All interview panels adhered to the principle of gender balance. The gender balance was maintained at 50% among middle management and deputies. Moreover, 5 Team Leaders were appointed of which 3 females and 2 males. The organisation's evolution continued with a comprehensive set of team events for all units. Staff forum at the level of the Directorate General as a whole, enabled organisational enhancements as a follow up to the staff survey in 2023. The Director-General and the management team, recognising the significance of staff engagement, met newcomers in two induction meetings. These close interactions between management and staff as well as staff involvement in shaping HERA contribute significantly to staff motivation and engagement.

### 3.2. Digital transformation and information management

#### Digital Transformation

In 2024, HERA started the development of the foundation of an information platform, that will allow for detection, analysis and monitoring, of pertinent health threats, related to an outbreak of a specific disease and bottlenecks in supply chain of crisis-relevant Medical Counter Measures. This HERA IT platform (HERA's Advanced Technology for Health Intelligence and Action IT Platform or ATHINA) will support the HERA activities in both preparedness and crisis mode. In addition, HERA successfully completed the development of the ATHINA Stakeholder Portal Hub, a dynamic space that aims to contribute to a stable and innovative supply of medical countermeasures and critical medicines across the EU.

In line with the Commission Digital Strategic objectives, HERA has identified the following key initiatives:

#### ***Strategic Objective 1: Improving Digital Culture:***

To ensure that all key users of the HERA IT platform have sufficient digital skills to be able to leverage the full functionality, training sessions will be provided for the HERA IT platform, and it is expected to be a key success criterion for the implementation of the platform.

In 2024, HERA promoted Cyber Security awareness and the use of Artificial Intelligence by knowledge hours and info sessions, and this in collaboration with other Commission Services. Data Protection best practices were provided to newcomers to HERA as part of the welcome pack.

### ***Strategic Objective 2: Digital-ready EU policymaking:***

While no major IT related policy making initiatives were on the 2024 horizon for HERA, the planned activities in 2024 were carried out to implement the current legislative initiatives and to provide a return on experience towards the policy teams on the ease of IT implementation of policy initiatives. Furthermore, HERA promoted awareness around digital-ready policymaking within the DG by promoting training on digital-ready policymaking.

### ***Strategic Objective 3: Impact on Business-driven Digital Transformation:***

In 2024, as part of the analysis of future needs for the HERA IT platform, the potential to leverage Artificial Intelligence and other innovative approaches with other Commission Services across the emergency health response community at EU level and internationally, started.

In addition, HERA started analysing solutions on the use of data lakes and data spaces to facilitate collection, dissemination and analysis of large data sets.

In 2024, with the implementation of the first functionalities of the HERA IT platform, HERA focused on ensuring useful data visualisation and reporting tools as well as a thorough analysis of all the processes and exchanges between HERA and other Commission Services. This will allow to properly map the need for automation more broadly.

Furthermore, the first functionalities of the HERA IT platform were developed to facilitate the gathering of information through a secured survey module, reducing the workload of the HERA desk officers while ensuring the secure processing of the collected data.

### ***Strategic Objective 4: Impact on Seamless digital environment:***

In 2024, during the analysis of the future additional functionalities of the HERA IT platform, HERA applied the dual pillar approach (i.e., HERA will first try to reuse existing, ideally open-source, solutions or if appropriate go for off-the-shelf products) and continued to ensure proper analysis of all digital investments. Since HERA is a young organisation, there is no legacy tooling to be phased out.

The development of the HERA IT platform started and is expected to offer a user-friendly and better access to information on HERA to internal and external stakeholders.

### ***Strategic Objective 5: Impact on Green, secure and resilient Infrastructure:***

HERA is fully focused on the use of cloud solutions where security and data protection constraints are respected.

Cybersecurity and the overall information and IT security were key priorities for HERA. In 2024, HERA onboarded the use of the Commission Information Technology Security Risk Management methodology (ITSRM) for security assessment and consequence plans for the HERA IT platform. As the platform matures, audits will be enforced, and an effort will be made to improve the resilience of the platform to help mitigate against cyber-attacks.

During the development of the HERA IT platform, HERA ensured its full compliancy with data protection rules by continuous implementation of the therein-embodied principles.

## Information and IT security rules

In particular in its relations with public and private stakeholders, HERA handles sensitive non-classified ('SNC') and classified information ('EUCI') in several topics. In 2023, HERA established internal guidance on the handling of sensitive non-classified information, especially in relation to interactions with external public and private stakeholders. In 2024, the HERA Local Security officer promoted security awareness, managed requests for building and information access including for Personnel Security Clearance (physical and personnel security), and advised the staff on the security of EU classified information including in relation to related to classified contracts (industrial security), several meetings at CONFIDENTIEL UE/EU CONFIDENTIAL level were held.

The following guidelines and objectives were applied by HERA:

- Secure deployment of new cloud workloads using the principles and rules on outsourcing of critical infrastructures (CIs), the European Commission Managed Landing Zone and the recommendations of the Cloud Council (such as the management of Sensitive Non-Classified data in Infrastructure-as-a-Service and Platform-as-a-Service, the secure use of Software-as-a-Service)
- Finalisation and approval of the IT security plan of the HERA IT Platform before its entry into operation, with associated implementation of all security controls foreseen in it.
- Implementation of an effective risk management methodology and toolset such as ITSRM in collaboration with and with guidance from DIGIT.
- Mandatory cybersecurity and information security training and briefing for all newcomers.
- All staff is invited by the Commission for a yearly knowledge assessment related to cybersecurity essentials and cyber hygiene, to take an online training and participate in phishing exercises.

## Data protection

HERA remained committed to ensuring full compliance with data protection rules and rigorous implementation of related privacy principles.

This commitment is embodied in three pillars of HERA's activities:

- **Awareness raising:** HERA continued to raise awareness at all levels of staff, focusing on the needs of every actor and practical implementation. Information sessions have been organised separately for each unit and newcomers are now provided with an introductory course on data protection compliance upon arrival. Moreover, an interactive Knowledge Hour on data protection rules has been organised to deepen understanding of applicable rules and best practices. To raise the number of staff participating in the awareness raising activities, HERA will send e-mails with information on the relevant trainings and ensure that the relevant Intranet page is up to date with the helpful resources. The Data Protection Coordinator (DPC) has completed a Data Protection Officer Certification organised by Maastricht University to further strengthen organisational compliance and foster a culture of data privacy within HERA.
- **Development and update of digital solutions and systems:** DPC continued to be involved in designing and updating HERA digital solutions and websites, notably the ATHINA IT system and Stakeholders' Hub.
- **Inventory of processing operations:** Record-keeping procedures have been included in all awareness-raising activities, with all concerned units actively contributing to the Data Protection Records Management System. HERA has updated its inventory of processing activities, including records transferred to HERA from DG SANTE.

## Document Management

In 2024, HERA continued working according to the established document management and access to documents procedures. Internal procedure on handling paper documents was developed and implemented. Guidelines are available in the Knowledge Portal and relevant colleagues received the necessary training.

## Knowledge Management

In 2024, the HERA team has continued to develop and curate the content of the HERA Knowledge Portal, a SharePoint Online site that serves as a centralised repository of high-relevance documents and a hub of information, expertise, and resources related to HERA. This initiative has been crucial in promoting a collaborative digital work culture, enabling colleagues to work more efficiently and effectively.

Key Achievements:

- **Encouraging a Collaborative Digital Structure:** Throughout the year, HERA has encouraged colleagues to transition to a more collaborative digital work environment. The Knowledge Portal has played a pivotal role in this effort, making it easier for

colleagues to find information, presentations, and reports through its structured categorization by work areas and files.

- **Quality Assurance and Expansion:** Regular checks have been performed to ensure the quality and accuracy of the portal's pages. Colleagues have contributed valuable information, expanding the portal's content and enhancing its relevance. This is particularly important during crisis mode, where access to reliable information is crucial.
- **Supporting Newcomers:** The Knowledge Portal has proven to be an invaluable resource for new colleagues, providing a centralized repository of HERA's policy making, processes, work practices, and relevant templates. This has enabled newcomers to seamlessly integrate into the work of different units without having to seek out information from multiple sources.
- **Increased Trust and Engagement:** Colleagues are increasingly trusting the portal and providing more input, thanks to the support of the team and correspondents. This growing engagement has been instrumental in the portal's continued growth and relevance.

### 3.3. Sound environmental management

HERA continues to operate from its temporary site in Brussels, with a decision on a permanent location expected at the end of 2025. In the meantime, HERA has been actively contributing to Commission-wide environmental initiatives and energy-saving measures.

In July 2024, HERA appointed a new EMAS correspondent, ensuring HERA's participation in EMAS corporate activities. This includes attending network meetings, training sessions, and corporate events.

HERA intends to establish a local volunteer team and organise a dedicated EMAS action/event in 2025 to strengthen its engagement in environmental management.

HERA has also maintained its commitment to sustainability in missions and travel by continuing to prioritise teleworking and videoconferencing. These efforts reflect the principles of the Pledge for the Greening of Missions and Meetings signed in 2022, while supporting sustainable operations, events, and communication across the organisation.

### 3.4. Examples of economy and efficiency

HERA is not yet at its full expected capacity, but for HERA to be able to deliver on its mission, much more staff would be required, between 2024 and 2027 as assessed in the context of the annual budgetary process. These scarce resources generate constant need for reinforcement of teams via internal redeployment on priority files and a project-based approach with teams across units depending on competences' needs. HERA has therefore developed a lot of activities in this format which is saving resources but also creates a lot of pressure on staff to contribute to numerous initiatives. For each vacant post, the top

management analyses where are the areas that have the maximum priorities and most urgent and important deliveries to allocate the posts accordingly. The new initiatives, the outputs mentioned in the management plan and the budgetary process are part of the assessment process for the needs. Moreover, managers are in constant exchange with the HR Correspondent and the Senior management to signal their needs/difficulties. This combination of elements informs the decision on post allocation internally with the best possible prioritisation and efficiency.

