



# Annual Activity Report 2023

Health Emergency Preparedness and  
Response Authority

# Contents

|  |    |
|--|----|
| HERA IN BRIEF .....  | 3  |
| EXECUTIVE SUMMARY .....  | 5  |
| A. Key results and progress towards achieving the Commission’s general objectives<br>and department's specific objectives .....      | 5  |
| B. Key performance indicators .....  | 9  |
| C. Key conclusions on internal control and financial management .....  | 10 |
| D. Provision of information to the Commissioner(s) .....   | 11 |
| 1. KEY RESULTS AND PROGRESS TOWARDS ACHIEVING THE COMMISSION’S GENERAL<br>OBJECTIVES AND SPECIFIC OBJECTIVES OF THE DEPARTMENT ..... | 12 |
| 2. INTERNAL CONTROL AND FINANCIAL MANAGEMENT .....   | 24 |
| 2.1. Control results .....   | 25 |
| 2.1.1. Effectiveness of controls .....   | 27 |
| 2.1.2. Efficiency of controls .....  | 31 |
| 2.1.3. Economy of controls .....   | 31 |
| 2.1.4. Conclusion on the cost-effectiveness of controls .....  | 31 |
| 2.2. Audit observations and recommendations .....  | 32 |
| 2.3. Assessment of the effectiveness of internal control systems .....   | 33 |
| 2.4. Conclusions on the assurance .....  | 35 |
| 2.5. Declaration of Assurance [and reservations] .....   | 36 |
| 3. MODERNISING THE ADMINISTRATION .....  | 37 |
| 3.1. Human resource management .....   | 38 |
| 3.2. Digital transformation and information management .....   | 39 |
| 3.3. Sound environmental management .....  | 41 |
| 3.4. Examples of economy and efficiency .....  | 42 |

# 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)**”.

The core mission of HERA is to support the Commission’s priorities for public health, preparedness, and crisis management in the sectors of health, research and innovation and industry as regard the supply of medical countermeasures. 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 contributes to the general objective set out in President von der Leyen’s Political Guidelines - **Promoting Our European Way of Life**.

HERA functions in two modes: one for ‘peace’ time and one for crisis. In recognition that preparedness is essential in order to mitigate the risks of future health threats, HERA **works first and foremost in preparedness mode**. HERA offers an end-to-end solution to ensure the development and equitable distribution of critical medical countermeasures in case of cross-border health threats. More specifically, HERA’s **tasks** include:



HERA’s **emergency measures** include monitoring, procurement, purchase and manufacturing of crisis relevant medical countermeasures, activation of flexible manufacturing capacities, activation of emergency research and innovation plans,

establishing an inventory for crisis-relevant medical countermeasures production facilities and the facilitation of emergency funding.

At the **international level**, HERA collaborates with global partners to exchange intelligence on threat prioritisation, coordinate global research activities in the area of medical countermeasures and address international supply chain bottlenecks.

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, Horizon Europe falls under the budget implementation of DG RTD, and 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 operates under the political leadership of **Commissioner Stella Kyriakides, responsible for Health and Food Safety**.

HERA has grown during 2023. With 90 staff members at the end of December 2023, it has not reached its full staff capacity yet.

HERA received some administrative support from DG SANTE. By the end of 2023, support is mainly limited to financial initiation and verification.

# 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>(1)</sup>.**

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

This executive summary recaps major results towards achieving the objectives of HERA in 2023, and shows how the HERA activities contribute to the general objective of **Promoting Our European Way of Life**. As reflected below, HERA achieved to deliver important and substantive outcomes.

### **General Objective: Promoting our European Way of Life**

In 2023, HERA continued to work with Member States and 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.

### **Specific objective 1: Crisis response readiness for health emergencies**

HERA continued during 2023 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-relevant medical countermeasures in the event of a public health emergency at Union level. <sup>(2)</sup> More specifically, HERA established procedures for the **activation, prolongation and expiration of the framework**. This included the development of response blueprints and the preparation and conduction of an internal exercise to **stress-test the emergency response protocol**.

### **Specific objective 2: Preparedness for health emergencies**

In recognition that preparedness is essential to mitigate the risks of future health threats, HERA worked throughout 2023 first and foremost in preparedness mode.

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

<sup>(2)</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

In line with the HERA Work Plan 2022 and Work Plan 2023, HERA, in collaboration with Commission services, EU Agencies, and international partners and experts, updated its prioritisation exercise to add two new high-impact health threats. In addition to a) pathogens with high pandemic potential, b) chemicals, biological, radiological and nuclear (CBRN) threats and c) threats resulting from antimicrobial resistance, an additional emphasis was put on **two topics** supporting the three previously identified overarching categories, notably environmental health threats, mainly associated to climate change, as well as biosecurity and emerging technologies. HERA's Advisory Forum endorsed the selection in summer 2023.

In addition, throughout 2023, HERA has strengthened its activities on **intelligence gathering** and analysis. Thanks to DURABLE and EIOS <sup>(3)</sup>, HERA allowed for increased and up-to-date knowledge on health threats and gathering intelligence pertinent to medical countermeasures. In addition, HERA is supporting projects to advance genomics and surveillance capabilities in EU Member States and globally and to enhance data collection in Africa also including clinical evidence for filoviruses. In particular, in 2023, the preparatory work for establishing a global wastewater consortium for public health was kicked-off, in collaboration with key global players such as the World Health Organization (WHO) and the Bill and Melinda Gates Foundation (BMGF). Also, HERA contributed to improving the readiness of adequate databases and ensuring their interoperability for the exchange of data through EU-HIP <sup>(4)</sup> and ATHINA.

In 2023, HERA continued to consolidate R&D efforts in the field of pandemic preparedness and supported **research projects on innovative medical countermeasures**, including those relevant against antimicrobial resistance (AMR), and related technologies. To further support investment in R&D for promising MCMs, HERA designed and started establishing HERA INVEST under the InvestEU fund and also continued to financially support European based Small and Medium Sized enterprises developing innovative medical counter measures. Regarding early-stage research, HERA through the Horizon Europe programme supports projects aiming to increase knowledge on immunity induced by vaccines against viruses with a high epidemic or pandemic potential as well as to define optimal vaccine design for pathogens, where information on host-pathogen interaction and viral surface structures is available. Building on existing adaptive platform trials and cohort studies, HERA, in cooperation with DG RTD, facilitates strategic coordination mechanisms in the Union and beyond to enable the conduct of perpetual platform trials and perpetual strategic cohorts to pivot to emerging diseases if an epidemic strikes and generate scientific evidence on different possible medical countermeasures. Moreover, other research actions for MCMs focus on advancing broad-spectrum anti-viral compounds targeting viruses with high epidemic or pandemic potential and on in-vitro diagnostics and medical devices for cross-border health threats.

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

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

**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>(5)</sup>, the Commission adopted a set of actions to better prevent and mitigate critical medicine shortages in the EU. This included the operationalisation of a **Strategic Alliance for Critical Medicines**, for which HERA is responsible 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.

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 2023 the governance and coordination mechanisms** with Member States, other Commission Services and Agencies as well as specific groups of stakeholders. In 2023, 13 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).

### **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; notably the administrative arrangement with Korea's Ministry of Health and Welfare and the working arrangement with Japan's Agency for Medical Research and Development (AMED), signed in May and October 2023 respectively. 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.

In 2023, HERA has played a significant role in the European Commission's external representation in global forums (e.g. 3rd International Conference on Public Health in Africa (CHPIA)). Furthermore, HERA has strengthened cooperation with regulatory authorities, agencies involved in health emergency preparedness and response (e.g. EUR 6 million grant agreement to support Africa CDC's Pathogen Genomic Initiative 2.0), health ministries of other non-EU countries (e.g., Republic of Korea, Japan), and relevant international organisations (e.g., WHO, BMGF <sup>(6)</sup>, UNEP <sup>(7)</sup>, etc.).

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<sup>(5)</sup> [https://commission.europa.eu/document/da376df1-c70e-48ba-8844-3024f25746b6\\_en](https://commission.europa.eu/document/da376df1-c70e-48ba-8844-3024f25746b6_en)

<sup>(6)</sup> Bill & Melinda Gates Foundation

<sup>(7)</sup> UN Environment Programme



## **B. Key performance indicators**

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

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

**In line with the Commission's Internal Control Framework HERA has assessed its internal control systems 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 payment times, the average time to reply to requests to access to documents, and the number of exception reports. Please refer to annual activity report section 2.3 for further details.**

**In addition, 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. Improvements are necessary concerning minor deficiencies that were identified related to payment times, the average time to reply to requests to access to documents, and the number of exception reports. The improvements and remedial measures implemented or envisaged are setting up further procedures to ensure deadlines are met in accordance with the rules. 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, management matters, the main elements of this report and assurance declaration, have been brought to the attention of Commissioner Kyriakides, responsible for Health and Food Safety.**

# 1. KEY RESULTS AND PROGRESS TOWARDS ACHIEVING THE COMMISSION'S GENERAL OBJECTIVES AND SPECIFIC OBJECTIVES OF THE DEPARTMENT <sup>(8)</sup>

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

HERA contributes to the Commission's **headline ambitions <sup>(9)</sup>**. 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 health 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 health security and more specifically the 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.

HERA has checked the application of the criteria for a strengthened common control approach on the reliability of performance information on its financial programmes and no issues were identified.

## Specific objective 2: Preparedness for health emergencies

Future serious cross-border threats to health <sup>(10)</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 focused

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<sup>(8)</sup> An Executive Agency uses as heading: "Implementation of the Agency's Annual Work programme - Highlights of the year".

<sup>(9)</sup> [https://commission.europa.eu/strategy-and-policy/priorities-2019-2024\\_en](https://commission.europa.eu/strategy-and-policy/priorities-2019-2024_en)

<sup>(10)</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.

on activities under its **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 together with its subgroups.

### **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 line with the HERA Work Plan 2022 and Work Plan 2023, HERA, in collaboration with Commission services, EU Agencies, and international partners and experts, updated its prioritisation exercise to select three high-impact health threats, to ensure global alignment and close collaboration on global health security. In addition to a) pathogens with high pandemic potential, b) chemicals, biological, radiological and nuclear (CBRN) threats and c) threats resulting from antimicrobial resistance, an additional emphasis was put on two topics supporting the three previously identified overarching categories, notably environmental health threats, mainly associated to climate change, as well as biosecurity and emerging technologies. HERA's Advisory Forum endorsed the selection in summer 2023.

In 2023, HERA further worked on the development of the HERA IT platform – a **state of the art, real-time data and intelligence tool to collect information on threats, medical countermeasures and enabling technologies, as well as for real-time analytics and modelling to inform needs' quantification**. A call for tender was successfully launched and the analysis and development contracts were awarded in December 2023.

In addition, throughout 2023, HERA continued supporting projects to advance genomics and surveillance capabilities in EU Member States and globally and to enhance data collection in Africa also including clinical evidence for filoviruses. In particular, in 2023, the preparatory work for establishing a global wastewater consortium for public health was kicked-off, in collaboration with key global players such as the World Health Organization (WHO) and the Bill and Melinda Gates Foundation (BMGF). Also, HERA contributed to improving the readiness of adequate databases and ensuring their interoperability for the exchange of data through EU-HIP and ATHINA.

In 2023, HERA supported the technological development of the EIOS <sup>(11)</sup> Platform and the expansion of its community of users, through a contribution agreement with WHO (EUR 2M) and an administrative agreement with JRC (EUR 1.5M). In addition, HERA joined the EIOS coordination group to participate in strategic decisions and organised a training of its staff to use EIOS. 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 the DURABLE consortium to start the implementation, in coordination with ECDC, a network of laboratories supporting HERA's function of intelligence

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<sup>(11)</sup> Epidemic Intelligence from open source

gathering and threat assessment (, and speeding-up the detection and characterisation of relevant threats.

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

In 2023, consolidated R&I efforts in the field of pandemic preparedness and support to **research projects on innovative medical countermeasures**, including those relevant against antimicrobial resistance (AMR), and related technologies **as** well as fostering the development of **next generation vaccines (Vaccines 2.0 strategy)**. In addition, HERA is closely involved in the creation of a common **EU research and innovation agenda** for pandemic preparedness.

In the next edition of the Horizon Europe Work Programme covering 2023-2024, further investment in pandemic preparedness and response research was prioritised. This included, for instance, further support to sustainable clinical trial networks, platforms and infrastructures that can be adapted quickly to emerging or previously unknown pathogens. Focus was given on increasing knowledge on vaccine-induced immunity and optimal vaccine design for pathogens with high epidemic or pandemic potential<sup>(12)</sup>. In addition, resources were allocated to advancing research on broad-spectrum anti-viral compounds targeting viruses as well as developing in-vitro diagnostics for detection and characterisation of pathogens with pandemic potential. At global level, the Commission continued its support to vaccine research and development for emerging pathogens conducted by the Coalition for Epidemics Preparedness Initiative (CEPI) as well as to the operationalisation of the clinical trials partnership with sub-Saharan Africa (EDCTP3).

To further support investment in R&D for promising MCMs and to incentivise enterprises to develop innovative medical countermeasures, HERA established the **HERA INVEST** initiative by contributing to the Research, Innovation and Digitisation Thematic Innovation financial product implemented by the European Investment Bank (EIB) under the InvestEU Fund. HERA INVEST supports investments, through venture loans, into innovative European companies which are developing interventions (i.e. diagnostics, therapeutics, vaccines) against priority cross-border health threats (i.e. pathogens with high pandemic potential, AMR, CBRN). Currently, a market failure in the development of such interventions exists in the form of a lack of private investment due to the high-risk nature of such investments (i.e. low probability of success, low expected revenue). This action shall reduce the risk for potential investors, thereby incentivising private investment, and contributing to the R&D pipeline of MCMs against cross-border health threats. First venture loans are envisaged to be signed between the EIB and selected companies in 2024.

As a part of its Threat Prioritisation Exercise, HERA has identified antimicrobial resistance (AMR) as one of its priority threats in July 2022. In this context, HERA has the goal of promoting research, innovation and development of relevant technologies and countermeasures to address the issue of antimicrobial resistance, through:

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<sup>(12)</sup> such as those identified in the list of priority threat of HERA or included in the list of priority diseases of the World Health Organization (WHO)

- Publishing the study bringing AMR Medical Counter Measures to the Market in May 2023, which evaluated four different schemes to improve innovation and access to antimicrobials. The results of the study were discussed with Member States and the first next step is the implementation of a revenue guarantee procedure under EU4Health to improve the access of newly developed antimicrobials.
- The implementation of the contribution agreement signed with WHO on AMR (EUR 8M) to fund WHO's activity on priority signalling (i.e. maintaining and updating the list of priority bacterial and fungal pathogens, carrying out pipeline analyses for antimicrobial and diagnostics, designing target product profiles), as well as to fund the GARDP and the SECURE initiatives.
- The organisation of a competitive call for tenders to speed-up the development of vaccines to combat AMR (EUR 24M) and the development of point of care metagenomics diagnostics for universal pathogen detection (EUR 22M, better diagnose of viral disease help reduce antibiotic consumption).
- The launch of HERA Invest (see above).
- The support to RTD in the establishment of the One Health AMR Partnership under Horizon Europe.
- The co-organisation of a breakout session on phage therapy during the transatlantic task force on AMR (TATFAR) meeting in Luxembourg (14-15 Nov).
- The preparation of a call for tender to speed up the development, availability and access to anti-tuberculosis medicines for children <sup>(13)</sup>.

### **Addressing market challenges and boosting the Union's open strategic autonomy.**

Shortages of medical countermeasures 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 2023, HERA jointly with EMA engaged in a pilot exercise to identify potential mismatches between the industry-planned supply and EU demand for selected antibiotics against seasonal infections. After consultation of the HERA Board, HERA implemented a set of short-term actions aiming at mitigating the risk of occurrence of shortages. HERA proposed to Member States a launch of joint procurement initiative to purchase RSV <sup>(14)</sup> vaccines and therapeutics, given that complications of seasonal viral infections require use of antibiotics. HERA offered to Member states the support the deployment and operationalisation of the new voluntary solidarity mechanism established by the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG).

On 24 October 2023, the Commission published the Communication on Addressing shortages of medicines, setting out comprehensive proposals for short-, mid- and long-term actions to mitigate critical shortages. HERA has started work towards their implementation, including among others the assessment of the vulnerabilities of the supply chain of a first tranche of medicines from the Union list of Critical Medicines, preparations for the launch in early 2024

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<sup>(13)</sup> Prior information notice: tender to speed up the development, availability and access to anti-tuberculosis medicines for children - European Commission (europa.eu)

<sup>(14)</sup> Respiratory syncytial virus

of the Critical Medicines Alliance and of a study assessing the need for a Critical Medicines Act. Furthermore, the tender for the HERA Stakeholders' Portal has been launched. The portal will create an eco-system for stakeholders to engage with HERA on different levels. It will facilitate industry matchmaking and provide a secure space for stakeholders to present their innovative proposals, while ensuring the respect of confidentiality and the EU competition law.

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 2023, HERA continued the implementation of the **EU FAB tender** launched in April 2022, a network of vaccine manufacturing facilities in the EEA, to reserve manufacturing capacity and secure early availability of vaccines in case of a future public health emergency. EU FAB thus complements capacity reserved by Member States at national level.

HERA has developed in coordination with industry and Member States a questionnaire to identify vulnerabilities, strategic dependencies in the production as well as to establish demand forecasts. The questionnaire will support surveillance of the availability of critical MCMs during preparedness and crisis periods. In December 2023, HERA kicked-off the ATHINA project and in particular Lot 3 that foresees the development of an MCMs supply chain risk management framework for improving the visibility, agility and resilience of end-to-end MCM supply chain networks and transforming gained knowledge and information (data) to actionable insights. Through this project, HERA will map and assess supply chain network criticalities of critical medical countermeasures through exchange of qualitative and quantitative data with final product manufacturers and Active Pharmaceutical Ingredients (APIs), intermediate ingredients and raw material suppliers, including within the Joint Industrial Cooperation Forum (JICF) which brings together the Commission, Member States and industry.

### **Provision of medical countermeasures**

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. In line with this, HERA funded seven selected Member States in 2023 for an amount of EUR 690M to put in place **stockpiles of medical countermeasures** under rescEU. These medical countermeasures will be available to Member States in case an emergency overwhelms national capacities. HERA also continued coordinating, with Member States and relevant Commission services, the drafting of an **EU medical countermeasures stockpiling strategy** to enhance the effectiveness and sustainability of EU level stockpiles of medical countermeasures, with a view to develop a common strategic approach to medicines stockpiling.

The results of the study “stockpiling antimicrobials and active pharmaceutical ingredients (APIs)” carried out and completed in 2022 were used to inform the drafting of the

Commission's proposal for a revised EU pharmaceutical legislation <sup>(15)</sup>, notably as regards the means to address antimicrobial supply chain disruptions. These results also informed HERA's decision to include medicines against tuberculosis in the list of items proposed for stockpiling by Member States in RescEU calls.

### Strengthened knowledge and skills

In 2023, HERA developed **a training strategy and programme** to address Member States learning needs in the field of medical countermeasures to enhance preparedness and response capacity to cross-border health threats. In close cooperation with all relevant EU services and stakeholders. HERA will design and develop its training programme on medical countermeasure management based on a needs and gap analysis of Member States capacities. HERA organised two trainings sessions for Member States in 2023: a training on stockpiling in October, and a training on procurement in November. HERA also held an internal exercise in November to test its emergency response protocol.

### Governance and coordination

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. In 2023, HERA made fully operational the **governance and coordination mechanisms** put in place in 2022. It continued interactions with Member States, other Commission Services and Agencies as well as specific groups of stakeholders. Also, HERA focused on building knowledge on **HERA-like** structures in the EU and globally, including in EU member states (e.g. national agencies as well as departments/divisions/units specifically responsible for carrying out tasks related to the availability and accessibility of relevant medical countermeasures in case of a health emergency) and launched an intelligence gathering study in this respect. The aim of the study is to build a good understanding of the different actors who have or may have similar missions and tasks to HERA in the field HERA is coordinating, which is often spread out over several entities in the same country. A secondary aim is to identify new collaboration partners globally. In addition, with the HERA Advisory Forum as well as the Joint Industrial Cooperation Forum and the Civil Society Forum, HERA has enabled effective communication channels with crucial stakeholders.

### Communication activities

The "Is the EU now better prepared?" conference took place in Brussels on the 5th of December 2023 under the auspices of President von der Leyen, and with the participation of Vice-President Schinas and Commissioner Kyriakides.

The conference, which gathered 500 participants, in person and online, brought together stakeholders from industry, academia, civil society, national, local, and regional authorities, as well as international organisations and partner countries, to ignite reflections on the topics

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<sup>(15)</sup> [https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation\\_en](https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en)

of resilient supply of medical countermeasures, research and innovation for better preparedness, global epidemic intelligence, and the correlation between climate change and infectious outbreaks. Posts on HERA's social media account X about the conference gained over 21,000 impressions (number of times posts are seen).

As for press and media, to ensure that policy activities are supported and complemented through external communication, there are regular news items published targeting press and media through press releases and Daily News via the Spokesperson's Service (SPP), as well as the use of HERA's website and social media X (formerly Twitter) account. Interviews took place between the press and the Director-General in targeted Member States to promote and improve the knowledge of HERA and its functions took place throughout the year. HERA's communication officer for press and media and social media press meets with their counterparts in EMA, ECDC and HaDEA weekly to biweekly, as well as the SPP and Cabinet to ensure HERA's activities are also shared with these key EU agencies and Commission services.

In 2023 intensive preparatory work took place towards the establishment of a new LinkedIn presence to achieve greater reach, especially to key interested and specialist stakeholders, on social media beyond only X. HERA now co-manages with DG ECHO the "EU in Emergencies" showcase page of the European Commission's LinkedIn account.

When it comes to external communication, preparatory work has been conducted to launch the publication of the first issue of the quarterly external newsletter. The newsletter represents an occasion to present the outcomes of our flagship initiatives and to raise awareness on the activities of HERA.

The promotion of HERA within the Commission in terms of communication comes through the intranet. Additional visibility has been ensured in 2023 via the publication of articles in CenD showcasing the activities and main successes of the DG. As for external communication, a revamp of the website has been performed, and a new outline of HERA's webpages went online in December 2023.

The communication cell has also been reinforced with another communication officer, in charge of developing projects targeting internal and external audiences to raise the visibility of HERA.

### **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 COVID-19 vaccines, without which our ability to overcome the pandemic is severely hampered and the human costs of the pandemic will continue to rise. At the same time, COVID-19 has also clearly shown deficiencies in global preparedness, prevention and detection of health emergencies. HERA has therefore pursued several activities at the international level: 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, building expertise to develop local manufacturing and distribution capacities and supporting access to EU funded or EU procured medical countermeasures. The cooperation with Korea and Japan on these issues, in particular, has been formalised through the conclusions of administrative and working arrangements, respectively, in 2023. In addition, HERA continued 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 continues to support the Commission's efforts as Union negotiator in the negotiations on a Pandemic agreement in particular with regard to medical countermeasures. HERA also continued supporting the Commission's ambition to increase the availability of funding for pandemic preparedness response (PPR) globally, in particular through the new Pandemic Fund.

### **Global health security and access to medical countermeasures**

In 2023, HERA, in close cooperation with other responsible Commission services has continued to support the **international roll-out of COVID-19 vaccines**, notably via donations of medical countermeasures to low- and middle-income countries (LMIC) through COVAX and bilaterally.

In addition, HERA has continued supporting global, regional and national initiatives, to **ensure the availability and accessibility of medical countermeasures** and **strengthen the local production capacities of LMIC and to support enhancing of surveillance and whole genome sequencing activities to facilitate data collection and exchange**. For example, in 2023, HERA continued to work closely with Commission services on the ongoing initiatives for African vaccine manufacturing (PAVM) and local production capacity in Africa and in other regions and with the Team Europe Initiative on Health Security.

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

Importantly, HERA is responsible for implementing the **joint procurement contracts for COVID-19 vaccines and therapeutics**. Participation in the Joint Procurement Agreement now totals 36 signatories, **covering around 470 million people, including all EU, EEA EFTA population and the Western Balkans**.

### **Collaboration with global partners**

Collaboration with global partners is of paramount importance during response to crisis. Organisations like Africa CDC, USAID, WHO, CEPI, GAVI play an essential role in the identification, assessment and response to international health crises. Mpox outbreaks and the war in Ukraine are two concrete examples demonstrating the interconnectedness of global actors' activities.

HERA has ongoing active collaboration with the United States, Japan, the Republic of Korea, Canada, and the African Union agencies: the Africa Centres for Disease Control and Prevention (Africa CDC), and the African Medicines Agency. 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 and the WHO Hub in Berlin, such cooperation has been formalised through **administrative or working arrangements**; with the Coalition for Epidemic Preparedness Innovation (CEPI) HERA has signed a letter of intent. Further cooperation arrangements will be signed in the near future with other key partners.

In 2023, HERA established action CP-g-06.7 under EU4Health AWP 2021 for strengthening preparedness and response to cross-border health threats at global level, for which HERA signed a **contribution agreement with WHO** in 2022. This action supports WHO activities on epidemic and pandemic intelligence; on the acceleration and coordination of global effort to develop tools to fight COVID-19; on the development of new medical countermeasures relevant against antimicrobial resistance; and on support to specific regional initiatives with the biggest possible impact to prevent cross border health threats and support to genome sequencing laboratory network in Africa. Specifically, the C-TAP action has supported the COVID Technology Access Pool (C-TAP), actively encouraging R&D funders, technology holders, governments and other stakeholders, to develop transparent, public-health-driven, non-exclusive licensing agreements for COVID-19 technologies and to create a supportive environment for voluntary licensing and technology transfer agreements of health products.

Further, HERA contributed to enhancing national public health capacity in Africa for Whole Genome Sequencing and/or Reverse Transcription Polymerase Chain Reaction capacity through a direct grant under EU4Health to support the Pathogen Genomics Initiative (PGI) from Africa CDC, which has been signed in 2023.

### **Specific objective 1: Crisis response readiness for health emergencies**

In 2023, HERA continued to be at the forefront of the Union's efforts to provide effective response to serious cross-border health threats, including COVID-19, working to ensure that vaccines, therapeutics and other crisis-relevant medical countermeasures were accessible throughout and beyond the Union, as well as ensuring that the EU can manage the threat of emerging SARS-CoV-2 variants.

In 2023, HERA carried 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>(16)</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**. In terms of emergency readiness, HERA continued its activities aimed at improving the EU's and Member States' ability to respond quickly and effectively to health emergencies through relevant medical countermeasures. An emergency response protocol was developed in 2023 setting out the internal steps to be taken by HERA when responding to emergencies. HERA started a preparatory work to develop response

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<sup>(16)</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

blueprints to test the HERA emergency response protocol. In 2023, HERA worked on scenario planning for smallpox and in November 2023 an internal emergency exercise took place.

### **COVID-19 detection and response to variants and COVID-19 therapeutics**

The Commission-appointed expert group on SARS-CoV-2 variants were requested to assist the Commission in 2023, and one digital meeting was held with the group to discuss emerging variants and vaccine efficacy. In addition, the expert group also provided assessment on variants by written procedure.

In 2023, countries participating to the Joint Procurement Agreement (JPA) continued to have access to the two COVID-19 therapeutics authorised by the EMA for the EU market (Veklury and Paxlovid) for which framework contracts were signed in 2022. Furthermore, the availability of doses procured under the JPA also served – through donations – to respond to urgent needs of Member States not party to the JPA.

### **COVID-19 vaccines**

In 2023, HERA has been working with vaccines manufacturers and Member States to align supply of and demand for COVID-19 vaccines in the most optimal fashion while ensuring that Member States have the strategic stock of vaccines they need to deal with the potential epidemiological evolution of the virus.

In January 2023, an amendment to the Advance Purchase Agreement with Novavax was concluded to adapt the contract following the delays in deliveries of the Novavax vaccine doses. The agreement was reached with the company to stop deliveries of doses with short shelf-life and postpone the deliveries of replacement doses.

In May 2023, due to the improved epidemiological situation, the Commission and BioNTech-Pfizer reached an agreement to better address Member States' needs for COVID-19 vaccines. The Fifth Amendment to the second Purchase Agreement concluded in 2021 reduced the 450 million originally contracted doses to 285 million. The amendment has also extended the duration of the contract to end- 2026 and ensures continued access to vaccines adapted to new variants as soon as authorised by the regulators.

Access to vaccines adapted to the latest variants ensures the availability of efficient and effective vaccines, enhancing Member States's preparedness for a potential outbreak of infections. On 31 August 2023, the Commission authorised BioNTech-Pfizer's XBB.1.5-adapted COVID-19 vaccine, and deliveries to Member States started in early September 2023. Novavax' Nuvaxovid XBB 1.5 adapted vaccine was authorised on 31 October 2023 and deliveries to Member States started end-November 2023.

Member States and other countries participating to the Joint Procurement Agreement with HIPRA for the Bimervax protein-based COVID-19 vaccine continued to have access to the framework contract. However, the adapted vaccine has not been approved on time (and currently still under review by EMA).

In the second half of 2023, HERA prepared a call for tender for a second mRNA COVID-19 vaccine (launched in January 2024). The resulting framework contract will ensure the participating countries to have access to a diversified portfolio of COVID-19 vaccines, will ensure the security of supply and improve the preparedness.

### **Joint procurement as a response to health threats**

Through the EU-level joint procurement mechanism, which involves all EU and EEA Member States and the six Western Balkans, the Commission contributes to the security of supply of medical countermeasures to target cross-border health threats, strengthens cooperation, enhances more equitable access to such medical countermeasures, by aiming at the economies of scale and better contractual conditions.

Aside from the COVID JPA activities (see above) HERA engaged in the call for applications to the first phase of the Dynamic Purchasing system for personal protective equipment (PPE) which has been ongoing and applications have been evaluated in 2023.

The work is ongoing to sign, in early 2024, the framework contract for the supply of diphtheria antitoxin, which is a rare product at the EU market, but nevertheless in demand in quite a few EU Member States, to target occasional diphtheria cases,

Work is also ongoing to conclude a framework contract for the supply of pre-pandemic zoonotic vaccine, to enable the Member States to vaccinate target groups in a risk of being transferred influenza from birds or animals, such as farm workers.

In parallel, HERA has two reservation contracts in force for the reservation – and, in the case of a declared pandemic, supply – of the pandemic influenza vaccines. The two contracts combined cover more than 110M vaccine doses.

### **Response to outbreaks**

In 2023, HERA signed a framework contract for the therapeutic tecovirimat, with a view to provide a mid and long-term option to participating countries. This is in light of HERA's response to the mpox outbreak, for which it purchased and donated vaccine doses in 2022, and also concluded a joint procurement for vaccine doses.

### **Response to Russia's invasion of Ukraine**

HERA contributed to the Commission response to Russia's invasion of Ukraine, focusing on medical countermeasures needed by Ukraine and leveraging its strong contacts with the private sector. To monitor the health of Ukrainian refugees, HERA supported Member States on wastewater surveillance for different pathogens. Finally, HERA also collaborated with the EMA to monitor any shortages of medicines that may arise out of the invasion.

## HERA Review

This review fulfils the obligation under article 8 of the Commission Decision C(2021)6712 of 16 September establishing HERA. The article prescribes an in-depth review of the implementation of the operations of HERA before 2025, including its structure and governance, addressing in particular any need to modify the mandate of HERA and the financial implications of any such modification. The main objective of the report on the review of the implementation of the operations of HERA is to assess the extent to which HERA's mandate and tools (legal basis, structure, governance, funding) has allowed it to effectively and efficiently contribute to the political objective of strengthening the EU's health emergency preparedness and response , and fulfil the tasks as laid down in Commission Decision C(2021) 6712. The report will also look at the complementarity with work carried out by other EU bodies. This analysis will support the 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 will also analyse to what extent the HERA mandate fits the current health challenges and if any changes to this mandate are needed. SG is the responsible service for the publication of the report. The report will be informed by an open public consultation which was launched in "Have Your Say" portal on 27 November 2023 <sup>(17)</sup>. HERA launched in 2023 a study with an external contractor to support the review. The results of this study will be published in April 2024.

## EU added value

HERA exemplifies the EU's added value by streamlining the availability of Medical Countermeasures (MCMs) crucial for pandemic preparedness. Given the costly and complex nature of MCM development and procurement, HERA's centralized approach offers economies of scale, reducing duplication of efforts among Member States. By pooling resources and expertise at the EU level, HERA enhances coordination, accelerates response times, and ensures equitable access to vital medical supplies across borders. This collaborative framework not only optimizes resource allocation but also fosters synergies in research and development, ultimately fortifying EU's resilience against health emergencies.

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<sup>(17)</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14035-Health-Emergency-Preparedness-and-Response-Authority-HERA-review\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14035-Health-Emergency-Preparedness-and-Response-Authority-HERA-review_en)

## 2. INTERNAL CONTROL AND FINANCIAL MANAGEMENT

Assurance is provided on the basis of information on the efficiency and effectiveness of internal control systems and governance processes.

The management monitors the functioning of the internal control systems on a continuous basis and carries out an objective examination with internal and external auditors. The results are explicitly documented and reported to the Director-General. The following reports / documentation have been considered:

- the reports from Authorising Officers in the Directorates-General/services managing budget appropriations in co-delegation. The controls cover the part of the budget entrusted to them by HERA;
- the contribution by the Director in charge of Risk Management and Internal Control (RMIC) on the annual assessment of the internal control principles;
- the reports on recorded exceptions and non-compliance events;
- the limited conclusion of the Internal Auditor on the state of internal control, and the observations and recommendations reported by the Internal Audit Service (IAS);
- the observations and the recommendations reported by the European Court of Auditors (ECA).

The systematic analysis of the available evidence provides sufficient guarantees as to the completeness and reliability of the information reported and results in the full coverage of the budget delegated to the Director-General of HERA.

This section covers the control results and other relevant elements that support management's assurance. It is structured into 2.1. Control results, 2.2. Audit observations and recommendations, 2.3. Effectiveness of internal control systems, and resulting in 2.4. Conclusions on the assurance.

## 2.1. Control results

This section reports on the control results used by management to support the assurance on the achievement of the internal control objectives (ICO) <sup>(18)</sup>. The HERA's assurance building and materiality criteria are outlined in annual activity report annex 5. The annual activity report annex 6 outlines the main risks together with the control processes to mitigate them and the indicators used to measure the performance of the relevant control systems.

In 2023, HERA had payments of EUR 8.8 million under the EU4Health programme.

Approximately half of it (54% of the total payments), EUR 4.7 million, were paid as pre-financings to the WHO under indirect management for 2 contribution agreements signed in 2023. The focus of these actions was to strengthen preparedness and response to cross-border health threats at global level.

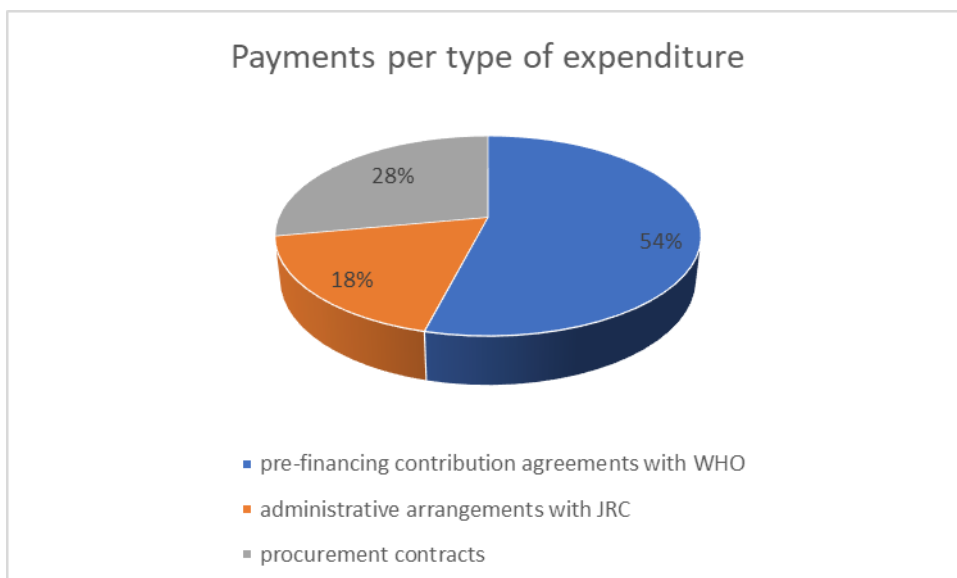
Thus, excluding the pre-financings, the amount that represents relevant expenditure for HERA's assurance in 2023 comes up to EUR 4.1 million.

In 2023, HERA paid around EUR 1.6 million (18% of the total payments) under 2 administrative agreements with JRC which target the mitigation and prevention of public health emergencies through the institutionalization of wastewater-based surveillance for public health and the development of networks of experts in the field.

In 2023, HERA made procurements for approximately EUR 2.45 million (28% of the total payments), including the purchase of devices for wastewater surveillance to deliver to Member States through a JRC-managed framework contract, IT services to support the ATHINA project, communication services to raise awareness and understanding of its purpose and actions, and legal advice.

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<sup>(18)</sup> 1) Effectiveness, efficiency and economy of operations; 2) reliability of reporting; 3) safeguarding of assets and information; 4) prevention, detection, correction and follow-up of fraud and irregularities; and 5) adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the multiannual character of programmes as well as the nature of the payments (FR Art 36.2). The 2nd and/or 3rd Internal Control Objective(s) (ICO) only when applicable, given the DG's activities.



All HERA 2023 payments were executed by DG SANTE on the basis of a Memorandum of understanding, in compliance with DG SANTE control strategy.

HERA delegated budget in 2023:

In line with the EU4Health work programme, in 2023, HERA co-delegated EUR 100 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.

Further, around 55% of HERA 2023 EU4Health budget was implemented by the Health and Digital Executive Agency (HaDEA) for a total amount of EUR 132 million in commitment appropriations.

In 2023, HERA co-delegated EUR 685.5 million to DG ECHO under the Union Civil Protection Mechanism for the development of stockpiles of medical countermeasures to respond to large-scale Chemical Biological Radiological Nuclear (CBRN) emergencies.

Further, projects for approximately EUR 245 million, contributing to HERA objectives were earmarked for HERA by DG RTD under the Horizon Europe 2023 programme.

The partner DGs and HaDEA bear sole responsibility for implementing the amounts co-delegated to them. In their own Annual Activity Reports, they provide assurance and further details on the use of the received appropriations.

HERA recorded 3 exceptions to the standard procedures in financial management and 2 non-compliance events in 2023. 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.

The new reporting requirements stemming from the 2018 Financial Regulation, and listed below, do not apply to HERA:

- Cases of financing not linked to costs (new FR art 125.3);
- Financial Framework Partnerships >4 years (new FR art 130.4);
- Cases of flat-rates >7% for indirect costs (new FR art 181.6); HERA\_aar\_2022 Page 29 of 38
- Cases of "Derogations from the principle of non-retroactivity pursuant to Article 193 FR" (new Financial Regulation Article 193.2).

### 2.1.1. Effectiveness of controls

#### ***a) Legality and regularity of the transactions***

HERA uses internal control processes to ensure sound management of risks relating to the legality and regularity of the underlying transactions it is responsible for, taking into account the multiannual character of programmes and the nature of the payments concerned.

##### ***1) Control objective***

In 2023, 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 AAR.

##### ***2) Assessment of the control results***

HERA's portfolio consists of low-risk type of expenditure (payments on administrative agreements and 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%.

For the 2023 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.

For the 2023 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 AAR.

The 2023 co-delegation agreement signed with DG ECHO requires the authorising officer responsible to report on the use made of the delegated appropriations. For 2023, the authorising officer of DG ECHO did not communicate any events, control results or issues which could have a material impact on assurance.

### *3) Overview of HERA risk profile*

HERA's portfolio consists of segments with a relatively low error rate. This is, respectively, thanks to the inherent risk profile of the funding modalities and the performance of the related control systems. In accordance with DG SANTE control strategy, the error rate is set at 0.5%, there are no ex-post controls, and the future corrections are estimated at 0%.

### *4) Table (X): Estimated risk at payment and at closure*

Based on the above, HERA presents in the following Table X an estimation of the risk at payment and risk at closure for the expenditure managed during the reporting year:

**Table (1): Estimated risk at payment and at closure (amounts in EUR million)**

The full detailed version of the table is provided in annex 9.

| HERA   | Payments made | Relevant expenditure | Estimated risk (error rate %) at payment |               | Estimated future corrections and deductions |              | Estimated risk (error rate %) at closure |              |
|--|---------------|----------------------|--|---------------|---|--------------|--|--------------|
|  | m EUR         | m EUR                | m EUR                                    | %             | m EUR                                       | %            | m EUR                                    | %            |
| <b>EU4Health programme contribution agreements</b>   | 4.71          | 0                    | 0.00                                     | 0.00 %        | 0.00  | 0.00%        | 0.00                                     | 0.00%        |
| <b>EU4Health programme procurement</b>               | 2.45          | 2.45                 | 0.01                                     | 0.50%         | 0.00  | 0.00%        | 0.01                                     | 0.50%        |
| <b>EU4Health programme administrative agreements</b> | 1.64          | 1.64                 | 0.01                                     | 0.50%         | 0.00  | 0.00%        | 0.01                                     | 0.50%        |
| <b>Administrative expenditure</b>                    | 0.01          | 0.01                 | 0.00                                     | 0.00%         | 0.00  | 0.00%        | 0.00                                     | 0.00%        |
| <b>HERA total</b>                                    | <b>8.80</b>   | <b>4.10</b>          | <b>0.02</b>                              | <b>0.50 %</b> | <b>0.00</b>                                 | <b>0.00%</b> | <b>0.02</b>                              | <b>0.50%</b> |

The estimated overall risk at payment for 2023 expenditure, 0.50%, 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. Since HERA does not carry out ex-post controls (as explained in annex 6) no further corrections to the expenditure are expected and the estimated future corrections are thus set at 0%. As a result, the estimated overall risk at closure corresponds to the estimated overall risk at payment.

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.

### 5) Preventive and corrective measures

As regards the corrections carried out in 2023, HERA relies on DG SANTE's effective mechanism for correcting errors, through ex-ante controls, resulting in preventive measures, amounting to EUR 0.01 million.

## ***b) Fraud prevention, detection and correction***

HERA has developed and is implementing its own anti-fraud strategy since June 2023, based on the methodology provided by OLAF. It will be updated again in 2025. Its implementation is being monitored and reported to the management annually through the internal control monitoring process. All necessary actions were taken except the launch of a staff survey on the level of awareness of how to report fraud, which is scheduled to take place in the first quarter 2024. HERA also contributed to the revised Commission anti-fraud strategy and did not receive any financial recommendations from OLAF.

The results achieved during the year thanks to the anti-fraud measures in place can be summarised as follows: the fraud risks and controls have been assessed and the risk of fraud remains low; thanks to the ethics guidance and the several corporate specific ethics trainings available, staff has a good level of awareness of the Commission ethics rules and how they apply to HERA's work.

On the basis of the available information, HERA has reasonable assurance that the anti-fraud measures in place are effective.

### 2.1.2. Efficiency of controls

In 2023, 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 2023, 78% of the amounts due were paid on time. In 2023, HERA had a relatively limited number of payments (45 in total); however, there were 2 payments to JRC of relatively big amounts (EUR 1.6 million in total) that were late and affected the result for this indicator. <sup>(19)</sup>

HERA has taken remedial measures to improve the result for this indicator such as the centralization of the follow-up of payments.

### 2.1.3. Economy of controls

In 2023, 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.

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

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

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<sup>(19)</sup> The late payment was due to delays in the communication between HERA and DG SANTE; JRC set payment deadline of 3 months; however, DG SANTE's payment deadline is 45 days for these type of payments; thus, although paid within the deadline set by the JRC, these payments appear late.

## **2.2. Audit observations and recommendations**

**This section sets out the observations, opinions and conclusions reported by auditors – including the limited conclusion of the Internal Auditor on the state of internal control. Summaries of the management measures taken in response to the audit recommendations are also included, together with an assessment of the likely material impact of the findings on the achievement of the internal control objectives, and therefore on management's assurance.**

In 2023, there were no audits carried out by the European Court of Auditors that resulted in financial management and internal control related recommendations for HERA. However, in 2023 IAS conducted a limited review on HERA's assessment of its Internal Control Framework where it did not raise any critical or very important recommendations to HERA.

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

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 2023, there were 3 recorded exceptions, 2 non-compliance events 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 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.

Following the limited review on HERA's assessment of its Internal Control Framework for the 2022 AAR, carried out by the Internal Audit Service in 2023, HERA revised its Internal Control Framework to address the Internal Audit Service recommendation. The revision of the monitoring criteria was conducted in parallel with the annual risk assessment exercise. 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 2023. The self-assessment was based on the revised monitoring criteria and took into consideration the fact that HERA was still a relatively new DG (established in September 2021) and was still in the process of building institutionally with many processes and procedures being introduced for the first time in 2023.

The self-assessment conducted by HERA concluded that in 2023, HERA had 12 internal control principles that were present and functioning well, 4 internal control principles present and functioning with some improvements needed, and 1 internal control principle that was partially present with major improvements needed.

In 2023, HERA addressed the control deficiencies that were identified in 2022 and developed a Business Continuity Plan, a Procedure for reporting exceptions and non-compliance events, and an Anti-Fraud Strategy.

However, the risk assessment exercise has identified again the complex funding structure of HERA as a risk with high potential impact on the achievement of HERA's objectives <sup>(20)</sup>.

In 2023, HERA drew funding from different programmes (EU4Health, Horizon Europe, Union Civil Protection Mechanism), and each of the programmes was governed by an individual legal base, objectives, implementing rules and procedures. Moreover, the programmes fell under the responsibility of partner lead parent DGs. It is DG SANTE for EU4Health, DG RTD for Horizon Europe, and DG ECHO for the Union Civil Protection Mechanism.

HERA is in a position where, counting on its quite limited resources, it needs to seek constantly enhanced coordination with its partner DGs to ensure that its objectives are met through effective implementation of the corresponding programmes. Further, as HERA needs to co-delegate almost its entire budget to its partner DGs/ HaDEA, the budget is implemented at different management centres under the responsibility of other AOSD.

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 some improvements are needed as minor deficiencies were identified related to payment times, the average time to reply to requests to access to documents, and the number of exception reports. The improvements and remedial measures implemented or envisaged are setting up further procedures to ensure deadlines are met in accordance with the rules.

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<sup>(20)</sup> The same risk was identified in 2022 as well.

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

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 [and reservations]**

### **Declaration of Assurance**

***I, the undersigned,***

***Acting Director-General of HERA***

***In my capacity as authorising officer by delegation***

***Declare that the information contained in this report gives a true and fair view <sup>(21)</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, 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, 09.04.2024***

***(signed)***

***Laurent MUSCHEL***

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<sup>(21)</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 2023, HERA's expansion persisted, reaching a staff of 90 by the end of the year. All interview panels adhered to the principle of gender balance. Key appointments marked the year, with the Deputy Head of HERA appointed on 16/02/2023, and the Principal Advisor on 16/12/2023. The Director General post became vacant on 16/09/2023. Although HERA did not have a target assigned for the period 2023-2024, HERA made one female appointment (the Head of Unit responsible for policy and coordination) in 2023. The organisation's evolution continued with a comprehensive set of team events for all units, management and for the Directorate General as a whole, fostering discussions on achievements, organisational enhancements, and future policy reflections. The Director-General, 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. Following the Staff survey in November 2023, the first ever staff engagement index is 67% and will be the benchmark or future assessment.

## 3.2. Digital transformation and information management

HERA's intranet which was the first in the Commission with Sharepoint Online format, became a Hub (migration to DG Hub template) in 2023, continuing the path towards digital transformation. A knowledge portal was created and encapsulated in the Intranet, DG Hub, with a view to save time and gain efficiency in finding the relevant key documents related to HERA's policies and governance. This is only the start of the journey but a stepping stone on the path towards the future digital environment of the Commission. HERA pursued the strategic objective <sup>(22)</sup> of shifting towards a digital culture by launching several awareness raising activities on cybersecurity among its staff.

On the basis of the Memorandum of Understanding between DG SANTE and HERA <sup>(23)</sup>, HERA is still being administratively supported by DG SANTE for the IT governance activities.

### Data protection

HERA has established a full inventory of all its current processing operations in accordance with the EC Implementing Rules. Further, HERA is in the process of updating its inventory of records of processing, including records transferred to HERA from DG SANTE.

The DPC conducted awareness raising activities through emails, bilateral meetings and presentations across all four Units, covering recurring questions and situations. As a result, HERA colleagues increasingly followed training and information sessions, updated privacy statements, and continuously addressed data protection considerations in the design of a new IT platform. As a result of awareness raising sessions, units are pro-actively involving the DPC in projects involving issues related to the protection of personal data, thereby allowing the DPC to assist and advise the operational and delegated controllers in complying with EU data protection requirements.

HERA has devoted additional resources by formally appointing the Assistant to the DPC in 2023.

### Document Management

While the year 2022, following the creation of HERA in September 2021, was a time of building competence and establishing procedures for the functioning of Document Management within HERA, the focus for year 2023 shifted to consolidating and strengthening competences, as well as addressing and clearing backlogs.

On the basis of the Memorandum of Understanding between DG SANTE and HERA, SANTE Document Management Officer (DMO) supported HERA staff in document management tasks until it reached full independence in early 2023.

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<sup>(22)</sup> European Commission Digital Strategy - [c\\_2022\\_4388\\_1\\_en\\_act.pdf \(europa.eu\)](#)

<sup>(23)</sup> Ref.ARES(2022)1863605

In autumn 2023, a new HERA DMO was recruited and new secretaries were trained as Document Management Correspondents (DMCs). Following the change of resources, and once the DMO and DMCs reached full competency after conducting the necessary trainings, the Network of Document Management Correspondents was reestablished, by appointing one Document Management Correspondent (DMC) per unit. Both the DMO and DMCs participated in the necessary training sessions.

The following tasks were the main focus in 2023:

- The filing plan was continuously under review in order to meet the needs of all units. By the end of the year, the DMO identified the files to be closed and created new serial files.
- Once the Network of DMCs was reestablished, the division of tasks and responsibilities was clarified. The Network met on a biweekly basis, providing a way to distribute information and channel questions from the units, discuss DM developments and establish procedures.
- The DMO pursued the decision to decentralise DM tasks, particularly the creation of files and provided necessary training to the units' DMCs regarding the procedure to follow.
- The DMO decided to place DM as a recurring point on the agenda of unit meetings. Hence, the DMCs use this time to continuously raise awareness of colleagues on how to properly use ARES: what documents need to be registered in ARES, how to file, etc.
- The DMO prepared material and put the necessary procedures into place to introduce newcomers to Ares and e-domec policy. The HERA Intranet and HERA Knowledge Portal were updated accordingly.
- The DMO sent regular reporting exercises to the Network of DMCs to encourage filing, registration and cleaning tasks in Ares. By the end of the year, HERA reached the target of having over 95% documents filed.

### **3.3. Sound environmental management**

In 2023 HERA remained temporarily hosted in a site in Brussels, because the move to the permanent Brussels location was not implemented, HERA could not start its integration into EMAS (Commission Eco-Management and Audit Scheme). Regarding missions and business travels of staff and experts, teleworking and videoconferences have increasingly been used and efforts will continue to reduce emissions to air. When organising its “one year conference” all sustainability aspects were integrated in the design of the event.

### **3.4. Examples of economy and efficiency**

As HERA is still not at its expected size due to pressure on EC resources, a small financial cell was put in place for better monitoring of the budget execution and advice on financial matters. This centralisation should bring more efficiency in how financial matters are dealt with in the DG. Moreover, a group of M365 champions were appointed end 2023 aiming at boosting and supporting the digital transformation of HERA in the coming years. Finally, the first step towards a centralised knowledge portal were taken that should rationalise the access to information and documents in the future.

