



# Annual Activity Report 2022

Health Emergency Preparedness and  
Response Authority (HERA)

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## HERA IN BRIEF

The Health Emergency Preparedness and Response Authority (HERA) was established as an internal Commission service 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**, and the policy area of the European Health Union in which EU countries respond together to health crises.

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**. The core tasks of HERA offer 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 **core 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 an **international level**, HERA collaborates with global partners to address international supply chain bottlenecks, expanding global production, reinforcing global surveillance, facilitating cooperation and support to ensure availability and accessibility for medical countermeasures for the Union and third countries, including donations, building expertise to develop local manufacturing and distribution capacities and supporting access to EU funded or EU procured medical countermeasures.

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 the majority 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**.

While being operational in early 2022 with limited number of staff, HERA has grown rapidly during 2022 and built itself progressively, institutionally and internally with many processes and procedures. With 80 staff members at the end of December 2022, it has not reached its full staff capacity yet.

In 2021 and 2022, in line with the Legislative Financial Statement accompanying the HERA package of 16 September 2021, HERA received some administrative support from DG SANTE, to put in place procedures and practices, as well as training for new staff. By the end of 2022, these procedures are in place and support is now mainly limited to financial initiation and verification.

## EXECUTIVE SUMMARY

**This Annual Activity Report is a management report of the 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>.**

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

## 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 2022, in particular contributing significantly to the general objective of **Promoting Our European Way of Life**. As reflected below, HERA achieved in just one year not only to become operational but also to deliver important and substantive outcomes.

### General Objective 1: Promoting our European Way of Life

In 2022, HERA continued to work with Member States and other services on all fronts to ensure the development, manufacturing, procurement, stockpiling and equitable distribution of key medical countermeasures. HERA's actions in 2022 did not target only the COVID-19 pandemic, but also other challenging health emergencies.

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

On 24 October 2022, the Council formally adopted the **Regulation on a framework of measures<sup>2</sup>** for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

The key measures of the regulation are: the establishment of a Health Crisis Board to ensure coordination and integration of approaches to crisis-relevant medical countermeasures at Union level in the event of a public health emergency; the establishment of mechanisms for the monitoring, activation of emergency funding, procurement and purchase of crisis-relevant medical countermeasures and raw materials; the activation of EU FAB facilities, the activation of emergency research and innovation plans, and the use of Union-wide clinical trial networks and provisions and platforms for the rapid sharing of data; and measures concerning the production of crisis-relevant medical countermeasures.

During 2022, HERA continued at an unabated pace its efforts to **respond** to the COVID-19. HERA was continuously engaging with the companies to review and adapt the COVID-19 contracts in line with Member States' needs and in line with the volatile epidemiological situation. HERA leads the Expert group on SARS-CoV-2 variants, advising the Commission on the need to develop new or adapted vaccines. HERA has been closely liaising with Member States and with vaccines producers throughout 2022. The coordination, and in particular the procurement of **therapeutics**, of the EU COVID-19 therapeutics strategy<sup>3</sup> lays with HERA since 1 October 2021. In 2022, HERA signed two framework contracts under the joint procurement agreement for covid-19 therapeutics.

In 2022, HERA proved that it is a key player in the response to various outbreaks that affected the Union. First of all, HERA reacted quickly and efficiently to **Russia's invasion of Ukraine**. HERA contributed to the general Commission response focusing on the medical

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<sup>(2)</sup> Council Regulation (EU) 2022/2372 of 24 October 2022

<sup>(3)</sup> EUR-Lex - 52021DC0355R(01) - EN - EUR-Lex (europa.eu)

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. HERA also supported DG ECHO in setting up a system for channelling private donations to Ukraine, and managed to guarantee donations of essential items such as childhood vaccines.

Later in 2022, HERA demonstrated its capacity to purchase in a short period of time **334,540** doses of vaccines to fight the **MPOX outbreak** in the EU. These doses were subsequently donated to all Member States and associated countries to EU4Health Programme.

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

In recognition that preparedness is essential in order to mitigate the risks of future health threats, HERA worked throughout 2022 first and foremost in preparedness mode.

The first **State of Health Preparedness Report**, announced in June 2021 in the Commission Communication “Drawing the early lessons from the COVID-19 pandemic”<sup>4</sup>, was adopted on 30 November 2022 by the College. The first edition<sup>5</sup> focuses on preparedness capabilities related to medical countermeasures. The report presents an overview of the progress made throughout the past three years to reinforce preparedness in the EU. Second, it outlines the state of play and actions that are planned to fill the gaps in relation to ensuring sufficient availability and supply of medical countermeasures.

On the same day, it was also adopted the **HERA Annual Work Plan 2023**<sup>6</sup> which presents the actions HERA will implement to support Member States’ preparedness for future cross-border threats to health with a focus on availability and accessibility of medical countermeasures.

In line with the HERA Work Plan 2022, HERA, in collaboration with Commission services, EU Agencies, and international partners and experts, conducted this prioritisation exercise to select three high-impact health threats, to ensure global alignment and close collaboration on global health security. Concluding the exercise in July 2022 with the endorsement of the HERA Board, three serious cross-border health threat categories were defined, notably a) pathogens with high pandemic potential, b) chemicals, biological, radiological and nuclear (CBRN) threats and c) threats resulting from antimicrobial resistance.

In 2022, HERA consolidated 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.

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

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<sup>(4)</sup> COM/2021/380 final

<sup>(5)</sup> COM(2022) 669

<sup>(6)</sup> C(2022) 8774

on third countries. In 2022, HERA **began addressing identified industrial and market bottlenecks** that are impeding or have the ability to impede access to medical countermeasures.

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 **put in place in 2022 the governance and coordination mechanisms** with Member States, other Commission Services and Agencies as well as specific groups of stakeholders, aiming to establish a pan-European network.

2022 ended with a successful event for HERA which attracted significant attention on social media. The **“One Year of HERA” conference** took place in Brussels on the 8th of December under the auspices of EC President von der Leyen, with the participation of EC Vice-President Schinas, Commissioner Kyriakides, in charge of Health, together with Commissioner Breton, in charge of Internal Market.

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

The collaboration with **global partners** is a key element to ensure equitable global access to COVID-19 vaccines and to remedy the deficiencies in global preparedness, prevention and detection of health emergencies. HERA managed in a short time to build strategic relations and to conclude critical agreements with key third countries and organisations. The purpose of those agreements was to increase global intelligence capacities and intelligence gathering and to strengthen cooperation on countermeasures to prevent, prepare, detect and rapidly respond to serious cross-border threats to health.

Taking into account the new Global Health Strategy along with the State of Preparedness report, HERA contributed to Commission's exercise of the external representation in global fora, it built up resilience via administrative arrangements with key international stakeholders. Specifically, HERA concluded an administrative arrangement in 2022, with the US Department of Health and Human Services, linking as well with the work of the EU-U.S. COVID-19 Manufacturing and Supply Chain Taskforce. HERA also enhanced cooperation with regulatory authorities, agencies active in the field of health emergency preparedness and response and with health ministries of other third countries (e.g. Republic of Korea, Japan) and with relevant bodies within international organisations (e.g. WHO).



## **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 financial management and internal control**

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 partially effective as internal control principles 4,8, 10 and 12 need major improvements. The improvements and remedial measures envisaged are the development of a Business Continuity Plan, Procedure for reporting exceptions and non-compliance events, and an Anti-fraud Strategy. Please refer to annual activity report section 2.1.3 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 2.1 for further details.

Further, in 2022, in line with the the Commission's Internal Control Framework, HERA carried out a risk identification and assessment exercise as part of the 2023 Management Plan preparation. HERA has identified its complex funding structure as a risk with high potential impact on the achievement of HERA objectives.

HERA draws funding from different programmes (EU4Health, Horizon Europe, Union Civil Protection Mechanism), and each of the programmes is governed by an individual legal base, objectives, implementing rules and procedures. HERA funding programmes and the associated HERA budget is implemented by partner DGs under the responsibility of other AOSDs. This complexity could limit HERA's ability to fully attain its political objectives within each of the programmes and to mobilise the necessary budget for their attainment. This risk has been assessed to determine its impact on management's assurance about the achievement of the control objectives. Please refer to Section 2.1 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 business continuity, selection and development of control activities, and deployment through policies and procedures. The following actions are/will be taken in this respect: development and adoption of HERA Business Continuity Plan, Anti-Fraud Strategy, and IT Security Plan. HERA will also engage in mitigating actions specifically addressing the risk related to its complex funding structure. The 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

## General Objective 1: 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 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: Crisis response in case of health emergencies

The European Health Union<sup>7</sup> has been further strengthened with a new Regulation on serious-cross-border threats to health<sup>8</sup> adopted on 24 October 2022. The Regulation calls for the creation of a Union Prevention, Preparedness and Response plan, complementary to Member States' plans which will promote an effective and coordinated response to serious cross-border threats to health. Complementing this set-up it was adopted on the same day, the Council Regulation<sup>9</sup> (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

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(<sup>7</sup>) [https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-of-life/european-health-union\\_en](https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-of-life/european-health-union_en)

(<sup>8</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

(<sup>9</sup>) Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

Union level, in order to prepare for a possible declaration of health emergency<sup>10</sup> at Union level, and to be able to adopt swiftly the necessary implementing measures. The “Emergency Framework” Regulation provides the framework for HERA’s proposed crisis mode and enables the Union to take necessary measures for sufficient and timely availability and supply of crisis-relevant medical countermeasures in case of future public health emergencies.

While the Council reached a political agreement on the proposed Emergency Framework Regulation already on 20 December 2021, its formal adoption was postponed to the last part of 2022 because it required simultaneous adoption with the Regulation on serious cross-border threats to health.

HERA’s preparatory work for the implementation of the Emergency Framework Regulation started at the end of 2022.

### **COVID-19 vaccines**

In 2022, HERA was continuously engaging with the companies to review and adapt the COVID-19 vaccine contracts in line with Member States’ needs. Several amendments to the contracts with BioNTech-Pfizer and Moderna have been made to postpone doses initially scheduled for the second, third, and fourth quarters of 2022 to a later stage.

These doses are being delivered in the new formulations of the vaccine adapted to the Omicron variant of the virus. On 1 September, the EMA approved the BA.1 mRNA Omicron-adapted vaccines (both Spikevax and Comirnaty). The respective follow-up of vaccine contracts was followed by HERA and deliveries of BA.1 mRNA-adapted vaccines have started the week of 5 September 2022. Member States have transitioned from Comirnaty BA.1 to BA.4/5 starting the week of 19th September onwards and adapted BA.4/5 Spikevax from 19 October 2022 on.

In addition, an amendment was concluded with Valneva to adapt the contract following delays in obtention of Marketing Authorisation. Negotiations were conducted with Novavax, following delays of deliveries in Q2/Q3 2022, to ensure the delivery of doses with adequate shelf life according to an adapted delivery schedule, with signature aimed for January 2023. Similarly, adaptation of the Sanofi delivery schedule was implemented at the end of 2022. The EU’s advance purchase agreement with Janssen for COVID-19 vaccine was closed after the last contractually foreseen deliveries in June 2022. Under this agreement, EU Member States ordered 237 million vaccine doses, of which they donated 166 million doses to third countries through COVAX.

Due to the changing epidemiological situation, Member States had significant quantities of vaccine doses scheduled for delivery for which they needed additional storage capacity. On 8 November 2022, HERA, on behalf of Participating Member States, signed an amendment to the BioNTech-Pfizer purchase agreement, opening the possibility to participating Member

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<sup>(10)</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

States to have their doses delivered to a central storage facility, which provides for extra storage capacity in addition to their national storage capacities.

Finally, in August 2022, HERA has signed the framework contract under the Joint Procurement Agreement with HIPRA giving access to 13 participating countries to up to 250 000 000 doses of vaccines as soon as the marketing authorization will be granted.

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

The Commission-appointed expert group on SARS-CoV-2 variants were requested to assist the Commission also in 2022, and two digital meetings were held. In addition, the expert group also provided assessment on variants by written procedure. In 2022, the expert group's mandate was extended by two more years, and the secretariat has been taken over by HERA, from DG SANTE.

### **COVID-19 therapeutics**

In 2022, HERA signed two framework contracts under the joint procurement agreement for covid-19 therapeutics. In July 2022, HERA signed the framework contract with Gilead giving access to 23 participating countries to up to 2 250 000 vials of Remdesivir. In November 2022, HERA signed the framework contract with Pfizer in the name of 13 participating countries for the purchase of up to 3,5 million treatment courses of Paxlovid. The procedure to establish a framework contract for the therapeutic to treat MPOX (Tecovirimat) was also initiated in 2022 and the negotiations are still ongoing. Through Joint procurement mechanism, the Commission strengthens cooperation, allows equitable access to all participating countries to medical countermeasures, as well as aims for economies of scale, and better contractual conditions.

### **Response to outbreaks**

In 2022, HERA demonstrated its capacity to purchase in a short period of time 334,540 doses of vaccines to fight the MPOX outbreak in the EU. These doses were subsequently donated to all Member States and associated countries to EU4Health Programme (Norway, Iceland and Ukraine) wishing to participate as from June 2022. HERA was able to do such a swift purchase because there was an action in the 2022 EU4Health programme to procure vaccines against infectious disease threats. One of the main challenges in achieving the vaccine purchase was the limited availability of the vaccine, which is produced by only one company. HERA also purchased 10,008 treatment courses of the antiviral tecovirimat (using NGEU budget which is available until the end of 2023), efficient for severely ill patients, which were included into a rescEU stockpile that Member States can access in case of urgent needs. To ensure that Member States also have access to these important vaccines and therapeutics in the medium-term, HERA organised two joint procurement procedures. In November 2022, HERA secured a framework contract for the purchase of up to 2 000 000 doses of vaccines against MPOX on behalf of 14 participating countries under the Joint Procurement Agreement. The negotiations on the framework contract for the therapeutic tecovirimat are still ongoing with a view of providing a mid and long-term option to participating countries.

## 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. HERA also supported DG ECHO in setting up a system for channelling private donations to Ukraine, and managed to guarantee donations of essential items such as childhood vaccines. To coordinate the global crisis response in the area of health, HERA set up bi-weekly coordination meetings with the World Health Organisation, UNICEF, the US Department for Health and Human Services, and the US Agency for International Development. Finally, HERA also collaborated with the EMA to monitor any shortages of medicines that may arise out of the invasion.

## Specific objective 2: Preparedness for health emergencies

The first State of Health Preparedness Report<sup>11</sup>, announced in June 2021 in the Commission Communication "Drawing the early lessons from the COVID-19 pandemic", was adopted on 30 November 2022 by the College. The State of Health Preparedness Report, the first of its kind for the Commission and to become an annual exercise, is to focus on different aspects of preparedness every year. It reflects the changing risk landscape in the EU and the state of health preparedness to address the main health threats which the EU may have to face in the future.

The first edition focuses on preparedness capabilities related to medical countermeasures. The report presents an overview of the progress made throughout the past three years to reinforce preparedness in the EU. Second, it outlines the state of play and actions that are planned to fill the gaps in relation to ensuring sufficient availability and supply of medical countermeasures. In future editions, the focus could also be on other elements, beyond medical countermeasures, which are indispensable to reaching sufficient levels of health preparedness.

The 2023 Annual Work Plan of HERA<sup>12</sup>, adopted on 30 November 2022, presents precisely the actions HERA will implement to support Member States' preparedness for future cross-border threats to health with a focus on availability and accessibility of medical countermeasures.<sup>13</sup> In terms of process, the text of the Annual Work Plan is the result of a joint effort with Member States (consulted through the HERA Board) but reflects also valid contributions from stakeholders (Joint Industrial Cooperation Forum and Civil Society

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<sup>(11)</sup> COM(2022) 669

<sup>(12)</sup> C(2022) 8774

<sup>(13)</sup> Budgetary figures and actions included in the Annual Work Plan are indicative and therefore subject to change, pending the adoption of the decisions of the underlying funding programmes (Horizon Europe (2023-2024), EU4Health (2023) and the Union Civil Protection Mechanism (2023).

Cooperation Forum) consulted on HERA's strategic priorities for 2023. It also draws on the combined contributions of various Commission services.

### **Threat assessments and intelligence gathering<sup>14</sup>**

In line with the HERA Work Plan 2022<sup>15</sup>, HERA, in collaboration with Commission services, EU Agencies, and international partners and experts, conducted this prioritisation exercise to select three high-impact health threats, to ensure global alignment and close collaboration on global health security. Concluding the exercise in July 2022 with the endorsement of the HERA Board, three serious cross-border health threat categories were defined, notably:

- pathogens with high pandemic potential: this includes looking into specific viral families of concern, taking herein also into account the zoonotic nature of most high consequence emerging infectious diseases. This category includes mainly respiratory RNA viral families;
- Chemical, biological, radiological and nuclear threats: these can originate from accidental or deliberate release, taking into account global geopolitical tensions, as well as incidents caused by rogue actors. CBRN substances have been identified based on their likelihood to occur and their potential impact on human health; and
- Threats resulting from antimicrobial resistance, which pose one of the greatest risks to human health, with antibacterial resistance alone causing an annual estimate of over 1.2 million deaths globally.

This task specifically targeted the HERA's deliverables 1.9 and 1.10, notably the 'establishment of a regular prioritisation exercise' (deliverable 1.9) as well as the 'selection of three high impact threats [...] as final step of the prioritisation exercise' (deliverable 1.10), and informed and fed into major ongoing and subsequent HERA actions, namely the threat assessment and intelligence gathering (task 1), the promotion of advanced research and development of medical countermeasures and related technologies (task 2), the ensuring of provision of medical countermeasures (task 4), and the international dimension (task 6), and thus constitutes a major milestone in HERA's endeavour.

As a continuation of this health threat prioritisation exercise, HERA has established a prioritisation methodology in consultation with Member States, the Joint Industrial Cooperation Forum and the Civil Society Forum, consisting of a set of criteria (taking into account the criteria established under the structure dialogue on security of medicines supply) to prioritise the medical countermeasures according to the needs for action at EU level. The prioritisation will be carried out taking as a basis the catalogue of medical countermeasures for preparedness and response that includes threat specific medical countermeasures and horizontal medical countermeasures to address the high priority threats. The objective is to establish lists of critical MCMs for specific purposes such as monitoring of supply, research and development, purchase and stockpiling. The prioritisation itself will be conducted

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<sup>(14)</sup> In line with tasks identified in COM(2021) 576 final

<sup>(15)</sup> [https://health.ec.europa.eu/publications/hera-work-plan-2022\\_en](https://health.ec.europa.eu/publications/hera-work-plan-2022_en)



between HERA and Member States and be validated by the HERA Advisory Forum and HERA Board.

In 2022, for threat detection and threat modelling, HERA started the analysis work for establishing state of the art, real-time data and intelligence capacity on threats, medical countermeasures and enabling technologies, as well as functions for real-time analytics and modelling to inform needs' quantification. HERA encountered some challenges with the feasibility study for the definition of the requirements for the IT platform and had to terminate the specific contract. HERA took immediately an action to remedy this situation and decided to pursue the work with a new contract which was signed in December 2022.

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

HERA signed an administrative agreement with WHO for the implementation of the action "Strengthening preparedness and response to cross-border health threats at global level" (CP-g-06.7) under EU4Health Work Programme for 2021. The main focus of this action is to support ongoing and effective global initiatives coordinated by the WHO that can bring an added value to the EU health protection in improving significantly pandemic prevention, preparedness and response. This action will support the activities of the WHO on AMR, including activities related to GARDP<sup>16</sup> and SECURE<sup>17</sup>, as well as WHO activities for priority signalling in the development of new medical countermeasures against AMR: maintaining of Bacterial and Fungal priority pathogen list (WHO BPPL and FPPL), review of antibacterial and antifungal agents in clinical and preclinical development to guide R&D investments, and establishment of target product profiles.

The study commissioned by HERA on "bringing more AMR countermeasures" has been finalised. Its assessment of various options for pull incentives for antimicrobials based on procurement mechanisms was shared and shared with the HERA-Board Members on 30 January 2023. HERA included an EUR 22 million action (CP-p-23-16 Support innovation and access to antimicrobials) in the EU4Health work programme 2023 in order to establish a network of public bodies supporting HERA in the implementation of the option(s) to be prioritised by the HERA-Board.

HERA has collaborated with DG RTD for the establishment of the One-Health AMR Partnership under horizon EUROPE, which will support the discovery and early development of antimicrobial and diagnostics relevant for AMR, as well as for the deployment of the adaptative clinical trial platform ECRAID and its use for AMR MCM.

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<sup>(16)</sup> GARDP is a not-for-profit research entity that was initiated in 2016 by WHO and the Drugs for Neglected Diseases Initiative (DNDi) to develop new antibacterial treatments for priority drug resistant infections. Under this partnership, GARDP is developing new antibiotic treatments against WHO priority pathogen

<sup>(17)</sup> WHO and GARDP collaborate to set-up SECURE – The Antibiotic Facility: a public health consortium dedicated to accelerating access to newly registered and generic essential antibiotics and support countries in addressing drug-resistant bacterial infections.

In 2022, HERA designed and started establishing HERA INVEST by dedicating EUR 100 million to the Research, Innovation and Digitalisation Policy Window (RIDW) Thematic Innovation financial product implemented by the European Investment Bank (EIB) under the InvestEU Fund. HERA INVEST will support investments, through venture loans, into innovative European companies developing interventions (i.e. diagnostics, therapeutics, vaccines) against priority cross-border health threats (i.e. pathogens with high pandemic potential, AMR, CBRN).

On 9 December 2022, HERA organized a virtual workshop on next generation vaccines. The workshop was attended by 141 participants, including industry representatives, national authorities, scientific experts and vaccine developers. The workshop was an opportunity to discuss and showcase current advances towards the development of innovative vaccines, including a new generation of COVID-19 vaccines, that are more broadly protective and provide longer lasting immunity, use innovative modes of administration and delivery systems, and could potentially ensure vaccine equity worldwide.

The allocation of the 2022 Horizon Europe budget earmarked for HERA proved rather complex due to several reasons, and mainly because HERA had not yet been established at the time of the negotiations for the Work Programme 2021-2022. As a result, HERA did not participate in the co-creation process, and therefore there was only a very limited amount of topics relevant for pandemic preparedness. On the contrary, during 2022, HERA participated in the co-creation of the Horizon Europe Work Programme for 2023 and 2024. Research topics relevant for preparedness for serious cross-border health threats were developed for cluster 1 (health research) and cluster 3 (Civil security for society). Topics focus on immunogenicity profiles of priority viruses, their host-pathogen interactions, the development of novel vaccine technologies, innovative diagnostics and adaptive clinical trial platforms.

HERA has collaborated with DG RTD on the existing clinical trial networks in the EU. Existing European COVID-19 clinical trial networks help HERA to evaluate the values of the ongoing studies and their possibility to bring out any innovative elements. HERA has also participated in the meetings of Emergency Task Force (ETF) which is an advisory and support body that handles regulatory activities in preparation for and during a public-health emergency, such as a pandemic. The European Medicines Agency (EMA) established the ETF in accordance with the Regulation on EMA's Reinforced Role (Regulation (EU) 2022/123).

### **Addressing market challenges and boosting the Union's 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 2022, HERA began addressing identified industrial and market bottlenecks that are impeding or have the ability to impede access to medical countermeasures.

In 2022, HERA set up the Joint Industrial Cooperation Forum (JICF) as a sub-group of the HERA Advisory Forum. The JICF brings together Member States and industry representatives. Its main aim is to identify and provide recommendations on supply chain vulnerabilities that could limit the production of relevant medical countermeasures. The Forum, which met twice

in 2022, has enabled the Commission to closely follow the situation across critical supply chains. It has also provided a platform to foster cooperation with Member States and industry by consulting members on other relevant topics related to medical countermeasures (e.g. research and development, stockpiling). Bi-yearly meetings will continue in 2023 including to explore options to boost the EU's open strategic autonomy.

On 3 March 2022, the first “Important Projects of Common European Interest” (IPCEI(s)) related to health was launched under the lead of France. A Manifesto<sup>18</sup> was signed by 16 Member States. As announced, the IPCEI health aims to promote the strategic autonomy of Europe in the field of health. . The project portfolio covered by the ICPEI are of high relevance to HERA, notably in the field of antimicrobial resistance. As such, HERA is closely following the notification process and is expected to be represented in the governance of the IPCEI during its implementation.

### **Provision of medical countermeasures**

In 2022, the Commission, including HERA, started the work to set up a network of ever-warm manufacturing facilities for vaccines (EU FAB). The call for tender was launched on 27 April 2022 and offers were submitted on 14 October. The evaluation of the offers is ongoing.

In addition to the various framework contracts for therapeutics and vaccines against COVID-19, under the joint procurement agreement, HERA has signed a framework contract with GSK in July 2022 for the reservation of the pandemic influenza vaccines in the name of 13 participating countries. As specified under the point on response to outbreaks, HERA secured the framework contract for the MPOX vaccines in November 2022, and HERA is also working on the FWC for the therapeutic against MPOX. HERA also launched the first phase of the pilot project in June 2022 for the dynamic purchasing system (DPS) for personal protective equipment (PPE). The call is open for applications for 4 years in order to establish a list of potential suppliers of PPE that would be invited to submit a tender in the second phase of the project.

HERA commissioned a study on flexible manufacturing in March 2022 to assess potential options for consideration to ensure flexible production capacity for therapeutics and vaccines at times of crisis. The draft final report was received in December 2022 and the study is due to conclude in Q1 2023. This will inform strategic decision on how to secure the provision of medical countermeasures in the coming years.

### **Stockpiling**

The study entitled “AMR feasibility study on stockpiling” has been finalised and its reports published<sup>19</sup>. The results of this study have been used for the following purposes

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(<sup>18</sup>) Press\_Manifesto\_towards\_health\_IPCEI.pdf (economie.gouv.fr)

(<sup>19</sup>)<https://op.europa.eu/en/publication-detail/-/publication/c68221dd-80e0-11ed-9887-01aa75ed71a1/language-en/format-PDF/source-278668958>

-The contractor's proposals for improving antimicrobial supply chain continuity that require legal basis to be implemented, notably the establishment of mandated increase of inventories within existing commercial supply chains, have been submitted to the Commission service in charge of revision of the EU Pharma legislation (DG SANTE) for further assessment and potential inclusion in the revised act

-The contractor's proposals of establishing a physical EU-owned stockpile of anti-TB drugs has been shared with MS and relevant Commission services, in preparation of the stockpiling actions to be undertaken under the EU funding programme rescEU (see below).

-Finally the methodology developed for the prioritization of antimicrobials for stockpiling, and the assessment of supply chain vulnerabilities has been used for the further building of HERA's own capacity for intelligence gathering on MCM.

To enhance the EU preparedness for the main health threats identified by HERA (pathogens with high pandemic potential, AMR and CBRN threats), in 2022 HERA has started establishing stockpiles of priority medical countermeasures under rescEU. In close collaboration with DG ECHO a call for proposals was launched in March 2022 for CBRN stockpiles specifically. This call closed in June 2022 and the evaluation process resulted in the signature of four grants for stockpiles with Croatia, Finland, France and Poland. The items that will be stockpiled have been selected as priority items together with the Member States. In 2023, another call for proposals will be launched focusing on medical countermeasures against all three priority threats, with a budget available of 641.5M EUR.

### **Strengthened knowledge and skills**

Throughout 2022, HERA started to prepare its future training programme. Lessons learned from the Covid-19 pandemic and other health emergency responses are being compiled and analysed, alongside lessons learned from emergency responses implemented by HERA (e.g. mpox and ebola response). To ensure budget availability, three calls have been prepared and included under the EU4Health work programme 2023 and not under the 2022 budget as originally foreseen. One call is dedicated to a comprehensive analysis of training needs and gaps in Member States to inform HERA's training strategy and programme. A second call will fund the first table top exercises to test coordination and inter-operability between HERA and Member States. A third call will fund training activities linked with ongoing actions, e.g. joint procurement and stockpiling exercise. HERA has also started contacts with main stakeholders, e.g. WHO Academy and other services, looking for opportunities for cooperation and synergies.

### **Governance and coordination**

Political steer is provided by the HERA Coordination Committee, which in line with the provisions set forth in the decision establishing HERA has brought together on regular basis:

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the Vice-President of the Commission in charge of Health; the Commissioner in charge of Health; and Commissioners in charge of the Internal Market, Innovation and Research and Crisis Management. Two meetings of it took place: one in April and the second in December 2022.

As a contribution to strengthening the EU health security framework, HERA has in the course of 2022 conducted discussions to set the cooperation and coordination mechanisms aimed to prevent, detect and respond to cross-border health emergencies with SANTE, EMA and ECDC through dedicated working arrangements. The process suffered some delays as the guidance from SG internal coordination and procedure for cooperation instruments and agreements with EU decentralised agencies was issued in November 2022<sup>20</sup>. Signature is now aimed at first quarter of 2023.

HERA Board is composed of members at senior level with ECDC, EMA, Norway participating as observers. HERA Board is also flanked by a Sherpa group to assist it. It was registered as expert group on 01/07/2022 and rules of procedure were adopted, meeting on numerous occasions (9) in 2022 in regular format but also at Ministerial level under the Czech Presidency on vaccines as well as on ad hoc basis because of Omicron and Mpox crisis.

Through the HERA Board, HERA has further strengthened the close relationship between Member States and the Commission. Building on this dedicated governance structure, HERA has increased its outreach beyond the Member States with the health, research and industry communities in setting-up of the HERA Advisory Forum ("Forum"). HERA Board members were asked to designate members for the Forum from technically competent bodies in the field of research/science, health and industrial matters. The Forum met for the first time in April 2022 to kick off the works of this group. Two subsequent meetings took place in September and in December 2022, while two workshops (one on clinical data collection for Mpox and one on next generation vaccines) were organised in August and in December 2022 respectively.

In accordance with Article 7 of HERA Decision, a sub-group to the Forum, called "Joint Industrial Cooperation Forum" (JICF) composed of the representatives of the industry and Member States was created. In the course of 2022, the JICF was convened four times. Mirroring the engagement of industry in the work on the Forum, HERA valued that the civil society should be also be represented in order examine specific questions which have impact on the EU citizens and set-up the Civil Society Forum (CSF). CSF met four times during 2022.

In accordance with the Commission Decision C(2014) 2258, the Joint Procurement Agreement Steering Committee (JPASC) is established in order to steer matters relating to the Joint Procurement of medical countermeasures, namely taking decisions on which medical countermeasures should be purchased. The JPASC is composed of representatives of countries participating in the Joint Procurement Agreement. The JPASC is consulted prior to launching a procurement procedure and nominates a sub-group (Specific procurement

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(20) Ares (2022)8156827-25/11/2022

procedure steering committee “SPPSC”) for a particular procedure, which is in turn consulted throughout the procedure. In 2022, HERA organised 8 meetings with the JPASC.

On the 15th of February 2022, HERA invited DGs SANTE; RTD; GROW; ECHO; INTPA; NEAR; JRC; SJ; SG and EEAS to participate in a HERA Inter-Service Steering Group (ISSG).

A first Memorandum of Understanding with DG SANTE signed in March 2022 followed by a tripartite one with the European Health and Digital Executive Agency (HaDEA) on the Specific provisions for the implementation of the EU4Health Programme (2021-2027) and its legacy Third Health Programme (2014-2020) in December 2022.

Finally completing the governance set-up, HERA activated the HERA Board in February 2022 asking Member States for the proposal/nomination of the “HERA like agencies/entities”. Very few contributions, mostly informal, were received highlighting the difficulty of such nominations as often such entity, at national level, does not exist yet. Several avenues will need to be pursued in 2023 to see how such collaboration can be established.

### **Communication activities**

The “One Year of HERA” conference took place in Brussels on the 8th of December 2022 under the auspices of EC President von der Leyen, with the participation of EC Vice-President Schinas, Commissioner Kyriakides, in charge of Health, together with Commissioner Breton, in charge of Internal Market.

This conference was the first time that actors from the institutional EU governance (including the European Parliament and the Czech Presidency) networks but also from industry, research, academia, civil society, national/local/regional authorities, key international organisations, partner countries as well as other stakeholders could gather together. More than 380 participants convened in person on the day, making of this first conference a success story and attracting attention on social media.

To ensure that policy activities are supported and complemented through external communication, there are frequent 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 own Twitter account, which was operational as of 1 September 2022. The promotion of HERA within the Commission in terms of communication comes through the intranet, which became operational in Q3. HERA’s communication officer meets with their counterparts in EMA, ECDC and HaDEA weekly to biweekly to ensure HERA’s activities are also shared with these key EU agencies.

### **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.

### **Vaccine sharing, COVAX and access to COVID-19 therapeutics.**

HERA has been supporting Member States' donations of COVID-19 vaccines to Low- and Middle Income Countries (LMIC) via COVAX and bilateral donations. In 2022, Member States shared 132 million doses, of which 101 m via COVAX and 31 m bilaterally. Almost 19 m of those were the new adapted COVID-19 vaccines.

### **Collaboration with global partners**

In 2022, HERA built a new network of global partners united in the goal to better prevent, prepare, and respond to serious cross-border health threats.

International cooperation is essential to avoid the failures of the COVID-19 crisis. In Africa, HERA works closely with the Africa Centres for Disease Control and Prevention (Africa CDC) and with WHO.

The Commission, with HERA at the forefront, and the U.S. Department of Health and Human Services signed in June 2022 an administrative arrangement<sup>21</sup> to strengthen the cooperation on preparedness and response to public health threats, aiming to work closely on a broad range of topics to jointly tackle health emergencies, contributing to establishing a strong global health architecture, with regular exchange since taking place, notably with the Administration for Strategic Preparedness and Response's (ASPR) Biomedical Advanced Research and Development Authority (BARDA).

In October 2022, the Coalition for Epidemic Preparedness Innovations (CEPI) and HERA signed a Letter of Intent<sup>22</sup> to develop a process of cooperation and the exchange of information.

In November 2022, HERA jointly with DG INTPA visited Africa CDC headquarters in Ethiopia to discuss the future collaboration.

The Head of HERA further deepened relationships with Africa by attending and presenting at the Conference on Public Health in Africa, in Kigali in December 2022.

In December 2022, HERA signed a contribution agreement with WHO AFRO for EUR 2 million to support the scale up of laboratory capacities both for clinical and environmental surveillance in several African regions. These capacities will ensure better detection of health threats and enhance preparedness and response.

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(<sup>21</sup>) [https://ec.europa.eu/commission/presscorner/detail/en/IP\\_22\\_3203](https://ec.europa.eu/commission/presscorner/detail/en/IP_22_3203)

(<sup>22</sup>) [https://health.ec.europa.eu/publications/letter-intent-regarding-cooperation-between-cepi-and-hera\\_en](https://health.ec.europa.eu/publications/letter-intent-regarding-cooperation-between-cepi-and-hera_en)

HERA has earmarked EUR 6 million to increase sequencing capacities in Africa in collaboration with the Pathogens Genomic Initiative of AfCDC. This collaboration will ensure that the current capacities that were developed as a response to COVID-19 will also be ready for other pathogens. HERA started, also, discussions with Africa CDC to donate mpox/smallpox vaccines to combat this endemic disease in Africa.

In addition, HERA has earmarked EUR 7 million for 2023, to increase intelligence gathering in Africa with the establishment of a new WHO Hub in the region and to support clinical trials for better response e.g. in Uganda.

In 2022, HERA has started negotiating administrative arrangements with the South Korea and Japan. This process was initiated by visits of the Head of HERA and the Deputy Head of HERA to both countries.

In December 2022, HERA and the WHO Hub for Pandemic and Epidemic Intelligence signed an administrative agreement to strengthen cooperation on countermeasures to prevent, prepare, detect, and rapidly respond to serious cross-border threats to health. HERA also signed a contribution agreement for EUR 4 million with the WHO Hub to increase global intelligence capacities including the support for a global market intelligence platform. These activities are in line with HERA's 2022 Work Plan's deliverable 1.3, 'establishing a structured collaboration'.

In December 2022, HERA signed a contribution agreement with WHO (EUR 8 million) to support to their global activities on AMR, including to GARDP to support the development of new antimicrobials. HERA also contributed with EUR 1 million to the further development of the COVID-19 technology access pool in order to assess its possible extension to other cross border health threats.

HERA started to collaborate with BMGF in 2022, among others in the area of wastewaters. This collaboration was particularly visible with the co-organisation of several sessions of the BMGF grand challenges event.

### **EU added value**

The signature of administrative or contribution agreements with a new network of global partners enforces the goal to better prevent, prepare, and respond to serious cross-border health threats. The administrative agreement with WHO for the implementation of the action "Strengthening preparedness and response to cross-border health threats at global level" is such an example. The support of ongoing and effective global initiatives coordinated by the WHO can bring an **added value to the EU health protection** in improving significantly pandemic prevention, preparedness and response.



## **2. MODERN AND EFFICIENT ADMINISTRATION AND INTERNAL CONTROL**

## 2.1. Financial management and internal control

Assurance is provided on the basis of an objective examination of evidence of the effectiveness of risk management, control and governance processes.

This examination is carried out by HERA management, which monitors the functioning of the internal control systems on a continuous basis, and by internal and external auditors. The results are explicitly documented and reported to the Director-General.

The following reports 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, non-compliance events and any cases of 'confirmation of instructions' (Art 92.3 FR);
- 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 2.1.1 Control results, 2.1.2 Audit observations and recommendations, 2.1.3 Effectiveness of internal control systems, and resulting in 2.1.4 Conclusions on the assurance.

### 2.1.1. Control results

This section reports and assesses the elements identified by management which support the assurance on the achievement of the internal control objectives (ICO)<sup>23</sup>. The DG's assurance building and materiality criteria are outlined in the annual activity report annex 5. 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 2022, HERA had payments of EUR 438 million.

DG INTPA paid EUR 430 million on behalf of HERA under the Emergency Support Instrument through a cross-subdelegation. This payment represented pre-financings to secure and support the distribution of 200 million COVID-19 vaccine doses to countries in need.

Further, HERA paid EUR 7.5 million under the EU4Health programme for 4 contribution agreements with WHO. This payment constituted pre-financings to strengthen preparedness and response to cross-border health threats at global level.

Thus, the total amount of pre-financings that does not represent relevant expenditure for HERA's assurance in 2022 comes up to EUR 437.5 million.

In 2022, under the Emergency Support instrument, HERA implemented EUR 0.5 million in direct management signing 3 grants with top class research institutes to carry out urgent characterisation of the SARS/CoV2 omicron variant. The payments were executed by DG SANTE on the basis of a Memorandum of understanding, in compliance with DG SANTE control strategy. This is the amount for which HERA provides assurance in 2022.

In 2022, 100% of HERA EU4Health 2022 budget was implemented by the Health and Digital Executive Agency (HaDEA) for a total amount of EUR 275 million in commitment appropriations. HaDEA also implemented 80% of HERA EU4Health 2021 budget, signing grants and procurement contracts for approximately EUR 50 million.

In 2022, HERA co-delegated EUR 580.5 million in commitment appropriations 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 125 million, contributing to HERA objectives were earmarked for HERA by DG RTD under the Horizon Europe 2022 programme.

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(<sup>23</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.

The partner DGs/ executive agencies provide assurance on the amounts co-delegated to them in their own Annual Activity Reports.

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.

In autumn 2022, HERA established the monitoring criteria against which the implementation of the internal control principles would be assessed and monitored. The selection of the monitoring criteria was conducted in parallel with the 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 HERA implementation of the internal control framework was finalized in time for the completion of the AAR 2022. The self-assessment took into consideration the fact that HERA is a newly established DG and is still in the process of building institutionally.

In February 2022, the Internal Audit Service carried out a limited review on HERA's assessment of its Internal Control Framework for the 2022 AAR. During the review, the IAS assessed the adequacy of the design and the effectiveness of the assessment process of the implementation of HERA Internal Control Framework.

The Internal Audit Service concluded that in 2022, HERA had 8 internal control principles that were present and functioning well, 5 internal control principles present and functioning with some improvements needed, 3 internal control principles that were partially present with major improvements needed, and only 1 principle that was not present.

In terms of major improvements, HERA needs to develop a Business Continuity Plan, Procedure for reporting exceptions and non-compliance events, and an Anti-Fraud Strategy. As in 2022 HERA was still establishing institutionally with many processes and procedures being introduced for the first time, these major documents will become the focus of attention in 2023.

In 2022, HERA recorded no exceptions to the standard procedures in financial management and no non-compliance events. 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);

- Cases of "Derogations from the principle of non-retroactivity pursuant to Article 193 FR" (new Financial Regulation Article 193.2).

## 1. Effectiveness of controls

### a) Legality and regularity of the transactions

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 2022 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 co-delegation agreement signed with DG ECHO requires the authorising officer responsible to report on the use made of the delegated appropriations. For 2022, the authorising officer of DG ECHO did not communicate any events, control results or issues which could have a material impact on assurance.

Based on a Memorandum of understanding, in 2022, DG SANTE carried out financial initiation and verification of all HERA transactions. These amounted to EUR 0.5 million of payments for three grants associated with the urgent characterisation of the SARS/CoV2 omicron variant. The payments were executed in accordance with DG SANTE control strategy, detailed in DG SANTE 2022 AAR.

HERA's portfolio for 2022 consists of only these three payments on grants (EUR 0.5 million).

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 X : 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	%
Emergency Support Instrument (cross subdelegation)	430	0	0.00	0	0.00	0	0.00	0
Emergency Support Instrument	0.5	0.5	0.01	2	0.00	0	0.01	0
EU4Health	7.5	0	0.00	0	0.00	0	0.00	0

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>HERA total</b>	<b>438</b>	<b>0.5</b>	<b>0.01</b>	<b>2</b>	<b>0.00</b>	<b>0</b>	<b>0.01</b>	<b>2</b>

The relevant expenditure of EUR 0.5 million represented payments under direct management for grants executed under the Emergency Support Instrument. HERA counts on DG SANTE for financial initiation and verification of its transactions, and these payments were initiated and verified in compliance with DG SANTE control strategy. As it was DG SANTE controls that applied, HERA had to rely on the estimated risk at payment and at closure that DG SANTE calculated and applied for similar type of expenditure. In that case, the estimated error rate that DG SANTE applied was 2%.

The estimated overall risk at payment for 2022 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. This limited expenditure will subsequently not be subject to ex-post controls<sup>24</sup>; thus, the estimated overall risk at payment equals the estimated overall risk at closure<sup>25</sup>.

Based on the above, HERA concludes that the DG's controls are effective and that the payments were legal and regular.

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.

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

HERA is a newly established DG, and it will develop and implement in 2023 its own anti-fraud strategy, on the basis of the methodology provided by OLAF. It will be updated every three years. Its implementation will be monitored and reported to the management twice a year. All necessary actions, in particular an awareness raising campaign, will be implemented by the end of 2023.

As HERA was created just a year ago and in 2022 was actively recruiting staff, special focus was placed throughout the year on promotion of ethics and good administrative behaviour at all levels of the organisation.

<sup>(24)</sup> In compliance with DG SANTE control strategy for this type of expenditure.

<sup>(25)</sup> This is the AOD's best, conservative estimation of the expenditure authorised during the year that would remain not in conformity of applicable regulatory and contractual provisions by the end of implementation of the programme.

HERA will contribute to the Commission anti-fraud strategy (CAFS) by further developing the existing channels of cooperation with OLAF.

Taking into account that HERA is a low-spending Directorate-General (EUR 0.5 million in payments in 2022), and on the basis of the available information, HERA has reasonable assurance that the currently applied anti-fraud measures with regard to financial management are effective.

## ***2. Efficiency of controls***

In 2022, HERA fully delegated its financial management; thus, the efficiency of controls depended on the systems and controls of its partner entities.

## ***3. Economy of controls***

In 2022, HERA fully delegated its financial management; thus, the cost of controls depended on the systems and controls of its partner entities.

## ***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.

### **2.1.2. Audit observations and recommendations**

In 2022, there were no audits carried out by IAS and the European Court of Auditors that resulted in financial management and internal control related recommendations for HERA.

However, with regard to Covid-19 vaccine procurement, in 2022, the European Court of Auditors issued a special report No 19/2022 that examined whether the Commission and the Member States procured COVID-19 vaccines up to the end of 2021 effectively. The Special Report resulted in 2 recommendations for HERA:

- Create pandemic procurement guidelines on the basis of lessons learnt,
- Stress-test the EU's medical countermeasures procurement approach.

HERA accepted the recommendations and implementation is on-going.



### 2.1.3. 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 2022, there were no recorded exceptions, non-compliance events and any 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<sup>26</sup>.

However, the risk assessment exercise has identified the complex funding structure of HERA as a risk with high potential impact on the achievement of HERA's objectives.

HERA draws funding from different programmes (EU4Health, Horizon Europe, Union Civil Protection Mechanism), and each of the programmes is governed by an individual legal base, objectives, implementing rules and procedures. Moreover, the programmes fall 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-

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<sup>(26)</sup> The 2 recommendations following the ECA special report No19/2022 on Covid-19 vaccine procurement have been discussed above.

delegate almost its entire budget to its partner DGs/ HaDEA, the budget is implemented at different management centres under the responsibility of other AOSD.

Based on the analysis of the information sources mentioned above, HERA has assessed its internal control system during the reporting year and has concluded that it is partially effective as internal control principles 4, 8, 10, and 12 need major improvements which could have a significant impact on the assurance. The improvements and/or remedial measures implemented or envisaged are the development of a Business Continuity Plan, Procedure for reporting exceptions and non-compliance events, and an Anti-fraud Strategy. Further details are provided in Annex 8.

As there are further mitigating controls within the affected principles, and in line with HERA's approach towards establishing its materiality threshold, HERA does not consider making a reservation for 2022.

HERA will also focus in 2023 on mitigating actions related to the identified risks.

#### 2.1.4. Conclusions on the assurance

This section reviews the assessment of the elements already reported above (in Sections 2.1.1, 2.1.2 and 2.1.3), and the sub-conclusions already reached. It draws an overall conclusion to support the declaration of assurance and whether it should be qualified with reservations.

As almost the entire expenditure under HERA remit is delegated to partner DGs and HaDEA, the AODs of these services bear the responsibility for their implementation and report in their AARs. Given that no issues were reported in this regard, HERA can conclude that the controls were effective, that the payments were legal and regular and that the resources were used for their intended purpose in conformity with the principles of sound financial management. According to the results of the self-assessment exercise, the internal control principles are partially effective as internal control principles 4, 8, 10, and 12 need major improvements to be done in 2023.

In conclusion, based on the elements reported above, HERA 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.

### 2.1.5. Declaration of Assurance

***I, the undersigned, Pierre DELSAUX***

***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>(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 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, 04.04.2023***

***(signed)***

***Pierre DELSAUX***

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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.

## 2.2. Modern and efficient administration – other aspects

### 2.2.1. Human resource management

HERA grew significantly in 2022. It started with 30 staff on 1/1/2022 and progressed with 80 staff at the end of 2022. For all recruitments, the panels were always gender balanced. As regards management posts, 2 Heads of Unit were appointed in 2022 of which one woman. The 50% target of female appointments in middle management was therefore reached. The Director post and one post of Head of unit were republished and the procedures were still ongoing at the end of the year. 2022 was also a year of development of the organisation, with a new intranet website, the establishment of an internal control framework as well as the appointment of a risk management officer. The Director-General, met HERA staff in 4 occasions, and the first meeting with newcomers took place in September 2022. This close communication with staff is very appreciated and contribute to the smooth reinforcement of HERA with better integration and understanding of top management vision and expectations.

### 2.2.2. Digital transformation and information management

HERA's intranet went live in Q3 2022, the first DG to do so with the new intranet format, providing a digitally transformed space for colleagues to see the latest news updates related to HERA's activities, as well as access to key documents, procedures, and HR updates. While key documents and latest news updates are uploaded to HERA's website for external communication, the website is lacking in richer content, search engine optimisation (SEO) and enhanced user experience (UX).

On the basis of the Memorandum of Understanding between DG SANTE and HERA<sup>28</sup>, HERA is still being administratively supported by DG SANTE for the IT governance activities.

### Data protection

HERA is in the process of establishing a full inventory of all its current processing agreements with external processors, and a full inventory of internal arrangements that are necessary in order to comply with the EC Implementing Rules. In addition, HERA established a full inventory of all its current Service-Level Agreements with other EU institutions and bodies and processing agreements with Member States.

The DPC conducted awareness raising activities through emails and bilateral meetings. As a result, units followed training and information sessions, updated privacy statements, and correctly addressed data protection considerations in the design of a new IT platform. Moreover, units involve the DPC in projects involving issues related to the protection of personal data, so that the DPC can that HERA's processing operations comply with EU data protection law.

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<sup>(28)</sup> Ref.ARES(2022)1863605

The DPC further replied to the calls by the Data Protection Officer to report on data subject requests and on the implementation of the EC Data Protection Action Plan.

## Document Management

Following the creation of HERA in September 2021, 2022 was a time of building competence and establishing procedures for the functioning of Document Management within HERA.

On the basis of the Memorandum of Understanding between DG SANTE and HERA, SANTE Document Management Officer (DMO) supports HERA staff in document management tasks until it reaches full independence. For this purpose, the HERA DMO was recruited and started in August 2022. In addition, the Network of Document Management Correspondents was established, 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 2022:

- With the support of SANTE DMO Team, HERA created its first filing plan. This exercise included the transfer of files from SANTE to HERA. The filing plan is continuously under review in order to meet the needs of all colleagues.
- The Network of DMCs was put into place, and the division of tasks and responsibilities were clarified. The Network started meeting on a biweekly basis, providing a way to distribute information and channel questions from the units, discuss DM developments and establish procedures.
- The DMO took 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.
- To increase the level of knowledge on the usage of Ares among HERA staff, the DMO and DMCs started conducting crash courses within units and with individual colleagues. The DMO and DMCs also prepared material and put the necessary procedures into place to introduce newcomers to Ares and e-domec policy.
- The DMO started to send regular reporting exercises to the Network of DMCs to encourage filing, registration and cleaning tasks in Ares.

### 2.2.3. Sound environmental management

In 2022 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). Nevertheless, HERA participated to the operation of closure of the buildings each time proposed by the OIB to achieve energy savings. It ranked 1<sup>st</sup> in the walking challenge and 5<sup>th</sup> in the Velomai operations. Regarding missions and business travels of staff and experts, teleworking and videoconferences have

increasingly been used and when organising its “one year conference” all sustainability aspects were integrated in the design of the event.