



Management plan 2022

DG Health Emergency Preparedness and
Response Authority (HERA)

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INTRODUCTION

In President von der Leyen's 2020 State of the Union Address, the President called for the creation of a "European BARDA – an agency for biomedical advanced research and development" with the purpose of supporting "capacity and readiness to respond to cross border threats and emergencies – whether of natural or deliberate origin"¹. A year later, President von der Leyen presented the fulfilment of this proposal: HERA – the Health Emergency Preparedness and Response Authority that would act as a key pillar of the European Health Union and fill a gap in the EU's health emergency response and preparedness framework². The Health Emergency Preparedness and Response Authority (HERA) was established on 16 September 2021³ as a service of the European Commission. It started its work as of 1 October 2021 and can mobilise an indicative total budget of EUR 6 billion for 2022-2027. Its overarching mission is to improve preparedness and response to serious cross-border threats and public health emergencies in the area of medical countermeasures⁴. It is thus by definition highly impacted by external factors such as pandemics. Throughout 2022 HERA will be looking at a wide range of medical countermeasures with a view to improving their development, manufacturing, procurement or purchase, stockpiling and distribution.

The establishment of HERA as a Commission service was a direct response to the ongoing **COVID-19 crisis** and it will therefore continue prioritising in 2022 the **response** and delivery of medical countermeasures to this health emergency. In particular, HERA is responsible for the implementation of the EU Vaccines Strategy to secure access for EU Member States to safe and effective COVID-19 vaccines. At the same time, HERA is also active in the detection of SARS-CoV-2 variants as well as advising on the need to develop new or adapted vaccines. HERA is also responsible for the implementation of the COVID-19 Therapeutics Strategy, including the Joint Procurement contracts for COVID-19 therapeutics. On the **global** scene, HERA is working to support access to COVID-19 vaccines and therapeutics, in coordination with COVAX⁵ and vaccine manufacturers, by assisting Member States in the process of sharing vaccine doses acquired under the EU's contracts.

Finally, the response given to the COVID-19 pandemic has demonstrated how public intervention can successfully contribute to the development and availability of relevant medical countermeasures. HERA will build on this experience to support the fight against **antimicrobial resistance** (AMR) in promoting the development and availability of medical

¹ https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_20_1655

² https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_4701

³ COM (2021) 576 final; C (2021) 6712 final; and COM (2021) 577 final

⁴ C(2021) 6712 final

⁵ COVAX is co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and World Health Organisation. Its aim is to accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world.

countermeasures relevant to combat AMR, including old and new antimicrobials, rapid diagnostics, and vaccine against resistant pathogens.

As put forth in the proposals of 16 September 2021, HERA has been constructed with **two modes: one for preparedness and one for crisis**.

In terms of crisis management, HERA must address gaps identified in the Union's capacity for crisis-relevant medical countermeasures to **respond to health emergencies**. HERA will therefore ensure that the EU and Member States are more ready to act in the face of cross-border crises by setting up crisis response tools and means. The **adoption of the Commission's proposal for a Council Regulation "on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level"** provides the framework for HERA's proposed **crisis mode** and will enable 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.

In recognition that preparedness is essential in order to mitigate the risks of future health threats, HERA has also been tasked with a **preparedness mode**, comprising five core tasks: (1) threat assessments and intelligence gathering; (2) Promoting advanced Research Development (R&D) of medical countermeasures and related technologies; (3) Addressing market challenges and failures and boosting the Union's open strategic autonomy; (4) Ensuring the provision of medical countermeasures; and (5) Strengthening knowledge and skills concerning medical countermeasures.

In 2022, HERA will be working closely with Member States, the European Parliament, EU Agencies and other relevant stakeholders such as industry, civil society, and researchers on operationalising these preparedness tasks. In the area of threat assessment and intelligence gathering, HERA will initiate several projects that serve to detect biological and other health threats soon after their emergence, whilst also being able to evaluate their impacts and identify the critical medical countermeasures needed to respond. In promoting R&D, HERA will be supporting research and innovation in order to develop effective, safe and affordable medical countermeasures. In the realm of addressing market challenges and boosting the Union strategic autonomy, HERA will be initiating projects that serve to identify and then ensure the availability of critical technologies and production sites for medical countermeasures in the EU. HERA will also work on strategic stockpiling and procurements to ensure that medical countermeasures are available across the EU. Finally, HERA will also start work on strengthening knowledge and skills with the objective of improving Member States' capacities in preparedness and response related to medical countermeasures.

In complementarity to these two modes, HERA is also tasked with several activities at an **international level**. COVID-19 demonstrated that serious cross-border threats to health represent risks of a global scale and that adequate responses necessitate global cooperation and coordination. HERA will therefore be initiating further work at an international dimension in order to coordinate and cooperate within and beyond the Union, with the purpose of contributing to the strengthening of the global health security architecture by increasing

resilience and ensuring the timely and appropriate availability of medical countermeasures to potential public health emergencies. To that purpose, initial administrative arrangements have been signed in May with departments from key national partner countries such as the US Department of Health & Human Services, Other bilateral arrangements with third countries and international organisations such as the World Health Organization's (WHO) Hub for Pandemic and Epidemic Intelligence, or with prominent international private organisations are also under preparation (which implementation will need to be followed as well). In addition, HERA contributes to activities promoted in the framework of international fora, such as G7 and G20 and the UN family. This concerns the work in WHO and health streams of G7 and G20 led by DG SANTE where HERA contributes on the particular issue of global pandemic preparedness and response.

To implement all of the above, HERA works closely with other Commission services⁶ as well as Union Agencies, such as the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA)

Part 1 of this management plan outlines the main priorities and outputs of HERA for 2022. These have been constructed in order to operationalize HERA's main objectives and activities as described above and as set out by the Commission via the Communication "Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union" and President von der Leyen's State of the Union Addresses.

Part 2 of this management plan describes HERA's main outputs for 2022 that serve to set up and complete its administration for 2022, with a view to ensure efficiency across human resources, finances, digital data management and fraud risk management.

⁶ Notably DG SANTE, DG GROW, DG RTD and DG ECHO. HERA is also coordinating with DG DEFIS regarding their research and development work related to medical response under the European Defence Fund. For development activities, this is specific to the defence sector and reserved for specific needs, whilst research activities allow for joint collaboration between the civilian and defence sectors, which HERA will follow up on.

PART 1. Delivering on the Commission’s priorities: main outputs for 2022

General Objective 1: Promoting our European way of life

HERA will contribute 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 (General Objective of this Management Plan).

Specific objective 1: Crisis response readiness for health emergencies

The COVID-19 pandemic has fundamentally affected and threatened the entire world and our European way of life within it. In 2022, the world will continue to face the evolving threats of the COVID-19 crisis, with the health emergency far from over. HERA will continue to be at the forefront of the Union’s **crisis response to the COVID-19 pandemic**, working to ensure that vaccines, therapeutics and other crisis-relevant medical countermeasures are accessible throughout and beyond the Union, as well as ensuring that the EU can manage the threat of emerging SARS-CoV-2 variants.

Building on the early **lessons learned from the COVID-19 pandemic**⁷, HERA will contribute to implementing a stronger European Health Union that will have **a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level** that can save human lives and mitigate economic shocks. The COVID-19 pandemic and the need to establish an adequate framework of measures in the event of a public health emergency at Union level will drive several activities of HERA in 2022.

COVID-19 vaccines⁸. In 2021, HERA took over the responsibility for the implementation of the EU Vaccines strategy to secure access for EU Member States to safe and effective COVID-19 vaccines⁹. As of end 2021, this strategy comprises eight advance purchase agreements and three purchase agreements signed so far, securing up to 4.2 billion doses of COVID-19 vaccines. Of these, five vaccines (BioNTech/Pfizer, Moderna, AstraZeneca, Janssen Pharmaceutica NV and NovaVax) have been granted conditional marketing authorisation by the Commission, following the European Medicines Agency (EMA) positive assessment of their safety and efficacy. In 2022, HERA will focus on the **implementation of these contracts** as well as the **‘EU’s vaccine strategy 2.0’, supporting the development, manufacturing, and availability of improved vaccines against COVID-19** as underlined in its Communication on COVID-19 sustaining EU preparedness and response¹⁰.

⁷ COM (2021) 380 final

⁸ Please see under General Objective 2 for activities related to Vaccine sharing/COVAX.

⁹ Communication from the Commission: EU Strategy for COVID-19 vaccines. COM (2020) 245 final.

¹⁰ COM (2022) 190 final

That strategy will also incorporate a longer-term view, beyond the immediate threat of COVID-19 vaccines, to develop the EU's capacity to manage emerging health threats.

COVID-19 detection and response to variants. Since the outbreak of COVID-19, several SARS-CoV-2 variants of concern have been detected, reported and monitored. These variants can pose a significant challenge to overcoming COVID-19, notably as they can undermine current vaccine strategies. Therefore, in 2022 HERA will be following up on HERA Incubator activities related to the **detection of variants**, such as **whole genome sequencing, testing capacity and wastewater monitoring**. In addition to this, HERA will continue mobilising the European **expert group on SARS CoV-2 variants to advise on the need to develop new or adapted vaccines** in view of new emerging variants. In line with the potential risk variants pose to COVID-19 vaccines, HERA will also **closely liaise with vaccine producers** who have started the analysis of the Omicron variant and testing effectiveness of their vaccines against the variant, in liaison with DG SANTE and EMA as regards regulatory aspects related to the authorisation of these vaccines. If **adaptations to vaccines prove necessary, the respective follow up of vaccine contracts will be followed by HERA** in the course of 2022. To support HERA's work on the **characterisation of SARS-CoV-2 variants** and ensure that scientific assessment guides decision making, HERA has also **enlisted the support of European laboratories** for this purpose and HERA will lead on this throughout 2022.

COVID-19 therapeutics. In May 2021, the Commission adopted an EU strategy on COVID-19 therapeutics. By the end of 2021, as part of this strategy, the Commission had concluded four joint procurements for access to COVID-19 therapeutics. In 2022, HERA will be responsible for the **implementation of these joint procurement contracts** as well as the **launch of new procurements for additional therapeutics**. These efforts will complement Member States' own efforts to ensure supplies of the medicines they need to fight the pandemic.

Crisis mode - legislation. In September 2021, the Commission put forward a proposal for a Council Regulation "on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level". In December 2021, a political agreement on the proposal was achieved. In 2022, HERA will work with relevant stakeholders towards achieving **the adoption of this proposed Regulation** and will then follow up accordingly with the needed **implementing structures and corresponding legislative proposals**.

Outputs for Specific objective 1: Crisis response readiness for public health emergencies

General objective: Promoting our European way of life

Specific objective 1: Crisis Response readiness for health emergencies

Related to spending programme(s): Emergency Support Instrument, EU4Health

Main outputs in 2022:

New policy initiatives

Output	Indicator	Target
Proposal for a Council Regulation “on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level”	Adoption	Q3 2022
Implementing Decisions and Delegated Acts necessary for the operationalisation of the Council Regulation on measures in case of a public health emergency at Union level.	At least 1 Implementing Decision or Delegated Act adopted	Q4 2022

Other important outputs

Output	Indicator	Target
Implementation of existing COVID-19 vaccine contracts and conclusion of new vaccines contracts	Completion of deliveries for all contracts running in 2022	Throughout the year
Enhanced and/or improved national public health capacity for Whole Genome Sequencing and/or Reverse Transcription Polymerase Chain Reaction capacity, including international collaboration e.g. with African CDC	Direct grants to MS launched	Q2 2022
Strengthened wastewater surveillance	Mapping of needs at EU level complementing activities under the HERA incubator, including ad-hoc support linked to Ukraine crisis	Throughout the year
Knowledge generation on need for new or adapted COVID-19 vaccines for variants: meetings of expert group on SARS CoV-2 variants	Organised (according to epidemiological events and adapted vaccine development milestones)	Throughout the year
Preparation for support for characterisation of the SARS-CoV-2 variants and publication of the call: European laboratories	Launched	Q2 2022

Output	Indicator	Target
Implementation of joint procurement contracts for COVID-19 therapeutics	Completion of deliveries scheduled for 2022 under all contracts	Throughout the year
Increased access to additional COVID-19 therapeutics: new joint procurement contracts	Launched	Throughout the year

Specific objective 2: Preparedness for health emergencies

Future serious cross-border threats to health¹¹ are likely to arise: 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. Intentional releases of biological or chemical agents also remain a persistent threat with the potential for significant impact. Given the acknowledgement of these risks, HERA has also been tasked with addressing preparedness gaps in the EU's health security framework. As such, in 2022, HERA will also be focusing on activities to **operationalise the five preparedness tasks** outlined in the Communication introducing HERA, as well as implementing the necessary **governance and coordination structures** required with relevant stakeholders as well as Commission services and Union Agencies.

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 countermeasure. In 2022, HERA will initiate work on threat detection, threat modelling, threat prioritisation, threat awareness and epidemic surveillance, which, in accordance with existing initiatives of other Commission's services and agencies on these matters, will contribute to medical countermeasures preparedness. In 2022, for threat detection and threat modelling, HERA will start the work of establishing **state of the art, real-time data and intelligence capacities on threats, medical countermeasures and enabling technologies, as well as functions for real-time analytics and modelling to inform needs' quantification**. In terms of threat prioritisation and threat awareness, in 2022, HERA will start by **identifying three high impact threats and then address any gaps in terms of related medical countermeasures**, acting as the initiator of a constant exercise which will eventually be broadened to cover all serious health threats and their related medical countermeasures. In 2022, HERA will also be responsible for **the first edition of an annual State of Preparedness report**, which will be presented to the European Council and the European Parliament.

Promotion of advanced R&D of medical countermeasures and related technologies. Supporting research on the source of risks – such as emerging pathogens or antimicrobial

¹¹ This includes threats of chemical, biological, radiological, nuclear or environmental origin, as well as threats of unknown origin – whether of natural or deliberate origin.

resistance (AMR) – as well as research, innovation and development of medical countermeasures and related technologies is essential in informing intelligence and analysis, ensuring discoveries and ultimately, accelerating pathways to market for medical countermeasures. In 2022, HERA will therefore be **releasing funding towards research projects on medical countermeasures, including those relevant against antimicrobial resistance (AMR), and related technologies**. In addition, HERA will be participating in the **creation of a common EU research and innovation agenda for pandemic preparedness**, support the **pooling of pandemic preparedness research capacities across the EU** and supporting the creation of **long-term and large-scale EU platform for clinical trials and data platforms**.

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 will therefore begin addressing identified industrial and market bottlenecks that are impeding or have the ability to impede access to medical countermeasures. The work will entail the **identification of bottlenecks, mapping and monitoring of supply chains and manufacturing capacities**, as well as the **creation of industrial partnerships and cooperation structures with Member States, research and civil society**. In addition to this, HERA will be setting up **a network of ever-warm manufacturing facilities for vaccines (EU FAB)** and engaging in the upcoming **Important Project of Common Economic Interest (IPCEI) on health**.

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, in 2022 HERA will be focusing on **assessing Union stockpiling capacities and needs** as well as initiating **procurements and stockpiling of top priority medical countermeasures, including those relevant against AMR**.

Strengthened knowledge and skills. In 2022, HERA will work with Member States in order to improve capacities in preparedness and response related to medical countermeasures. As a first step, HERA will be **identifying knowledge gaps** and supporting the **organisation of national/regional assessment processes of public procurement practices in the health sector**.

Governance and coordination. HERA’s work in health preparedness and emergency response to health emergencies involving medical countermeasures crosses several sectors, such as health, research, innovation and industry. In light of this, HERA will be **implementing and setting up appropriate governance and coordination mechanisms** with relevant stakeholders within and outside the Commission. This entails, for example, the running of the HERA Board, the creation of the HERA Advisory Forum of the HERA Board and stakeholder specific forums such as the Joint Industrial Cooperation Forum and the Civil Society Forum.

Coupling this, administrative working arrangements with relevant Commission services and Union Agencies will be established via Memoranda of Understanding.

Outputs for Specific objective 2: Preparedness for health emergencies

General objective: Promoting our European way of life
Specific objective 2: Preparedness for health emergencies
Related to spending programme(s): Horizon Europe; EU4Health programme; Union Civil Protection Mechanism (rescEU)

Main outputs in 2022:

Other important outputs

Output	Indicator	Target
Threat assessments and intelligence gathering		
Call for a feasibility study, design and prototype development for a mapping platform on COVID-19 therapeutics in the EU	Ongoing	Throughout the year
Preparation of IT platform for intelligence gathering (production and availability of medical countermeasures, threat assessment and mapping medical countermeasures, stockpiling management system) and publication of the call	Launched	Q4 2022
Strengthened Member States's IT systems ensuring interoperability with HERA's IT platform for intelligence gathering through direct grants	Launched	Q2 2022
Call for enhanced preparedness and management of High Impact Low-Probability or unexpected events	Ongoing	Throughout the year
Call for improved quality assurance / quality control of data used in decision-making related to risk management of natural hazards, accidents and Chemical, Biological, Radiological and Nuclear events	Ongoing	Throughout the year
Call for improved international cooperation addressing first responder capability gaps	Ongoing	Throughout the year
Call for advanced materials modelling and characterisation	Ongoing	Throughout the year

Output	Indicator	Target
Threat prioritisation and critical medical countermeasures list	Publication	Q3 2022
First edition of an annual State of Preparedness report	Publication	Q4 2022
Study on market research and mapping of innovative diagnostic testing solutions	Launched	Q3 2022
Promoting advanced R&D of medical countermeasures and related technologies		
Calls (14) for research projects to improve pandemic preparedness and response	Ongoing	Throughout the year
Partnership on pandemic preparedness to develop a common strategic EU research and innovation agenda for pandemic preparedness	Launched	Q3 2022
Call for long term and large scale EU platform for clinical trials and data platforms	Ongoing	Throughout the year
Preparation for a call for phase 3 clinical trials for certain vaccines/therapeutics	Launched	Throughout the year
Call for a study on options to bring more AMR medical countermeasures on the market	Ongoing	Throughout the year
Addressing market challenges and boosting the Union's strategic autonomy		
Call for a study on options for implementing a flexible (multi-technology) EU manufacturing and innovation capacity for vaccines and therapeutics	Ongoing	Throughout the year
Preparation on rapid reconfigurable production process chains and publication of the call	Launched	Throughout the year
Preparation for structured partnerships with companies and trade associations	Ongoing	Throughout the year
Meeting for identification of bottlenecks and solutions: Industry (Joint Industrial Cooperation Forum) and HERA	Organised	Q4 2022
HERA Industry Day (Matchmaking events at EU level for critical medical countermeasures)	Organised	Q4 2022
HERA website (Creation of section on HERA website for industry: 'Doing Business with HERA')	Publication	Q1 2022

Output	Indicator	Target
Preparation for the establishment of EU FAB and publication of the call	Launched	Q2 2022
Synergies between HERA and Important Projects of Common Interest (IPCEI) Health	Ongoing	Throughout the year
Provision of medical countermeasures		
procurement of vaccines against infectious disease threats and publication of the call	Launched	Q3 2022
Preparation for medical and Chemical Biological Radiological Nuclear (CBRN) rescEU stockpiling and publication of the calls	Launched	Q3 2022
Call for public procurement of innovative solutions for resilience of health systems	Ongoing	Throughout the year
Call for pre-commercial research and innovation procurement for resilience of healthcare systems	Ongoing	Throughout the year
Call for a feasibility study on stockpiling of medical countermeasures in the area of AMR	Launched	Throughout the year
Strengthened knowledge and skills		
Training schedule and targets based on identification of knowledge gaps	Publication	Q3 2022
National/regional assessment process of public procurements in health sector	Organized	Q3 2022
Governance and coordination		
Memorandum of Understanding with DG SANTE	set up	Q2 2022
Memorandum of Understanding with DG ECHO	set up	Q3 2022
Memorandum of Understanding with DG GROW	set up	Q3 2022
Memorandum of Understanding with DG RTD	set up	Q3 2022
Memorandum of Understanding with HaDEA	set up	Q3 2022
Interservice Group for partner DGs (RTD, GROW, ECHO, SANTE, INTPA, NEAR, SG, SJ, EEAS)	Creation	Q2 2022

Output	Indicator	Target
Memorandum of Understanding with ECDC	set up	Q2 2022
Memorandum of Understanding with EMA	set up	Q2 2022
Creation of HERA Advisory Forum and meeting of the Forum	Organised	Q2 2022
Creation of Joint Industrial Cooperation Forum and meeting of the Forum	Creation	Q2 2022
Creation of Civil Society Forum and meeting of the Forum	Creation	Q2 2022
Creation of the network of national or regional HERA-like agencies/entities and meeting of the network	Creation	Q2 2022

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

The COVID-19 crisis has clearly illustrated that global coordination and cooperation in the area of medical countermeasures is essential in response to serious cross-border threats to health. One clear example is 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 will therefore pursue several activities at an 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.** At the same time, HERA is also already operational internationally with regards to the response to the COVID-19 pandemic; HERA will therefore continue to work on **improving vaccine equity and support to vaccine sharing and improving access to other necessary COVID-19 medical countermeasures, including by actively raising awareness in international fora such as G7 and G20.**

Vaccine sharing, COVAX and access to COVID-19 therapeutics. The Commission services jointly work to ensure Team Europe's leading role in global vaccine sharing and uptake. HERA's role is to coordinate donations made under the EU's vaccines contracts, primarily through COVAX. At the same time, HERA is also responsible for implementing the **joint procurement contracts for COVID-19 therapeutics.** Participation in the Joint

Procurement Agreement now totals 37 signatories, **covering around 537 million people, including all EU and EEA population and almost all Candidate Countries and Potential Candidates.**

Collaboration with global partners. Addressing international supply chain bottlenecks, removing unnecessarily restrictions, and expanding global production capacity first requires structured collaboration and agreements with global stakeholders. HERA will begin work in this area by establishing collaboration or formal **working agreements with key partners**, such as the United States, the World Health Organization, philanthropic foundations, Africa Centres for Disease control and Prevention (AfricaCDC), Africa Medicines Agency.

Increased availability and accessibility of medical countermeasures & manufacturing and distribution capacities. In 2022, HERA will also continue to work closely with Commission services on the ongoing initiatives for African vaccine manufacturing (PAVM) and local production capacity in Africa.

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

General objective: Promoting our European way of life
Specific objective 3: International resilience and response readiness for health emergencies
Related to spending programme(s): Emergency Support Instrument, EU4Health

Main outputs in 2022:

Other important outputs

Output	Indicator	Target
Continue to work with COVAX in pursuit of global vaccination targets (strengthen the multilateral approach in pursuit of global vaccination)	Number of COVID-19 vaccine doses shared with COVAX as a total of total donations	Throughout the year
Continue implementation of joint procurement contracts for COVID-19 therapeutics	Number of participating States in the COVID-19 therapeutic joint procurement contracts	Throughout the year
Structured administrative arrangements with international stakeholders (e.g.; U.S. Department of Health & Human services Korean Ministry of Health and Welfare; WHO Hub for Pandemic and Epidemic Intelligence	Publication	Throughout the year

Output	Indicator	Target
Contribution agreement to support WHO initiatives strengthening preparedness and response to cross-border health threats at global level	Signature of agreement	Q3/Q4 2022

PART 2. Modernising the administration: main outputs for 2022

The internal control framework ⁽¹²⁾ supports sound management and decision-making. It notably ensures that risks to the achievement of objectives are taken into account and reduced to acceptable levels through cost-effective controls.

HERA is building up an internal control system tailored to its particular characteristics and circumstances. The effective functioning of the service’s internal control system will be assessed once the system is in place on an ongoing basis throughout the year and be subject to a specific annual assessment covering all internal control principles.

A. Human resource management

On 1st January 2022 HERA was counting 30 staff members. It should reach 96 staff, according to the LFS, if relevant budget was available, by the end 2022. 6 of these posts are management posts of which on 1st January 2022, 2 were occupied by men. The 4 vacant posts were advertised and will be filled with particular consideration for the gender balance. In 2022, the strategic approach for HERA HR management will be to focus on recruitments, integration, and organisational development aspects such as training, knowledge and information sharing, clarity of the structure, jobs, objectives, and internal procedures. In addition, and to further develop the compliance with the internal control framework, HERA will give regular information to its staff about ethics, IDOC recommendations about “do’s and don’ts” improvement of the EUROPA website and development of a new Intranet, monitor the compulsory trainings, and will appoint an official responsible for Internal control and financial issues. Dialogues will be organised to fix with each staff member its objectives and deliverables. DG meetings with staff will be organised on a regular basis as an open forum for clarity of both policy and organisational matters. It is important to mention that HERA has no result from the staff survey since the DG didn’t exist at the time of the staff survey and will therefore organise the follow up to the survey on the basis of the average Commission results. All the measures cited above should have a positive impact on staff engagement.

Objective: HERA employs a competent and engaged workforce and contributes to gender equality at all levels of management to effectively deliver on the Commission’s priorities and core business.

Main outputs in 2022:

Output	Indicator	Target
Recruitment of one director and 3 Heads of Unit	50% of female manager	At equal competence, 2/4 female managers should be appointed

⁽¹²⁾ [Communication C\(2017\)2373 - Revision of the Internal Control Framework](#)

B. Sound financial management

HERA budget is composed of contributions from EU4Health, Horizon Europe and UCPM/rescEU budgets.

The EU4Health and Horizon Europe budgets will be implemented by the HADEA executive agency through call for proposals and call for tenders. While the rescEU budgets will be implemented by DG ECHO through direct grants.

In addition, HERA will directly implement support expenditure budget through call for tenders or existing framework contracts.

This budget architecture calls for specific measures to ensure that the authorising officer by delegation has reasonable assurance that resources are used in accordance with the principles of sound financial management and that cost-effective controls are in place.

HERA will use the organisational structure and internal control systems suited to achieving its policy and internal control objectives in accordance with the internal control principles set by the Commission¹³.

To make its internal control system more effective, the following actions will be implemented in 2022:

- HERA will appoint an Internal control coordinator and establish a **control strategy** including all controls and anti-fraud measures for all types of expenditure directly managed by the DG in its policy areas. The control measures encompass risk assessment and risk management integrated into the planning process and control activities including ex-ante and ex-post verifications. HERA will co-operate with OLAF and implements fraud prevention and detection measures.
- On a regular basis, HERA management will receive **reports on budget implementation and control results** as well as communications on the progress of improvements plans.
- HERA will establish **clear segregation of duties** and **business continuity plan**.

In the internal control system to be developed, HERA will embed continuous monitoring measures to ensure that its management and internal control framework is effective.

HERA will also take into account feedback from audits of the Commission's Internal audit Service and the European Court of Auditors and compiles, implements and monitors the corresponding action plans.

¹³ Commission Communication (2017)2372 on the revision of the Internal Control Framework.

Objective: The authorising officer by delegation has reasonable assurance that resources have been used in accordance with the principles of sound financial management and that cost-effective controls are in place which give the necessary guarantees concerning the legality and regularity of underlying transactions.

Main outputs in 2022:

Output	Indicator	Target
Effective controls: Legal and regular transactions	Risk at payment	Becomes < 2 % of relevant expenditure
	Estimated risk at closure	Becomes < 2 % of relevant expenditure
Efficient controls	Budget execution	Becomes 95% of payment appropriations
Economical controls	Overall estimated cost of controls	Becomes < 0.5% of funds managed
Development of effective control system	Establishment of the referred control strategy	Q3
Development of effective control system	Adoption of a clear segregation of duties and a business continuity plan	Q3

C. Fraud risk management

Fraud risks are addressed by specific controls designed and implemented to mitigate the risks. To this end, HERA will develop and implement an **anti-fraud strategy** as well as an **action plan**.

The controls to prevent and detect fraud are basically the same as those intended to ensure the legality and regularity of the transactions. An assessment of the risks of fraud will be included in the annual risk management exercise. In addition, the tasks listed in the table below are especially important to HERA and will contribute to the objectives of the Commission Anti-Fraud Strategy (2019 CAFS).

An **Internal Control Coordinator** will be nominated to monitor the implementation of the anti-fraud measures. The ICC will also be responsible for the Risks Management and Internal Control.

In 2022, HERA will continue defining the responsibilities and reporting lines necessary to the fulfilment of its responsibilities and flow of information. It will pursue its commitment to ensure **integrity and ethical values**. In particular, HERA staff shall ensure full transparency and equal treatment regarding the relations between HERA and the vaccines and medical countermeasures producers, including the strict implementation of the Transparency Register and of the Code of Good Administrative Behaviour.

Objective: The risk of fraud is minimised through the application of effective anti-fraud measures and the implementation of the Commission Anti-Fraud Strategy (CAFS) ⁽¹⁴⁾ aimed at the prevention, detection and correction ⁽¹⁵⁾ of fraud.

Main outputs in 2022:

Output	Indicator	Target
Drafting of HERA Anti-Fraud Strategy	Adopted Strategy	Q3
Drafting of anti-fraud action plan taking into consideration the revised CAFS Communication ¹⁶	Adopted action plan	Q3
Increased level of awareness on anti-fraud measures	Number of fraud awareness actions undertaken during 2022	2 awareness raising activities (e.g. training, targeted communication, information session)
Arrangement of an appropriate level of cooperation with OLAF	Meeting OLAF-HERA at Director level	At least 1 meeting per year.
Increased level of awareness on integrity and ethical values	Number of ethical awareness actions undertaken during 2022	2 awareness raising activities (e.g. training, targeted communication, information session)

D. Digital transformation and information management

HERA is committed to advance the digital transformation, increase IT literacy, address IT legacy, improve data, information and knowledge management, and ensure rigorous implementation of the data protection and cybersecurity related rules.

Data, information and knowledge are strategic assets, and HERA will pay particular attention to improving the way these assets are managed and used. Intelligence gathering and analytics are important areas of work in HERA.

The COVID-19 crisis has created a considerable need for innovative IT solutions to be delivered at record bracing pace. HERA will support such solutions as needed to establish rapid reaction and support during this crisis.

⁽¹⁴⁾ Communication from the Commission ‘Commission Anti-Fraud Strategy: enhanced action to protect the EU budget’, COM(2019) 196 of 29 April 2019 – ‘the CAFS Communication’ – and the accompanying action plan, SWD(2019) 170 – ‘the CAFS Action Plan’.

⁽¹⁵⁾ Correction of fraud is an umbrella term, which notably refers to the recovery of amounts unduly spent and to administrative sanctions.

¹⁶ Communication from the Commission ‘Commission Anti-Fraud Strategy: enhanced action to protect the EU budget’, COM(2019) 196 of 29 April 2019 – ‘the CAFS Communication’ – and the accompanying action plan, SWD(2019) 170 – ‘the CAFS Action Plan’.

On the way forward to digitalisation, HERA will develop an IT platform to gather information and intelligence on threat detection using innovative artificial intelligence.

As far as collaborative working is concerned, HERA will fully exploit the possibilities offered by the Microsoft 365, as new collaborative tools implemented by the Commission, in order to facilitate the collaborative work between colleagues.

In 2022, HERA will develop and maintain full compliance with data protection rules and constant implementation of therein-embodied principles. In particular, it will ensure that all actions, digital solutions and systems, including legislative, that might lead to potential processing of personal data, respect the principle of data protection by design and by default. The necessary awareness will be achieved by a variety of awareness activities for HERA staff.

Finally, HERA will develop user-friendly, responsive website and intranet so offer better access to information on HERA to internal and external stakeholders.

Objective: HERA is using innovative, trusted digital solutions for better policy-shaping, information management and administrative processes to forge a truly digitally transformed, user-focused and data-driven Commission

Main outputs in 2022:

Output	Indicator	Target
Implementation of the corporate principles for data governance for HERA key data assets	Percentage of implementation of the corporate principles for data governance for HERA key data assets	Interim milestone by 2022: 50%
Increase in awareness of staff on cybersecurity	Number of awareness raising activities	2 awareness raising activities (e.g. training, targeted communication, information session)
Increase in awareness of staff on data protection compliance	Number of awareness raising activities	2 awareness raising activities (e.g. training, targeted communication, information session)
Design and development of HERA internet and intranet	Launch of the intranet and internet	Q3 and Q4

E. Sound environmental management

As of February 2022, HERA is temporarily hosted in a site in Brussels, with a permanent location in Brussels expected to be decided and implemented during the course of 2022. Once HERA’s long-term building location has been arranged, HERA will begin its full integration into EMAS (Commission Eco-Management and Audit Scheme), as well as the nomination of a respective EMAS correspondent/site coordinator. Once this has been established, HERA will then begin determining a roadmap for promoting staff awareness and

participation in the environmental management of HERA's building, reducing any potential negative impact on the environment as well as commuting via eco-friendly means.

Regarding missions and business travels of staff and experts, teleworking and videoconferences have increasingly been used and HERA will continue to benefit from these practices throughout 2022. This supports the sustainability of conferences and events as well as increased use of digital means for working and communication within HERA.

Objective: HERA takes account of its environmental impact in their actions and actively promotes measures to reduce the related day-to-day impact of the administration and its work, with the support their respective EMAS Correspondents/EMAS Site Coordinators.

Main outputs in 2022:

I. More efficient use of resources (energy, water, paper):

Output	Indicator	Target (2019 as baseline)
Final building location of HERA	Full staff transfer to new building	Q4 2022
HERA integration into EMAS	Nomination of EMAS correspond/site coordinator	Q3 2022
Preparation of the roadmap for environmental management of HERA building	Launch	Q4 2022
Participation in the end of the year energy saving action, by closing down DG's buildings during the Christmas and New Year's holiday period.	1 building participating	% of DG buildings participating

II. Reducing CO₂, equivalent CO₂ and other atmospheric emissions

Output	Indicator	Target (2019 as baseline)
Preparation of roadmap for sustainable commuting for HERA staff	Launch	Q4 2022
Maintained use of VC meeting rooms for meetings with stakeholders (avoiding business trips) in the DG, in collaboration with DG SCIC, OIB and OIL.	Percentage of VC meeting conducted with stakeholders	> 75% of all stakeholder meetings
Analysis of DG's missions trends /patterns (based on corporate EC-staff's professional missions,	Launch	Q3 2022

F. Initiatives to improve economy and efficiency of financial and non-financial activities

As HERA becomes fully operational in 2022, the DG will work to ensure that initiatives to improve economy and efficiency are implemented in the tasks of financial planning, monitoring, coordinating and adopting annual work programmes by centralising these tasks within the DG. Moreover, working arrangements with relevant DGs (DG ECHO, DG SANTE and DG RTD) will also be finalised, helping to improve economy and efficiency related to these tasks.

HERA will also look to improve IT and document management both within the DG as well as with outside stakeholders involved in the process of HERA's annual work programmes.