

Annual Activity Report 2025

Health Emergency Preparedness and Response
Authority

Contents

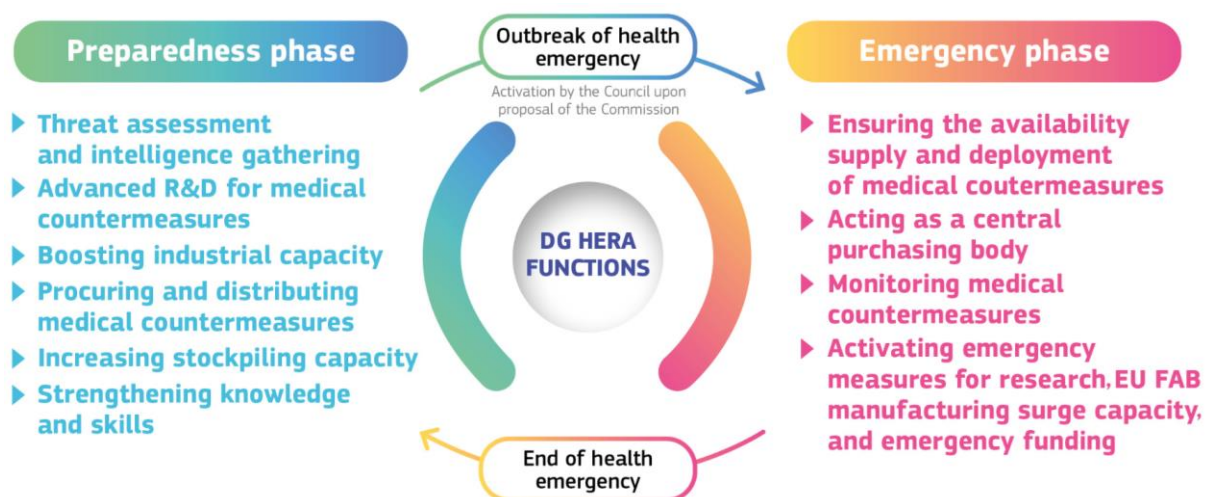
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DG HERA IN BRIEF

The mandate of the Health Emergency Preparedness and Response Authority (DG HERA) is 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)** ⁽¹⁾. DG HERA is a Commission Directorate-General under the leadership of Commissioner Hadja Lahbib and Director-General Dr. Florika Fink-Hooijer.

DG 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).

It works first and foremost in preparedness mode. Only when a public health emergency is recognised at the European Union (EU) level ⁽²⁾ or by World Health Organisation (WHO), DG HERA shifts into the emergency phase – an operational mode that enables swift decision-making and the activation of emergency measures. During this phase, DG HERA relies on the mechanisms established during its preparedness phase and deploy the necessary measures in the context of the EU's Emergency Framework Regulation (EFR).



For the period between 2021 – 2027, DG HERA draws funding from a number of sources: EU4Health, Horizon Europe and RescEU under the Union Civil Protection Mechanism (UCPM).

Throughout 2025, DG HERA has continued to fulfil its core mission of ensuring access to lifesaving MCMs, in line with its **end-to-end approach** – from the identification and characterisation of threats to the support for the development of innovative MCMs, their production and equitable distribution. All actions have been implemented in close collaboration with the Member States, other Commission services, international partners as well as other relevant stakeholders such as representatives of industry and civil society.

⁽¹⁾ [Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority 2021/C 393 I/02](#)

⁽²⁾ When the Emergency Framework Regulation ((EU) 2022/2372) is activated by the Council.

EXECUTIVE SUMMARY

The annual activity report is a management report of the Director-General of DG 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 ⁽³⁾.

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

In line with the Political Guidelines 2024-2029, the Union's economy must be more resilient and less dependent. DG HERA contributes, until 2029, to its General Objective 1 (A new plan for Europe's sustainable prosperity and competitiveness) and General Objective 2 (A new era for European defence and security). In 2025, DG HERA continued its role to contribute to Europe's competitive, innovative and sustainable MCMs industry, which is capable of providing key contributions to preparedness and in crisis time.

In support of the broader initiative to reinforce a new plan for Europe's sustainable prosperity and competitiveness, the College adopted the Communication '[Preparing the EU for the next health crisis: A Medical Countermeasures Strategy](#)' ('MCM strategy'), for which DG HERA was in lead, on 9 July 2025. The MCM strategy is a crucial initiative that was announced in the political guidelines for 2024-2029 of President von der Leyen ⁽⁴⁾. It was the first deliverable of the Preparedness Union Strategy ⁽⁵⁾.



Strong private-public partnerships are key to ensuring access to and availability of lifesaving MCMs. In 2025, DG HERA continued its engagement with the industry through the [Joint Industrial Cooperation Forum \(ICF\)](#), the [HERA Industry days](#) conference, and the [HERA Stakeholder's Hub](#), providing a space for key stakeholders to take part in strategic discussions and partnerships. DG HERA has also supported the publication of the [Strategic Report of the Critical Medicines Alliance](#) with crucial recommendations for policymakers and supply chain actors.

Contributing to the competitiveness of EU MCMs manufacturers, DG HERA continued to support innovative companies in the EU through **HERA Invest** – an initiative providing financial tools to accelerate the development and commercialisation of breakthrough technologies. Through the

⁽³⁾ Article 17(1) of the Treaty on European Union

⁽⁴⁾ [Political Guidelines 2024-2029 | European Commission](#)

⁽⁵⁾ [EU preparedness union strategy](#)

implementation of the **Joint Procurement Agreement**, DG HERA enabled equitable access to MCMs and improved preparedness against health crises of 38 participating countries. Framed within the MCM strategy, DG HERA initiated the design of a **RAMP UP (6)** network to create a rapid-response industrial force protecting citizens in times of crisis. Lastly, DG HERA has been conducting a structured, multi-track **vulnerability assessment of MCM supply chains** focusing predominantly on MCMs that are not critical medicines.



A vital part of DG HERA's mission is to promote the research and development of **innovative, safe, and affordable MCMs for EU citizens** in case health threats become reality. In line with this objective, DG HERA prepared the [Comprehensive 2025 Health Threat Prioritisation Assessment for MCMs](#) to identify four priority threats that require targeted interventions and investments to address vulnerabilities and strategic dependencies related to MCMs. The exercise, published in the first week of 2026, was supported by further mapping of relevant MCMs and assessment of current gaps and needs.



DG HERA's efforts to ensure the availability and accessibility of such MCMs are reflected in the **MCM Accelerator**, an initiative announced in the MCM strategy, designed to support innovators throughout the entire development cycle. Additionally, DG HERA supported various other actions, calls and investments targeted at development of innovative MCMs in Europe such as work on the launch of the 'European Partnership One Health Antimicrobial Resistance'.

Health preparedness is an integral part of European security. Through the ongoing intelligence gathering actions, development of the **ATHINA** system or advancing **wastewater surveillance**, DG HERA has been assessing emerging and ongoing health and MCMs-related events to ensure timely and appropriate responses. The drafting of the **industrial MCMs roadmaps for specific health emergency scenarios** has started, each addressing one of DG HERA's priority threats.

In line with the mission letter from Ursula von der Leyen to then Commissioner-designate Hadja Lahbib (7), DG HERA has adopted a strategic plan for MCMs stockpiling as an annex of the MCM strategy. Additionally, **DURABLE**, the consortium of first-class laboratories, continued to support DG HERA and Member States in addressing MCMs characterisation and innovation, strengthening the Union's resilience and preparedness against emerging health threats.

2025 was also a pivotal year for DG HERA's **capacity building activities**, with a novel, diversified training offer. In 2025, DG HERA continued to organise regular thematic workshops, aimed at exchanging on best practices and lessons learned, as well as at supporting policy development. This includes **a one-day simulation exercise** to test EU-level coordination and

(6) Rapid Agile Manufacturing Partnership for Union Protection

(7) [Mission letter from Ursula von der Leyen to then Commissioner-designate Hadja Lahbib](#)

decision-making aiming to ensure access and availability of MCMs in response to a cross-border health crisis.

As part of the Preparedness Union Strategy, DG HERA has initiated a preparedness and response plan to address **mass casualty events**, which included the development of a scenario to establish planning baselines and a comprehensive list of MCMs related to mass casualty events. The work is closely connected to the efforts that support the enhancement of civil-military cooperation, reflecting the recent Commission initiatives.



As stated by Commissioner Lahbib ⁽⁸⁾ *‘when we prepare together, we are safer together’*. At global level, DG HERA focused on increasing access to and availability of MCMs through implementing already existing as well as new administrative arrangements. Notably, this includes collaboration with the newly established Health Emergency Readiness Canada (HERC) and Pan-American Health Organisation (PAHO).





DG HERA has also focused its actions on building resilience crisis response mechanisms. In 2025, DG HERA adjusted its emergency response protocol to integrate the dimension of the MCM strategy as a deliverable of the Preparedness Union Strategy, reflecting upon the wider Commission priorities. Furthermore, the adoption of the **Union Prevention, Preparedness and Response Plan** (Article 5 of the SCBTH Regulation ⁽⁹⁾) allowed to confirm that DG HERA’s governance and coordination processes are aligned and support the wider health governance in times of crisis.

Ensuring rapid access to critical products during emergencies remained a key priority in 2025. Support for the **EU FAB network** of ‘ever-warm’ vaccine production facilities maintains manufacturing capabilities for mRNA, viral vector and protein-based vaccines within the EU. Lastly, DG HERA has continued to work closely with Member States to prepare **guidelines on crisis procurement of MCMs**.

⁽⁸⁾ [Speech by Commissioner Lahbib at the European Parliament on the EU Preparedness Union Strategy](#)

⁽⁹⁾ [Regulation \(EU\) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health](#)

B. Key performance indicators

KPI #	KPI Title	Baseline (2024)	2025		Interim milestone (2027)	Target (2029)
Specific objective 1.1: Economic security through sustainable and resilient supply chains of MCMs						
1.1.1	Number of selected MCMs (excluding critical medicines) assessed using the vulnerability assessment methodology during the 2025-2029 period	0	0		20	50
Specific objective 1.2: Investing in prevention through innovative MCMs						
1.2.1	Sum of the number of R&I projects related to HERA's mission funded per year and the number of new MCM brought to the market thanks to DG HERA's funding per year	6	12		18	30
Specific objective 2.1: European preparedness for health emergencies						
2.1.1	Number of strategic locations where wastewater and environmental monitoring is performed	1	23		25	30
Specific objective 2.2: Crisis response to health emergencies						
2.2.1	Percentage of managed cases when a crisis occurs	100%	100%		100%	100%

Comment on the KPI 1.1.1: The relevant methodology will only be available as a first version by Q2 2026. Consequently, MCMs will only be assessed using the vulnerability assessment method following that period.

Comment on the KPI 2.1.1: The high number is impacted by the changes in methodology. Consequently, the interim milestone and target were also adjusted to reflect it.

Comment on the KPI 2.2.1: The KPI has been changed from a 'number of managed cases when a crisis occurs' to better reflect what is under the control of the DG (managing the cases, rather than when they appear).

C. Key conclusions on internal control and financial management

DG 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.

The transition in 2025 to the Commission's new accounting system, SUMMA, has required the adjustment to a new system and has impacted budget implementation tasks, processes and financial management activities, particularly during the first part of the year. This has required careful management to ensure the same data quality as in previous years.

All the above elements have been assessed to determine their impact on management's assurance about the achievement of the control objectives. Please refer for further details to section 2 on Internal Control and Financial Management.

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

D. Provision of information to the Commissioner

In the context of the regular meetings during the year between DG HERA and the cabinet of Commissioner Lahbib on management matters, the main elements of this report and assurance declaration, have been brought to the attention of Commissioner Lahbib, responsible for Equality; Preparedness and Crisis Management.

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

General Objective 1: A new plan for Europe's sustainable prosperity and competitiveness

Specific objective 1.1: Economic security through sustainable and resilient supply chains of MCMs



As part of the broader effort to support a new plan for Europe's sustainable prosperity and competitiveness, the College adopted the Communication '[Preparing the EU for the next health crisis: A Medical Countermeasures Strategy](#)' ('MCM strategy'), for which DG HERA is in lead, on 9 July 2025. The MCM strategy is a crucial initiative announced in the political guidelines for 2024-2029 of President von der Leyen and a first deliverable of the Preparedness Union Strategy.

The MCM strategy puts forward **17 key actions** to reinforce the EU's preparedness and response to health threats. Since the adoption of the MCM strategy, DG HERA has started implementing several of these flagship projects. Milestones achieved by the end of 2025 include the launch of the [EU Wastewater Sentinel System](#), the organisation of the simulation exercise to test the EU's preparedness capacities in the area of MCMs, and the signature of an administrative agreement between DG HERA and PAHO in the margins of the EU-CELAC Summit ⁽¹⁰⁾.

Driving collaboration for strengthened economic security

DG HERA continued to engage with industry through the **Joint Industrial Cooperation Forum (ICF)**, to work together on identifying and, where possible, reducing supply chain vulnerabilities within and outside the EU. In 2025, the ICF contributed to discussions on supply chain resilience, joint procurement and funding, including inputs to the above-mentioned strategic report of the Critical Medicines Alliance.



⁽¹⁰⁾ The EU-CELAC Summit is a forum for dialogue and cooperation between the European Union and the Community of Latin American and Caribbean States (CELAC).

The eighth ICF meeting, held on 11 March 2025, marked the conclusion of the first three-year mandate. Following the autumn call for applications, the mandate of the ICF was renewed for another three years, with an expanded membership of 64 industry organisations and companies. The kick-off meeting of the renewed ICF took place on 18 December 2025, marking the start of the new mandate.



In addition, DG HERA fostered networking and business relationships through the first edition of the **HERA Industry days**, which took place on 2 and 3 June 2025 in Brussels. The event brought together over 400 participants including industry leaders, innovators, policymakers, and technical experts. The HERA Industry days were highly appreciated for their relevance and the quality of the programme, with many participants highlighting DG HERA's strong engagement with the industry.

Further contributing to this collaboration is DG HERA's **Stakeholders' Hub** platform that became fully operational in 2025. The Hub supported the work of the Critical Medicines Alliance by serving as a centralised channel for collecting stakeholder feedback for the strategic report. Its matchmaking functionality was also further enhanced through the development of additional features to facilitate stakeholder interaction. The platform has also been used to disseminate information on DG HERA-related news and events. To support user uptake, DG HERA published a dedicated user guide and developed promotional and tutorial videos.

Another crucial achievement of 2025 is the publication of the [Strategic Report of the Critical Medicines Alliance](#) with recommendations for policymakers and supply chain actors. Afterwards, the strategic report has served as basis for the preparation of the proposal for the Critical Medicines Act prepared by DG SANTE in collaboration with DG HERA.

Boosting EU's competitiveness through concrete actions

To drive the competitiveness of EU MCMs manufacturers, DG HERA further supported innovative companies in the EU through **HERA Invest**. In partnership with the European Investment Bank, this initiative provides the necessary capital to accelerate the development and commercialisation of breakthrough technologies. Until the end of 2025, HERA Invest has funded 3 European innovative small and medium-sized enterprises (SMEs), with loans of EUR 20 million each ⁽¹¹⁾. To leverage all available possibilities to fund MCM-related projects such as HERA Invest, DG HERA also contributed to the Strategic Technologies for Europe Platform (STEP) ⁽¹²⁾ Regulation ⁽¹³⁾, by designing actions that are STEP-eligible.

⁽¹¹⁾ This includes support to Fabentech (France) to develop broad-spectrum therapeutics, Leyden Labs (Netherlands) to advance nasal sprays for pandemic preparedness, and SNIPR Biome (Denmark) to develop new medicines for infections that are difficult to treat due to AMR.

⁽¹²⁾ [Strategic Technologies for Europe Platform - European Union \(STEP\)](#)

⁽¹³⁾ [Regulation - EU - 2024/795 - EN - EUR-Lex](#)



In 2025, DG HERA continued to support the preparedness against health threats of the Member States and other participating countries ⁽¹⁴⁾ by conducting several **joint procurements** ⁽¹⁵⁾. Notable milestones include also the establishment of a task force involving 13 countries to define candidate products to the pilot joint procurement for anti-tuberculosis antibiotics and engaging one more company in the work on a dynamic purchasing system for personal protective equipment (PPE). A country mapping project was also started to understand better the needs of the Member States.

Framed within the MCM strategy, DG HERA initiated the design of **RAMP UP** ⁽¹⁶⁾ as a voluntary network of EU-based pharmaceutical and MCMs manufacturers, innovators, and suppliers, creating a rapid-response industrial force to protect citizens in times of crisis.

Lastly, DG HERA has been conducting a structured, multi-track **vulnerability assessment of MCM supply chains** focusing predominantly on MCMs that are non-critical medicines. This action relies on 2 interim reports covering a preliminary partial outlook of the supply chain dependencies for 17 MCMs. In addition, considering the current geopolitical context, DG HERA continuously monitors and assesses the impact of trade measures and policies, and potential spillover effects on EU MCMs production capacity.

Specific objective 1.2: Investing in prevention through innovative MCMs

In 2025, DG HERA prepared the **Comprehensive 2025 Health Threat Prioritisation Assessment for MCMs** to provide detailed information on the Commission's measures to improve preparedness and response to serious cross-border threats. The assessment aimed to identify the priority threats that require interventions and investments to address vulnerabilities and strategic dependencies related to the development, production, procurement, stockpiling and distribution of MCMs.

Such identified priority threats are:



Respiratory or contact-based viruses with pandemic potential

Highly transmissible viruses with a history or likelihood of causing large-scale outbreaks

Outbreaks of infectious diseases with the potential to cause widespread, sustained transmission are becoming increasingly frequent, complex and severe. In order to address such

⁽¹⁴⁾ The [Joint Procurement Agreement](#) is now signed by 39 countries.

⁽¹⁵⁾ In particular: signing a reservation contract for pandemic influenza vaccines, signing contracts for mRNA COVID-19 vaccines, for protein-based COVID-19 vaccines, and for mpox vaccines, and starting the preparation for new contracts to further pandemic influenza vaccines (cell-based and intranasal) and for Influenza-COVID-19 combo vaccines.

⁽¹⁶⁾ Rapid Agile Manufacturing Partnerships for Union Protection

threats in 2025, DG HERA engaged in various projects aimed at the research and development of the relevant MCMs. This includes, but is not limited to, implementation of the calls for proposals to support the development of novel antivirals ⁽¹⁷⁾ or for next-generation respiratory protection ⁽¹⁸⁾.



Vector-borne or animal-reservoir viruses with epidemic potential

Viruses (such as those transmitted through mosquitos) whose spread is accelerated because of climate change and other environmental factors.

In 2025, DG HERA further strengthened its actions on vector-borne diseases as part of its broader efforts to address climate-driven health threats and reinforce EU preparedness. A key milestone was signing of the contribution agreement with Drugs for Neglected Diseases Initiative (DNDi) and Agence Française de Développement (AFD) to support the development of new therapeutics for dengue. In parallel, DG HERA supported, under EU4Health, innovation in diagnostics for vector-borne diseases and the scale up Member States' capacities for vector surveillance and control through a dedicated Joint Action.



Antimicrobial resistance (AMR)

A rising global concern that threatens the efficacy of existing treatments and increases the burden of infectious diseases.

DG HERA strives to continue to support the innovative products that can contribute to the fight against AMR. DG HERA worked with DG RTD on the launch of the Horizon Europe co-funded 'European Partnership One Health Antimicrobial Resistance'. The partnership strives to ensure consistency between the different national services/ministries responsible for the various aspects of AMR and the sectors involved.

In 2025, DG HERA invested in rapid diagnostics to help address the root causes of AMR. Through EU4Health programme and in close cooperation with HaDEA, a financial support of EUR 8.85 million was provided to a joint tender bringing together five partners from four EU countries. The consortium ⁽¹⁹⁾ will now have 4 years to develop and bring to the market a groundbreaking diagnostic device providing results in less than 1 hour that will help clinicians select the most appropriate treatment for patients requiring antibiotics. DG HERA also supports preclinical and clinical development of AMR MCMs through its contribution to GARDP ⁽²⁰⁾ and CARB-X ⁽²¹⁾ work.

⁽¹⁷⁾ [EU Funding & Tenders Portal](#)

⁽¹⁸⁾ [EU Funding & Tenders Portal](#)

⁽¹⁹⁾ The group is formed by ShanX MedTech B.V. (Netherlands), Aidian Oy (Finland), Biosurfit S.A. (Portugal), Unitron B.V. (Netherlands), and Fundación para la Investigación Biomédica del Hospital Universitario Ramón y Cajal (Spain).

⁽²⁰⁾ [The Global Antibiotic Research & Development Partnership](#)

⁽²¹⁾ [Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator](#)



Armed conflict related threats, including CBRN threats

Targeting the deliberate and accidental release of CBRN threats, including state-sponsored ones

In 2025, DG HERA focused on the current gaps in MCMs development and addressing emerging threats, including those at the intersection of AI and life sciences. DG HERA has also initiated support to the relevant Horizon Europe projects in enhancing efforts to prevent and prepare for CBRN threats for the years to come. This includes support for the development of the advanced protective gear optimised for CBRN-E ⁽²²⁾ and prevention and mitigation of misuse of synthetic biology for bioterrorism purposes.



The **MCM Accelerator**, announced in the MCM strategy, aims at providing an integrated and simplified framework to accelerate the development of MCMs for the priority threats. Designed to support innovators throughout the entire development cycle, the initiative leverages on existing and future tools to seek the most appropriate path to accelerate the availability and accessibility to MCMs. The first actions under this framework have been already launched, and a contract has been signed at the end of 2025 for the development of point of care AMR diagnostics.

DG HERA also concluded a set of studies on the applications of **artificial intelligence (AI)** as an enabler for health emergency preparedness and response. The work assessed the potential of AI across the MCMs lifecycle, including development, manufacturing, supply and demand monitoring, and biosecurity. Building on these findings, DG HERA launched a dedicated webinar series to share results and engage with Member States, industry, academia, and EU agencies, supporting a more coordinated uptake of AI technologies in preparedness and response.

In addition, in 2025 HERA launched a [Horizon Europe action on trustworthy AI tools for pandemic preparedness and response](#), aimed at advancing AI-based solutions for surveillance, prediction, and response to epidemics and pandemics.

General Objective 2: A new era for European defence and security

Specific objective 2.1: European preparedness for health emergencies

The Commission adopted on 16 July its proposal for the **Multiannual Financial Framework (MFF) 2028-2034**. To ensure the availability of and sufficient resources for the necessary tools and mechanisms to respond quickly to possible emerging health threats, DG HERA contributed to the preparation of the proposal for the Union Civil Protection Mechanism and Union support

⁽²²⁾ CBRN-E stands for Chemical, Biological, Radiological, Nuclear, and Explosives.

for Health emergency preparedness and response (UCPM/HER), to the proposal for the European Competitiveness Fund and to the next Horizon Europe programme.

As a part of the Commission-wide effort to foster **simplification** of EU policies and laws, and their better implementation, DG HERA has made preparatory work ahead of the implementation dialogue to be hosted in 2026.

Strengthening surveillance capacity for better preparedness

DG HERA remained committed to conducting comprehensive **threat assessment and intelligence gathering** to ensure round-the-clock preparedness for health emergencies. The threat prioritisation exercise ⁽²³⁾ was supported by further mapping of relevant MCMs and assessment of current gaps and needs. In addition, DG HERA continued to systematically assess emerging and ongoing health and MCMs-related events to ensure timely and appropriate responses.

One of the tools designed to collect intelligence on emerging health is DG HERA's IT system **ATHINA**. In 2025, DG HERA has been working on developing a minimum viable product. Additionally, DG HERA has been developing an ontology, which will organise different relevant terms and concepts related to the system in a clear and consistent manner.

The joint action EU-WISH continued to support Member States in advancing **wastewater surveillance** while ensuring synergies with the EU wastewater sentinel system established by DG HERA, in close collaboration with the JRC. In addition, international collaboration for enhancing capacities for wastewater surveillance for pandemic preparedness included partnerships with Africa CDC and Asia PGI, all contributing to the global consortium for wastewater and environmental surveillance for public health (GLOWACON).

DURABLE, the consortium of first-class laboratories, continued to support DG HERA and the Member States in addressing MCMs characterisation and innovation, strengthening the Union's resilience and preparedness against emerging health threats. The initiative strives to maintain ever-warm facilities for rapid, deep pathogen characterisation of emerging cross-border health threats and innovation of relevant MCMs. In particular, in 2025, DURABLE presented their work on modelling as well as avian influenza ⁽²⁴⁾.

Ensuring timely access to and availability of the relevant MCMs



In line with President von der Leyen's mission letter for Commissioner Hadja Lahbib, DG HERA has adopted a strategic plan for **MCMs stockpiling** as an annex of the MCM strategy. This included key actions to improve preparedness through stockpiling for the next years. In 2025, DG HERA worked closely with Member States and other Commission services to address challenges in stockpiling management, such as product shelf-life, maintenance, re-use, waste management and deployment in order to ensure continuous availability.

⁽²³⁾ More information on page 11.

⁽²⁴⁾ This included the immunogenicity studies in relation to the zoonotic vaccine of Seqirus as well as population seroprevalence studies.

Notable achievements in this area in 2025 include a launch of a pilot on shelf-life extension and a presentation of the first draft of a stockpiling compendium. In 2025, DG HERA also launched the Joint Action on Stockpiling, which represents a significant collaborative effort by the Member States to strengthen their stockpiling capabilities, with Finland taking a leading role and involving 21 member states. The initiative aims to contribute to more sustainable and efficient stockpiles and management of MCMs, better collaboration between Member States, and better evidence-base for future proposals on stockpiling of MCMs.

The work has also commenced on the drafting of the **industrial MCMs roadmaps for specific health emergency scenarios**, each addressing DG HERA's priority threats. These plans aim to identify and prioritise interventions that DG HERA could implement to accelerate innovation and improve access to relevant MCMs. This will be based on the thorough analysis of outbreak scenarios, current MCMs pipeline and landscape, as well as other relevant intelligence.

Finally, to scale up the EU's **sequencing capacities**, DG HERA continued to facilitate synergies between Member States, share best practices and provide additional support to those countries that were unable to benefit from previous programmes in this area. A funding call with direct grants to EU/EEA member states and EU4Health associated countries has been launched.

Driving strong partnerships for health emergency preparedness

In 2025, DG HERA strengthened its **collaboration with the Member States, industry, and civil society**. Related stakeholder groups have brought together over 225 experts from EU Member States, relevant EU agencies (such as European Medicines Agency (EMA) and European Centre for Disease Control and Prevention (ECDC)), international health experts, industry representatives, and civil society.



The **HERA Board** played a key role in driving strategic initiatives and fostering cooperation through regular meetings, training sessions, and consultations, with important gatherings hosted by Poland and Denmark under EU Council Presidencies. These efforts advanced the Preparedness Union Strategy and the implementation of the MCM Strategy. The Clinical Trials sub-group met frequently to provide expert advice on various issues, focusing on innovation.

High participation rates at **Joint Industrial Cooperation Forum (ICF)** and **Civil Society Forum (CSF)** meetings showed strong engagement, as stakeholders contributed to discussions on MCMs, supply chain resilience, and funding innovation. Building on earlier success, both sub-groups' mandates were extended for another three years in 2025. The renewed ICF now includes 64 organisations and companies key to health emergency preparedness and response, while the Civil Society Forum comprises of 28 members.

2025 was also a pivotal year for DG HERA's **capacity building activities**, with a novel, diversified training offer, in line with the approved DG HERA's training and exercise strategy as well as the recommendations from the Preparedness Union Strategy. In 2025, DG HERA continued to organise regular thematic workshops, aimed at exchanging on best practices and lessons learned, as well as at supporting policy development. In addition, DG HERA also participated in and supported training events and exercises organised by other Commission

services (such as DG SANTE), agencies (such as ECDC) and international organisations (such as WHO). These activities allowed for broader engagement with stakeholders who are not usually involved in DG HERA's activities.

DG HERA organised **five thematic workshops focussing on crisis procurement**, deployment of stocks, data collection, civil military cooperation, and on influenza pandemic preparedness. Overall, 364 participants from 30 countries, including the Member States and countries associated to the EU4Health programme, were present in these workshops, along with speakers from Japan, Canada and Switzerland. Participants satisfaction rate was over 82% in average, demonstrating the importance and added value of the topics and the quality of the delivered content.

DG HERA also started to develop its first **e-learning modules** on Joint Procurement and the EFR that will ensure practical and permanently available training to the Member States. Additionally, the EU4Health work programme 2025 included a call on a Joint Action to develop an Exchange Programme, supporting staff exchange and country visits. 22 Member States and associated countries have nominated entities to participate in the action and DG HERA has been closely supporting the Member States to develop the proposal.

DG HERA organised **a one-day simulation exercise** to test EU-level coordination and decision-making aiming to ensure access and availability of MCMs in response to a cross-border health crisis. The exercise was based on a fictitious outbreak leading to a pandemic. Participants included representatives from 21 Member States, Norway and Iceland, as well as NATO, WHO Europe, and from several Commission services and EU agencies (ECDC, EMA, DG HERA, DG SANTE, DG ECHO and DG RTD).



The initiative has helped to clarify the role of the HERA Board and of the Health Crisis Board, provided insights into the procedure for activating the EFR, and allowed discussion on clear and specific EU-level criteria for the allocation of the EU level-stocks of MCMs. The discussions during the exercise have also highlighted the importance of crisis procurement guidelines, currently being developed by DG HERA.

Fostering preparedness for mass casualty events and civil-military cooperation

As part of the Preparedness Strategy Union, DG HERA has initiated a preparedness and response plan to address **mass casualty events**, including preparedness for potential armed aggression in Europe. In line with this initiative, DG HERA has developed a scenario to establish planning baselines and prepared a comprehensive list of MCMs related to mass casualty events, which have been reviewed in consultation with Member States and will lead to the development of a shortlist of conflict-relevant MCMs in 2026.

The work is closely connected to the efforts that support the enhancement of civil-military cooperation, reflecting recent Commission initiatives. DG HERA regularly participated in the Commission and NATO exchanges on civil-military cooperation, including the senior-level Joint Health Group and the Committee of the Chiefs of Military Medical Services NATO (COMEDS) in November.



No one is safe until everyone is safe – global health preparedness

Steps were taken to **structure and advance the collaboration with international partners**, including by means of new administrative arrangements and agreements, ongoing multilateral cooperation, as well as the implementation of existing bilateral collaborations.



In 2025, DG HERA signed **new administrative arrangements** with the newly established **Health Emergency Readiness Canada (HERC) and PAHO**. DG HERA, together with DG SANTE, has also started the negotiation of a **non-binding agreement with the UK** for cooperation in the area of health security in November 2025. Negotiations on one or **more legally binding agreements with Iceland, Norway and Liechtenstein** have continued through 2025 in order to extend the EU's cooperation with EEA EFTA countries beyond health emergency preparedness.

DG HERA also continued to **engage with the international organisations** to foster global health initiatives. In 2025, the contribution agreement with the WHO R&D blueprint for advancing clinical trials in the context of Filovirus (Ebola, Marburg) outbreaks was extended for two additional years. The contribution agreement continued to be implemented through the Health Technology Access Pool (HTAP) ⁽²⁵⁾. Furthermore, building on the DG HERA's 2022 Administrative Arrangement with the WHO Hub, cooperation continued to advance the development of Epidemic Intelligence from Open Sources (EIOS), the WHO Collaboratory and the Market Intelligence Platform. DG HERA further continues to represent the Commission in the Interim Medical Countermeasures Network (i-MCM-Net).

DG HERA also continued to engage with the European and Developing Countries Clinical Trials Partnership (Global Health EDCTP3 Joint Undertaking) where it represents the Commission together with DG RTD, DG SANTE, DG INTPA, DG GROW in the Governing Board.

Finally, DG HERA, together with DG INTPA, was active in the setting-up of the governance of the newly established G20 Alliance for Local and Regional Production, Innovation and Access on neglected diseases.

⁽²⁵⁾ HTAP is the successor of the COVID-19 Technology Access Pool (CTAP), to be implemented in close relation with DG INTPA's work under MAV+. Launched in 2022, this initiative provides a platform for technology developers to voluntarily share intellectual property, knowledge and data, thereby accelerating technological innovation and expanding global production capacity.



Collaboration with Africa CDC has focused on the provision of MCMs for Mpox and AMR, wastewater surveillance, and technical support on manufacturing and procurement. In 2025, this partnership also aimed to enhance genome sequencing capacities and support logistical operations for MCMs in Africa as well as early detection and containment of cross-border health threats.

Building on the Commission's response to the ongoing 2024 mpox outbreak in Africa, DG HERA signed in May 2025 the '*Partnership to Accelerate Mpox and Other Outbreaks Testing and Sequencing in Africa (PAMTA)*'. It is a key initiative that supports Africa's diagnostics capacity and reinforces outbreaks preparedness and response building on previous projects, such as Africa PGI. Furthermore, DG HERA continued to share its joint procurement expertise in contributing to developing the African Pooled Procurement Mechanism.

Furthermore, DG HERA reinforced cooperation with the EU enlargement candidate countries and potential candidates as well as neighbouring countries. This included finalising a study on the pharmaceutical manufacturing potential of the Western Balkans and Ukraine, which will provide a base for future actions to support national authorities and local industry, in close coordination with DG ENEST and DG SANTE.

Finally, in 2025, the already established **bilateral partnerships** with public health agencies and services in the United States, Japan, Republic of Korea and the Africa Centre for Disease Control (Africa CDC) were further strengthened.

Specific objective 2.2: Crisis response to health emergencies



DG HERA strives to continue its efforts to boost the EU's and Member States' **capacity to respond swiftly and effectively to health emergencies**, including, but not limited to, the UCPM, with appropriate MCMs. In 2025, DG HERA continued to ensure that it was prepared to implement the emergency framework if needed. Various new materials and initiatives were fostered or introduced that can be used in times of a public health emergency.

DG HERA's **emergency response protocol**, which outlines the processes and steps to follow when DG HERA responds to an emergency and a case is opened in the Emergency Office, is constantly maintained alive. In 2025, the protocol was adjusted to integrate the dimension of the MCM strategy as a deliverable of the Preparedness Union Strategy, reflecting upon the wider Commission's new priorities. Further alignment was brought to take on board recommendations stemming back from June and October 2024 exercises with, respectively, other Commission services and relevant agencies as well as with the Member States on testing coordination and information sharing.

Such a revisited version supported the processes used for the simulation exercise with the Member States on testing EU-level coordination and decision-making, aiming to ensure access

and availability of MCMs in response to an outbreak of zoonotic avian influenza that took place in Copenhagen in autumn.

Furthermore, the adoption of the **Union Prevention, Preparedness and Response Plan** (Article 5 of the SCBTH Regulation ⁽²⁶⁾) allowed to confirm that DG HERA's governance and coordination processes, as documented in the protocol, are aligned and support the wider health governance response frame in times of crisis.

The **working arrangements** signed with EMA and ECDC establish specific methods and procedures for coordinating actions when a public health emergency is recognised within the EU. In 2025, DG HERA worked on clarifying the respective responsibilities, including the ongoing update of such working agreements. In accordance with Regulation (EU) 2022/123, which strengthens EMA's role in crisis preparedness and management of medicinal products and medical devices, EMA routinely shares information with DG HERA on the monitoring of these products, including supply and demand data. In addition, DG HERA supported ECDC in the assessment of national prevention, preparedness and response planning ⁽²⁷⁾.



Ensuring rapid access to critical products during emergencies remained a key priority in 2025. Support for the **EU FAB network** of 'ever-warm' vaccine production facilities maintains manufacturing capabilities for mRNA, viral vector and protein-based vaccines within the EU. EU FAB framework contracts continued in 2025 and run until 2027. DG HERA has been investigating a possibility to expand the EU FAB concept beyond vaccines (or to rely on other equivalent mechanisms such as capacity reservation contracts) to also cover PPE, reagents or medical devices.

In response to recommendations from the European Court of Auditors, DG HERA has continued to work closely with Member States to prepare **guidelines on crisis procurement of MCMs** with the adoption planned for Q2 2026. Member States were consulted in writing on the lessons learned from COVID-19 procurement, followed by a two-day workshop on the intended content of the guidelines.

⁽²⁶⁾ [Regulation \(EU\) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health](#)

⁽²⁷⁾ Article 8 Regulation (EU) 2022/2371

2. INTERNAL CONTROL AND FINANCIAL MANAGEMENT

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

2.1. Control results

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

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

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

This section presents an overview of DG HERA's activities, related amounts of payments for the year, and the relevant control systems (RCS) with the main indicators used to measure the level of compliance with legality and regularity. DG HERA's assurance building and materiality criteria are outlined in the annual activity report annex 5. The annual activity report annex 6 outlines the main risks together with the control processes to mitigate them and the indicators used to measure the performance of the relevant control systems.

In 2025, DG HERA made total payments of EUR 39.6 million.

Almost all of them, EUR 37.7 million, were under the EU4Health programme. A major part of it, approximately 77% or EUR 30.5 million, were paid as new pre-financings. Further, DG HERA cleared EUR 3.7 million of pre-financings paid in previous years. DG HERA's income of EUR 0.4 million corresponds to the financial contribution of Bosnia and Herzegovina and Montenegro to the EU4Health programme budget in line with the association agreements with these countries.

About 78% of all 2025 payments (approximately EUR 30.9 million) were under indirect management mode, contribution agreements, mainly with international organisations. Under indirect management, DG HERA paid a total of EUR 30.5 million as pre-financings under contribution agreements with the objectives to support the development of medical countermeasures (MCMs) against antimicrobial resistance and Dengue to assess the supply chains diversification of critical medicines and MCMs, to strengthen public health intelligence gathering and analysis, to support the WHO Health technology access pool. Under indirect management, DG HERA also made a final payment for the finalization of a project in support of the activities of the WHO Hub for pandemic and epidemic preparedness.

About 22% of all 2025 payments (approximately EUR 8.7 million) were under direct management mode.

With regard to DG HERA 2025 payments, all executed by DG SANTE on the basis of a Memorandum of understanding, DG SANTE has confirmed that there were no issues to report.

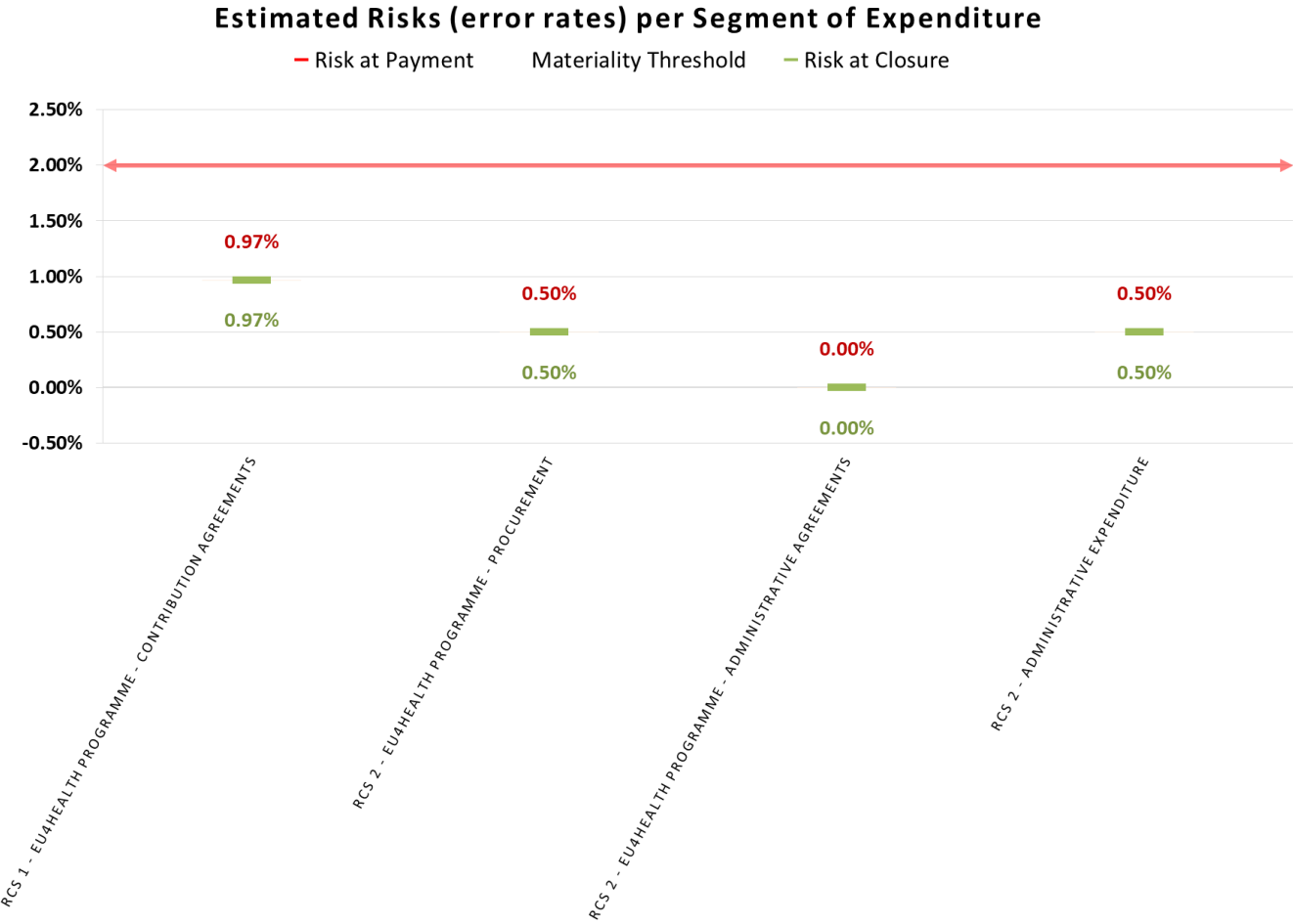
The majority of DG HERA payment budget in 2025, EUR 190 million, was delegated to the Health and Digital Executive Agency (HaDEA) in order to execute payments on DG HERA grants and contracts in the area of crisis preparedness, signed under the EU4Health programme. For the 2025 reporting year, the executive 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 2025 activity report.

In 2025, DG HERA further co-delegated EUR 2.5 million of payment credits to DG DIGIT for the provision of IT services related to the use of corporate tools and to ATHINA specific support. HERA has entrusted DG DIGIT with the implementation of internal control processes to ensure the adequate management of the risks related to the legality and regularity of the underlying

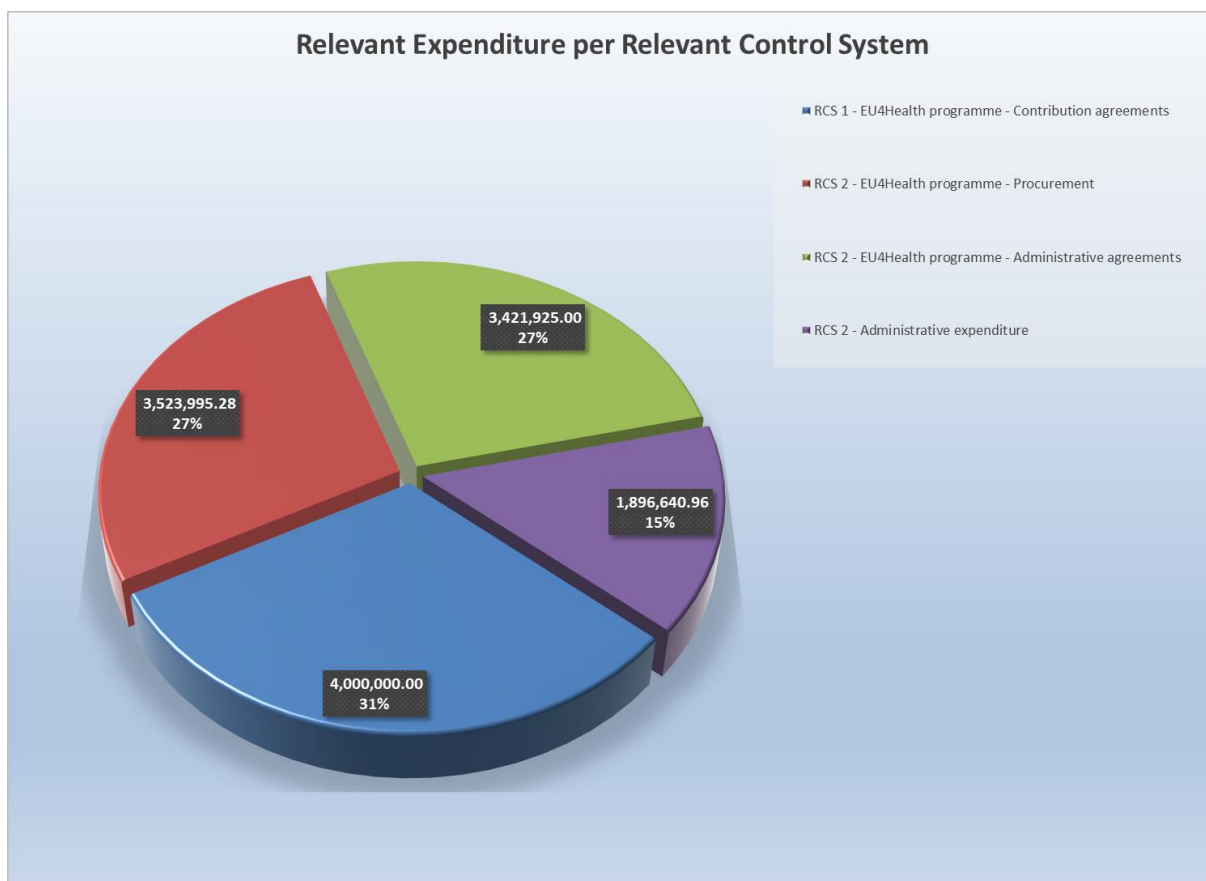
transactions they are responsible for, taking into account the nature of the payments concerned. The partner DG bears the responsibility for the delegated appropriations and reports on them in their own annual activity report.

2.1.2. Effectiveness of controls

a) Assessment of control results per segment of expenditure



DG HERA has entrusted the adequate management of the risks related to the legality and regularity of the underlying transactions, identified at the time of financial initiation and verification, to DG SANTE. All DG HERA payments were carried out in compliance with DG SANTE’s control strategy. A relevant description is available in DG SANTE 2025 activity report.



Excluding the pre-financings advanced and cleared, the amount that represents relevant expenditure for DG HERA's assurance in 2025 comes up to EUR 12.8 million. It includes:

Indirect mode:

- EUR 4 million paid to WHO for the finalization of the project in support of the activities of the WHO Hub for pandemic and epidemic preparedness.

Direct mode:

- EUR 3.5 million spent on procurement contracts, mostly corporate IT tools, IT services to support the ATHINA project, communication services to raise awareness and understanding of HERA purpose and actions, legal advice, audit services.
- EUR 3.4 million advanced to JRC on the basis of an administrative agreement signed in 2024 to support existing wastewater activities, including the establishment of an EU sentinel system
- EUR 1.9 million for administrative expenditure to sustain DG HERA functions

The most relevant key indicators to assess the control results are the 'risk at payment' and 'risk at closure' for the different types of expenditure that DG HERA managed in 2025. In line with DG SANTE approach, DG HERA assessed the risk at closure based on equivalent estimates to the detected error rates with no recoveries or corrections applied

between payment and closure. DG SANTE does not carry out ex-post controls for payments carried out under the EU4Health programme since the transfer of budget implementation tasks, including ex-post controls, to HaDEA in 2021.

2025 was the first year where DG HERA made a final payment to WHO for a contribution agreement in indirect mode and thus, cleared the initial pre-financing; the total amount of relevant expenditure for this RCS amounts up to EUR 4 million. In the absence of ex-post controls, DG HERA estimates prudently an error rate of 0.97% which is an equivalent to the error rate applied by DG INTPA to payments to third organizations in indirect mode.

With regard to procurement (EUR 3.5 million), since these were primarily payments on purchases carried out on the basis of existing framework contracts or on contracts of low and middle-value, an error rate of 0.5% is set for this RCS. This remains unchanged compared to 2024 as historically, the procurement pattern has not changed.

In 2025, DG HERA advanced EUR 3.4 million to DG JRC as stipulated with the signature of an administrative arrangement; however, no error rate is applied. This represents internal transfer for the Commission, and the advance will be cleared at the end of the project.

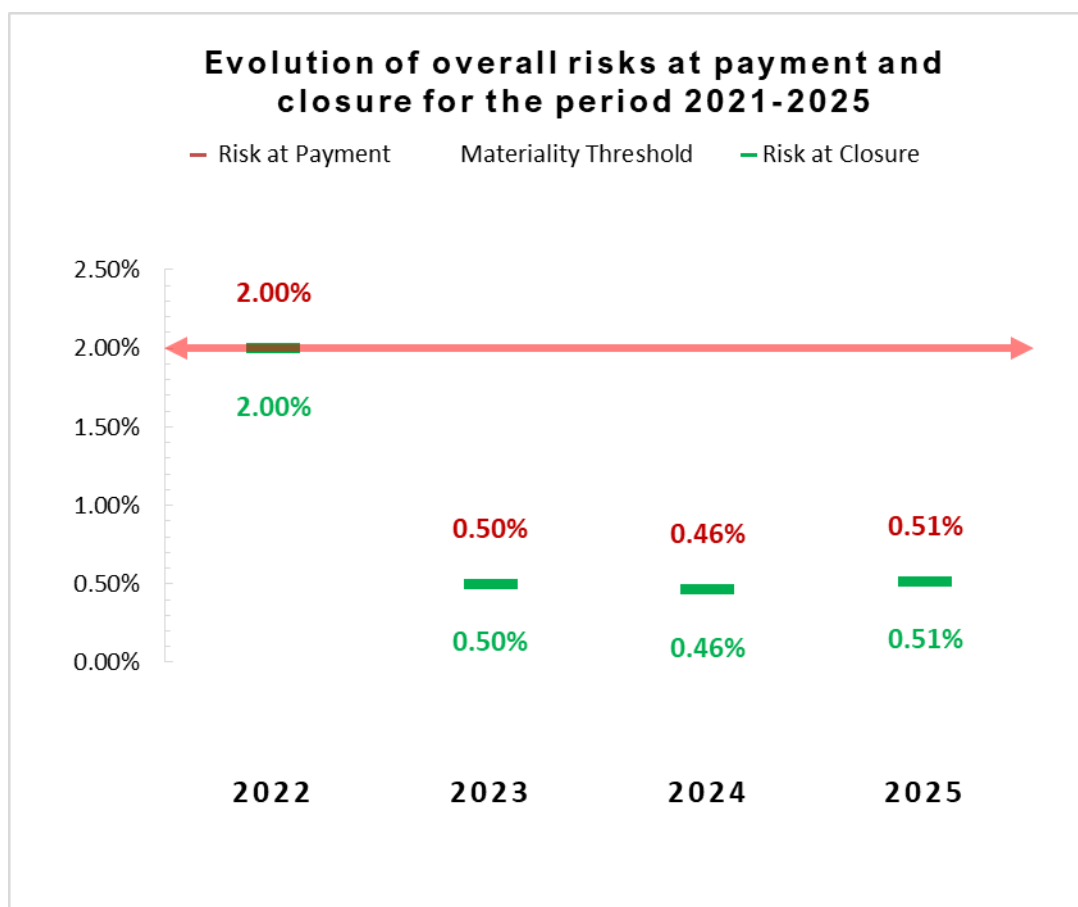
On the EUR 1.9 million of administrative expenditure incurred in 2025, DG HERA applies the standard for this segment 0.5% error rate.

For the 2025 reporting year, DG SANTE has not raised any significant issues which could have a material impact as regards the legality and regularity of DG HERA financial operations. Thus, DG HERA concludes that the control objectives as regards legality and regularity have been achieved.

Supervision of the executive agency

The executive agency HaDEA has signalled no serious control issues, and no reservation was made in the implementation of the EU4Health programme. See the Annual Activity Report 2025 of HaDEA. DG HERA's mechanism for supervision, coordination and monitoring encompasses the work of the Steering Committee where DG HERA sits as an observer, the Feedback to Policy Mechanism through which DG HERA gets feedback on high priority policy fields, collaboration on the assessment of deliverables during implementation phase, regular meetings at senior management level and day-to-day interactions at Unit level.

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



The estimated overall risk at payment for 2025 expenditure is the AOD's best conservative estimate of the amount of relevant expenditure during the year that is not in conformity with the contractual and regulatory provisions applicable at the time the payment was made ⁽²⁸⁾. A proportion of the underlying errors will be corrected in subsequent years and until the end of the programming cycle, corresponding to the conservatively estimated future corrections for 2025 expenditure. The difference between the risk at payment and the estimated future corrections results in the estimated overall risk at closure ⁽²³⁾.

There is a stable trend since 2022. Initially, in 2022, DG HERA's higher error rate compared to the rest of the years is attributable to payments on grants with higher error rate at closure based on ex-post controls. In 2025, the error rate at closure is a bit higher compared to 2024 as in 2025, DG HERA made, for the first time, payments to international organisations in indirect mode with a slightly higher expected error rate at closure.

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.

⁽²⁸⁾ 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.

c) Quantitative benefits of controls: Preventive and corrective measures

DG HERA continued to perform ex-ante controls as an effective mechanism for detecting and correcting errors.

In 2025, due to the transition to SUMMA, only preventive measures exceeding EUR 500,000 are reported. All corrections made by the DG HERA fall below this threshold and therefore are outside the reporting scope.

d) Assessment of control results for non-expenditure items (if applicable)

Not applicable.

e) Fraud: prevention, detection, and correction

DG HERA has developed and implemented its own anti-fraud strategy since 2023, based on the methodology provided by OLAF. It is updated every 3 years and was last updated in 2023 following a fraud risk assessment. Its implementation is being monitored and reported to the management through the yearly internal control framework exercise. All necessary actions, except launching a staff survey on the level of awareness of how to report fraud and having all newcomers follow ethics training, have been implemented.

When it comes to other results achieved during the year thanks to anti-fraud measures in place, DG HERA has raised awareness on the related challenges through a webinar organised on 17 October 2025. This one-hour training was led by a specialist from OLAF. It focused on enhancing staff's understanding of fraud in the management of public money, including defining and identifying fraud, appropriate responses to suspected fraud, and addressing conflicts of interest. Course attendance was mandatory, and 89 staff members participated in the course, contributing to the overarching objective of increasing fraud awareness.

Corrective measures based on OLAF recommendations are reported on in the context of annual monitoring exercises conducted by OLAF, in accordance with Article 11 of Regulation 883/2013 ⁽²⁹⁾.

On the basis of the available information, DG HERA has reasonable assurance that the anti-fraud measures in place are effective. DG HERA's anti-fraud strategy will be renewed in 2026.

⁽²⁹⁾ [REGULATION \(EU, EURATOM\) No 883/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office \(OLAF\) and repealing Regulation \(EC\) No 1073/1999 of the European Parliament and of the Council and Council Regulation \(Euratom\) No 1074/1999](#)

2.1.3. Efficiency of controls

The only efficiency indicator relevant for DG HERA is the ‘timely payments’. For 2025, 99% of the total amount paid was paid on time.

The transition in 2025 to the Commission’s new accounting system, SUMMA, has required the adjustment to a new system and has impacted budget implementation tasks, processes and financial management activities, particularly during the first part of the year. This has required careful management to ensure the same data quality as in previous years. In 2025, DG HERA added additional controls in order to manage payment times in coordination with DG SANTE, responsible for financial initiation and verification of all DG HERA financial transactions. Enhanced monitoring of payments ensured excellent results in terms of payment times.

2.1.4. Economy of controls

In 2025, DG SANTE carried out financial initiation and verification for all DG HERA financial transactions, based on a Memorandum of Understanding. Thus, the cost of controls depended on the systems and controls set up by DG SANTE.

2.1.5. Conclusion on the cost-effectiveness of controls

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

2.2. Audit observations and recommendations

2.2.1. Internal Audit Service (IAS)

In 2025, DG HERA has not been involved as ‘lead’ department for any IAS audits.

At the end of 2025, no IAS recommendations critical or very important were pending. While the IAS conducted the limited review on DG HERA’s assessment of its Internal Control Framework in 2023, it did not raise any critical or very important recommendations to DG HERA.



2.2.2. European Court of Auditors (ECA)






In its [Annual Report 2024](#), ECA reported the audit on the procurement procedures that the Commission carried out on behalf of the Member States to conclude purchase agreements. The ECA reported that they identified several issues, such as insufficient documentation of the negotiations with the suppliers on the terms and conditions of the contracts, including price and number of doses while they did not quantify the findings and no recommendations were

assigned to DG HERA. The Commission replied that these procedures, including the preliminary exchanges with the contractors, were fully in line with the Financial Regulation, in the specific context of extreme urgency under the pandemic and with the objective of ensuring the availability of sufficient safe vaccines for the populations in the Member States at the time of the pandemic.

In 2024, from an ECA audit (SR 12/2024) where HERA was associated service, 1 recommendation was received, and the implementation is on-going.

European Court of Auditors

Reported	Audit Title	Accepted Recommendation	State of play in 2025	Impact on the assurance for 2025
2025	Statement of Assurance (DAS) 2024	N/A	N/A	N/A
2024	Special Report 12/2024 The EU's response to the COVID-19 pandemic – The EU medical agencies generally managed well in unprecedented circumstances (lead DG for the audit: DG SANTE)	1		

State of play		Assurance	
	Action plan implemented		No impact on the assurance
	Action plan implementation is ongoing		Impact on the assurance
	Preparation of the action plan		

2.3. Assessment of the effectiveness of internal control systems

The Commission has adopted an Internal Control Framework based on the highest international standards. ⁽³⁰⁾

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

DG HERA has assessed its internal control system during the reporting year, finalising it on time for the completion of the AAR 2025 and has concluded that it is effective and the components and principles are present and functioning well overall. Only minor deficiencies were identified related to the number of exception reports under principle 6 ⁽³¹⁾.

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

- The results from the review of the internal control monitoring criteria set out in DG HERA Internal Control Framework;
- DG 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 2025, there were 5 recorded exceptions and no cases of confirmation of instructions (art. 93.2 FR). There were no weaknesses reported by staff and no issues were raised by the authorising officers by delegation. There were no recommendations reported by the IAS and the European Court of Auditors on DG HERA internal control framework.

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

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

The self-assessment conducted by DG HERA concluded that in 2025, DG HERA had 16 internal control principles that were present and functioning well overall and 1 internal control principle, namely principle 6, that needs minor improvements as a minor deficiency was identified related

⁽³⁰⁾ The Committee of Sponsoring Organizations of the Treadway Commission Internal Control Integrated Framework, the golden standard for internal control systems.

⁽³¹⁾ Principle 6 of the Internal Control Framework: "The Commission specifies objectives with sufficient clarity to enable the identification and assessment of risks relating to objectives".

to the number of exception reports. This deficiency is mainly attributable to a few instances of contractors being late in fulfilling their obligations and this resulted in breach of the financial rules. DG HERA will intensify the communication with the contractors on the importance of timely reporting and will introduce additional checks at the time of the final invoice submission in an attempt to avoid contractors requesting payment outside of the usual deadlines and in breach of the financial rules.

Improvements can be noted in comparison to 2024 like the increase of the percentage of staff that have attended the training on ethics and integrity, the implementation of the working arrangements with the Cabinet and the percentage of staff that have completed the course on “Fraud – staying vigilant”.

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

However, the risk assessment has identified that in order to be able to fully achieve its objectives, DG HERA would require more staff in particular on financial related issues, between 2026 and 2027 as assessed in the context of the annual budgetary process.

In line with the Commission’s Internal Control Framework, DG HERA has concluded that its internal control system is effective, and the components and principles are present and functioning well overall.

2.4. Conclusions on the assurance

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

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

In conclusion, based on the elements reported above, management has reasonable assurance that, overall, effective 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 her capacity as Authorising Officer by Delegation has signed the Declaration of Assurance.

2.5. Declaration of Assurance [and reservations]

Declaration of Assurance

I, the undersigned,

Director-General of DG HERA

In my capacity as authorising officer by delegation

Declare that the information contained in this report gives a true and fair view ⁽³²⁾.

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-ante controls, the work of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors for years prior to the year of this declaration.

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

Brussels, 31 March

.....

(signature)

Florika FINK-HOOIJER

⁽³²⁾ True and fair in this context means a reliable, complete and correct view on the state of affairs in the DG/Executive Agency.

3. A MODERN AND SUSTAINABLE PUBLIC ADMINISTRATION

3.1. Human resource management

DG HERA's total allocation remained at 104 FTEs. DG HERA needs more staff to effectively carry out its work, notably, but not only, in the light of the extended mandate stemming from the proposal for the Critical Medicine Act ⁽³³⁾, the implementation of the MCM strategy, and the growing importance of dual use MCM and civil military cooperation considering the tensed geopolitical context. Towards the end of 2025, DG HERA started exploring possible adjustment in its organisation to address better its emerging priorities and provide more clarity on who does what in the organisation aiming at launching a proposal of reorganisation early 2026.

In 2025, DG HERA maintained 50 percent of female middle management in accordance with the principle of balanced first appointments at middle management level (SEC (2023) 200). In 2025, HR management in DG HERA focused on improving organisational development aspects with a focus on knowledge and information sharing and boosting digital skills through the organisation of digital workshops as well as a dedicated AI session during a team event for all staff.

In addition, DG HERA further improved the clarity of the unit portfolios, procedures and workflows and finalised the implementation of the action plan to follow up on the results of the 2023 staff survey. Currently staff engagement (baseline: 66% in 2023) is boosted with significant teamwork across units, where staff can lead on specific projects of relevance to the DG. The functioning of the organisation is horizontal and allows young staff to attend high-level meetings and participate in important missions. In general, the level of autonomy and responsibility in DG HERA is higher than in more established DGs at all levels of the organisation. This is a strong factor of motivation and engagement.

⁽³³⁾ COM(2025) 102 final 2025/102 (COD) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 (Text with EEA relevance)

3.2. Digital transformation and data management

Digital Transformation

In 2025, the HERA team continued to develop and maintain the HERA IT Platform **ATHINA (Advanced Technology for Health Intelligence and Action)**, which aims to support the HERA Business Processes and facilitate decision making at HERA. End of 2025 the next modules reached their end-phase to be launched in production, being:

- the Case Management Module,
- Visualisation and Reporting for Case Management,
- Advanced Search and
- Administrative Features.

The go-live of these modules awaited the finalization of the IT Security Plan. The first actions on the business implementation kicked-off with knowledge sessions on ATHINA Updates, ATHINA state-of-play presentations in all HERA units by the HERA IT team etc.

To enhance **digital culture**, DG HERA promoted general IT training and consulted EU Learn. DG HERA promoted CyberAware campaigns and encouraged staff to participate in cybersecurity awareness training. Furthermore, Collaborative tools such as Teams and M365 were promoted by the appointed M365 Champion.

Committed to **digital-ready policymaking**, DG HERA continued in 2025 to involve local IT roles and DIGIT's central advisory service in the design of policy initiatives (Business Implementation of ATHINA in the design stage). With the local digital strategy still in development, DG HERA nonetheless, aimed for alignment with the corporate digital strategy and its principles integrated into its policymaking processes.

Business-driven digital transformation was driven in 2025 by all ATHINA projects, by the use of the Corporate ARIS environment, to improve business process modelling and automation. DG HERA continued in 2025 to improve its digital landscape, IT legacy, and cloud adoption by further developing ATHINA, which is mapped to business and technical capability models in the Corporate ARIS environment. DG HERA promoted AI training and encouraged the use of Commission-wide general-purpose AI solutions. In particular, the HERA-Away day had a strong focus on the practical use of AI.

To achieve a **seamless digital environment**, DG HERA initiated the onboarding of ATHINA in the Commission-wide European Crisis Management Platform. This has kicked off under a Partnership Agreement with DIGIT, to ensure that DG HERA follows the envisioned corporate architecture. DG HERA set out a roadmap in integrating the Stakeholder Hub into ATHINA.

In 2025 DG HERA promoted **green, secure, and resilient infrastructure**. DG HERA worked with DIGIT S to reduce risks and implement priority controls in ATHINA. Additionally, DG HERA will balance reducing risk with enhancing maturity.

Data and information management

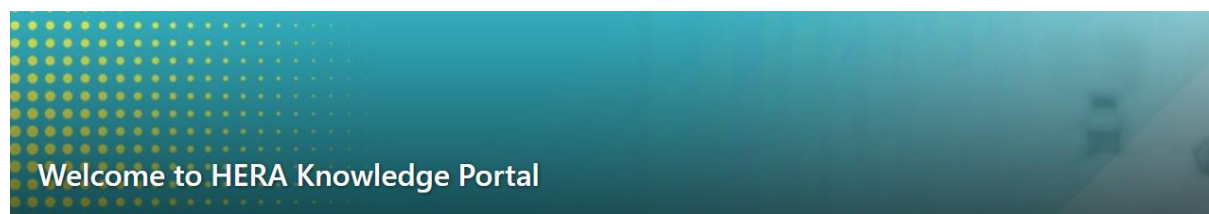
In 2025, there was no data about DG HERA on the Corporate Data Maturity Dashboard. DG HERA appointed its Local Data Correspondent in October 2025, and thus no specific data governance policies have been adopted yet. With the development of ATHINA, a first draft of the HERA Data Strategy has been defined, which still needs to be consolidated and approved.

The maturity level of data management is basic. In 2025, work has been ongoing to prepare a launch of a critical mass of ATHINA features (now planned for 2026), which will allow DG HERA to manage data in a more structured format. An inventory of data assets will be also generated. The purpose of the inventory is to report data assets systematically in the EC Data Catalogue when relevant to do so and to be informed of the data acquisition policies.

Maturity level of ownership and responsibilities is basic. DG HERA has an appointed data governance team ⁽³⁴⁾. In the ATHINA project, the roles for ownership and responsibilities for data governance and data management have been identified, but there are no persons yet assigned to those roles.

Maturity of data quality and FAIRness is basic. The FAIR principles are considered but not currently applied. This is also the case for the use of metadata and master/reference data.

Maturity level of data skills is basic. Due to strong engagement with the industry, DG HERA staff are aware of the importance of managing the business-related data with care. The data competencies regarding data governance and management however are limited to DG HERA IT staff.



In 2025, the HERA team continued to develop and maintain the **HERA Knowledge Portal**, a SharePoint Online site that serves as a central place for key documents and information related to HERA's work. The portal plays an important role in supporting a collaborative digital way of working and helps colleagues access information more easily and work more efficiently.

Key achievements of the HERA Knowledge Portal include:

Promoting collaborative digital working: Throughout the year, DG HERA encouraged colleagues to use more collaborative digital tools through organised feedback sessions. The Knowledge Portal has been central to this effort, offering a clear structure by work areas and file types.

⁽³⁴⁾ The team includes the data protection coordinator, local data correspondent, document management officer, and local security officer.

Content quality and expansion: Regular checks were carried out to ensure that the information on the portal remains accurate and up to date. In 2025, five new pages were added: Pipeline Analysis, MCM Strategy, MFF, Civil-Military Cooperation, and National Prevention. This expansion is particularly important in crisis situations, where quick access to reliable information is essential.

Supporting new colleagues: The Knowledge Portal has become a key resource for onboarding, providing new colleagues with easy access to DG HERA policies, processes, working methods, and templates. This helps them integrate more quickly and reduces the need to search for information in multiple places.

Trust and engagement: Colleagues are increasingly using and contributing to the portal, showing growing trust in the platform. With the support of the team and correspondents, this engagement continues to drive the portal's development and relevance.

DG HERA also continued to promote Cyber Security awareness and the use of Artificial Intelligence by knowledge hours and info sessions, in collaboration with other Commission Services (baseline: 0 in 2025).

In addition, DG HERA continued working according to the established document management and access to documents procedures. New colleagues have received the necessary training as part of the welcome pack.

DG HERA has also remained committed to ensuring full compliance with data protection rules and rigorous implementation of therein-embodied principles. DG HERA promoted participation in the data protection courses (baseline: 28% in 2025), while newcomers were specifically given an introductory course on data protection compliance in DG HERA. DG HERA mapped the implementation of data protection rules and increased monitoring capabilities, in particular by promoting record-keeping activities.

DG HERA has an appointed data governance team⁽³⁵⁾, but no specific data governance policies have been adopted yet. With the development of ATHINA, a first draft of the HERA Data Strategy has been defined which still needs to be consolidated and approved. The ATHINA roles for ownership and responsibilities for data governance and data management have been identified, but there are no persons yet assigned to those roles.

3.3. Sound environmental management

DG HERA's long-term building location is being planned, with a move scheduled for 2028. DG HERA began its full integration into EMAS (Commission Eco-Management and Audit Scheme). An EMAS correspondent was appointed in October 2025 and initiated a series of environmental awareness emails. These communications promoted environmentally responsible practices, suggested relevant trainings, shared environmental news and updates, and informed colleagues about upcoming environmental events and EMAS-related initiatives. The initiative

⁽³⁵⁾ The team includes the data protection coordinator, local data correspondent, document management officer, and local security officer

contributed to increased visibility of environmental actions and supported staff engagement with available resources and activities.

Regarding missions and business travel of staff and experts, teleworking and videoconferences have intensively been used, and DG HERA continued these practices throughout 2025 to further implement the Pledge for the Greening of missions and meetings signed by DG HERA in 2022. This includes the efforts in reducing the emissions from staff professional travel (baseline: ~ 378.779 in 2024 ⁽³⁶⁾). In 2025, such efforts resulted in a 47% reduction in the emissions from staff professional travel (178.285 in 2025).

⁽³⁶⁾ The baseline is set for 2024 as DG HERA was created at the end of 2021 and reached almost its full capacity in terms of staff in 2024.