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European Commission

Annual Activity Report 2025

annexes

Health Emergency Preparedness and Response Authority

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ANNEX 1: Statement of the Director in charge of Risk Management and Internal Control ([1])

I declare that in accordance with the Commission's communication on the internal control framework ([2]), I have reported my advice and recommendations on the overall state of internal control in the DG to the Director-General.

I hereby certify that the information provided in the present annual activity report and in its annexes is, to the best of my knowledge, accurate and complete.

Date 31 March

(signature)

Laurent Muschel

Deputy Head of DG HERA

([1]) In DG HERA, the Deputy Head of DG HERA is entrusted with the Risk Management and Internal Control (RMIC) function.

([2]) C(2017)2373 of 19.04.2017

ANNEX 2: Performance tables

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

Related to spending programme(s): EU4Health, Horizon Europe

Result indicator 1.1.1 Number of selected MCMs (excluding critical medicines) assessed using the vulnerability assessment methodology during the 2025-2029 period
Explanation: This indicator is based on the number of selected priority MCMs (excluding critical medicines) assessed using the vulnerability assessment methodology developed under this action, as part of efforts to establish a continuous assessment infrastructure.
Source of data: DG HERA
This result indicator is selected as a KPI

Baseline (2025)	**Interim milestone** (Q2 2026)	**Interim milestone** (2027)	**Target** (2029)	**Latest known results** (situation on 31/12/2025)
0	5	20	50	0 ([3])

Result indicator 1.1.2 Establishment of an open manufacturing readiness framework
Explanation: Establish an open manufacturing readiness framework to reinforce diversified supply chain network.
Source of data: DG HERA

Baseline (2025)	**Interim milestone** (2027)	**Target** (2029)	**Latest known results** (situation on 31/12/2025)
Initiation	In progress	Fully established	In progress (RAMP UP network)

Result indicator 1.1.3 Number of companies invested in under HERA Invest
Explanation: Increase in the number of companies invested in under HERA Invest.
Source of data: DG HERA

Baseline (2025)	**Interim milestone** (2027)	**Target** (2029)	**Latest known results** (situation on 31/12/2025)
3	8	12	3

([3]) 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.

Main outputs in 2025:			
New policy initiatives			
Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
Strategy to support MCMs against public health threats	Publication	Q3 2025	Published in Q3 2025
Strategic Report of the Critical Medicines Alliance	Publication	Q1 2025	Published in Q1 2025
Other major outputs			
Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
HERA Industry days	Event organised	Q3 2025	Organised in Q2 2025 ([4])
Blending under the Thematic Innovation financial product implemented by the European Investment Bank under the Invest EU Programme (HERA INVEST)	Number of companies receiving support	2	1 ([5])

([4]) Event organised earlier than initially planned.

([5]) HERA Invest aimed to sign 2 companies in 2025. One company was signed in March 2025, and the second was planned for November 2025. Unfortunately, some challenges on the side of the company and involvement of contractors' part of their supply chain hampered the further processing of the contract. The agreement is at this stage in stand-by until the situation is resolved. Work is ongoing to identify new companies for the 2026 wave of investments.

General objective 1: A new plan for Europe's sustainable prosperity and competitiveness ***Specific Objective 1.2: Investing in prevention through innovative MCMs*** *Related to spending programme(s): EU4Health, Horizon Europe*			
Result indicator 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 HERA's funding per year **Explanation:** Enhanced innovation and technological readiness to ensure better access and increased availability of medical countermeasures. **Source of data:** Horizon Europe, EU4Health **This result indicator is selected as a KPI**			
Baseline (2025)	**Interim milestone** (2027)	**Target** (2029)	**Latest known results** (situation on 31/12/2025)
6	18	30	12
Main outputs in 2025:			
Other major outputs			
Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
Support to speed up the development of access to and/or uptake of MCMs	Number of calls for proposals through DG HERA's funding	1	3 calls for proposals (€ 20 million through EU4Health 2025) were closed in December for medicinal products (therapeutic platforms), PPE and protecting equipment and diagnostics
Supporting the development of MCMs against AMR to strengthen global preparedness and response	Financing of the pre-clinical and clinical development of antimicrobials	Above € 82,5 million (37,5 + 45 from EU4Health and Horizon Europe work programme for 2025)	€ 78,5 million (33,5 + 45 from EU4Health and Horizon Europe work programme for 2025) ([6])

([6]) Actions under EU4Health: Contribution agreement signed with KfW (€ 30 million) to support preclinical and clinical development of AMR MCMs including supporting the organisations GARDP and CARBX and Contribution agreement signed with WHO (€ 3.5 million) to support their work on fostering innovation in AMR MCMs R&D and ensuring access to essential antibiotics. Actions under Horizon Europe: One Health AMR partnership launched in September 2025.

Output	Indicator	Target	Latest known results (situation on 31/12/2025)
Development of antibodies and antibody-derived proteins for the prevention and treatment of infectious diseases with epidemic potential	Projects funded under Horizon Europe call on this topic	At least 4	4 projects of which evaluation of proposals has been completed

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

Specific Objective 2.1: European preparedness for health emergencies

Related to spending programme(s): EU4Health, Horizon Europe

Result indicator 2.1.1 Number of strategic locations where wastewater and environmental monitoring is performed
Explanation: Improved threat detection systems.
Source of data: DG HERA
This result indicator is selected as a KPI

Baseline (2025)	Interim milestone (2027)	Target (2029)	Latest known results (situation on 31/12/2025)
1	25	30	23 ([7])

Result indicator 2.1.2 Number of preparedness actions for mass casualty events during the 2025-2029 period
Explanation: This indicator measures the number of activities implemented by DG HERA to enhance its readiness to respond to mass casualty events, in particular CBRN and medical response to conflicts including civil military cooperation, and its support to Member States to build up national response capacity in this area.
Source of data: DG HERA

Baseline (2025)	Interim milestone (2027)	Target (2029)	Latest known results (situation on 31/12/2025)
0	3	5	2

([7]) The high number is impacted by the changes in methodology. Consequently, the interim milestone and target were also adjusted to reflect it.

Main outputs in 2025:			
New policy initiatives			
Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
Administrative Arrangement with HERC	Signature of the arrangement and establishment of relationships	Q3-4 2025	Signed in Q2 2025 ([8])
Evaluations and fitness checks – part of the stress testing of the EU acquis			
Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
Pharmaceutical industry study in prospective EU candidate countries and potential candidates	Publication	June 2025	Published in December 2025 ([9])
Initiatives linked to regulatory simplification and burden reduction			
Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
Assessment on feasibility of a shelf-life extension programme for stockpiled MCMs	Implementation and conclusion of a pilot shelf-life extension programme	Q4 2025	Pilot programme ongoing ([10])
Major implementation activities and enforcement actions			
Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
Donation of all mpox vaccine doses committed by Team Europe in 2024	Delivery of 607 000 doses to African countries	Q2 2025	Doses delivered in Q2 2025

([8]) Arrangement signed earlier than initially expected.
([9]) Study delayed to December.
([10]) To be concluded soon.

Other major outputs			
Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
IT development for early warning, modelling, simulation and forecasting – ATHINA 2.0	Number of functional and technical requirements and specifications finalised and approved	Functional Requirements of ATHINA – 374 Non-functional Requirements of ATHINA – 288	Functional Requirements of ATHINA – 422 (321 functional requirements, 17 legal requirements, and 84 business requirements) Non-functional Requirements of ATHINA – 180 (all approved)
Global wastewater sentinel system	Number of super-sites participating in the sentinel system	20 super-sites	22 super-sites
Direct grant to Member States authorities: enhancing whole genome sequencing (WGS) and/or reverse transcription polymerase chain reaction (RT-PCR) national infrastructures and capacities to respond to the COVID-19 pandemic and future health threats	Number of Member States with integrated genomic based platforms for pathogen characterization and surveillance	26	25 ([11])
Support to the Commission on gathering intelligence on priority threats and MCMs	Number of studies performed on current or possible DG HERA threats or MCMs	At least 1	1 study ('*Study on broad-use PPE, IVD and MD: availability & shortage prevention actions*') launched in September 2025
Support to pandemic and epidemic intelligence	Contribution agreement signed with WHO Hub for pandemic and epidemic intelligence	1	Contribution Agreement under discussion with the Hub, foreseen invite to submit a proposal in Q1/2026

([11]) The previous 2022 grants to MS covered 24 EU countries (+ Norway). Bulgaria, Cyprus and Slovakia are missing. In our 2025 direct grants, we are targeting those (currently under evaluation). We now know that all of those applied for the new grants.

Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
Support of the independent panel for evidence and action against AMR (IPEA) generating evidence for global policy and response	Establishment and launch of the Independent Panel for Evidence for Action against AMR by 2025	By the end of 2025	The launch of the IPEA has been delayed to Q2 2026. DG HERA plans to sign the contribution agreement in 2026 ([12])
Training and exercise activities	Number of training activities (workshops, new eLearning modules, communities of practice) delivered or in which DG HERA participated	Minimum 7	10
Training and exercise activities	Number of participants from public authorities in EU Member States with a multi-sectorial approach (public health, but also e.g. research, civil protection or military) trained	Minimum 200	364
CBRN threats	Convene Member States to discuss specific CBRN threats	Organise at least one dedicated workshop	1 workshop organised
A compendium of MCMs suitable for EU stockpiling	The Commission will propose to Member States a compendium of MCMs suitable for EU stockpiling	Q3 2025	Draft submitted in Q3 2025

([12]) € 2 million have been allocated to support the Quadripartite in establishing the IPEA under the EU4Health 2025 work programme.

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

Specific Objective 2.2: Crisis response to health emergencies

Related to spending programme(s): EU4Health, Horizon Europe

Result indicator 2.2.1 Percentage of managed cases when a crisis occurs

Explanation: When a health crisis is developing or occurs, this indicator measures the percentage of cases, which has been managed by the Emergency Office in a timely and effective manner.

Source of data: DG HERA

This result indicator is selected as a KPI

Baseline (2025)	**Interim milestone** (2027)	**Target** (2029)	**Latest known results** (situation on 31/12/2025)
100%	100%	100%	100% ([13])

Result indicator 2.2.2 Number of lessons learned exercises following a health emergency response

Explanation: This indicator measures the number of lessons learned exercises conducted following a DG HERA emergency response.

Source of data: DG HERA

Baseline (2025)	**Interim milestone** (2027)	**Target** (2029)	**Latest known results** (situation on 31/12/2025)
1 per response	1 per response [in 90% of cases]	1 per response [in 90% of cases]	1 per response

Main outputs in 2025:

Other major outputs

Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
New version of the Response protocol	New version of the Protocol uploaded on the HERA Knowledge Portal	Updated processes and governance	Work in progress ([14])
Lessons learned and recommendations from mpox coordination 2024/2025	Lessons learned circulated and presented to the HERA Board meeting in October	Q4 2025	Mpox Lessons learned submitted to the HERA board in October 2025
Draft Guidelines on crisis procurement	Guidelines are made available	Q4 2025	Q3 2026 ([15])

([13]) 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).

([14]) The new version of the protocol will be uploaded as soon as possible.

([15]) The delivery of the guidelines is delayed.

ANNEX 3: Draft annual accounts and financial reports

The draft annual accounts and financial reports can be accessed through the above QR code. Should the code not work, you can also follow this link.

ANNEX 4: Financial scorecard

The financial scoreboard can be accessed through the above QR code. Should the code not work, you can also follow this link.

ANNEX 5: Materiality criteria

This annex provides detailed explanation on how the AOD defined the materiality threshold as a basis for determining significant weaknesses that should be subject to a formal reservation to his declaration.

In the analysis leading to the decision on whether to issue reservations or not, DG HERA assesses both qualitative and quantitative aspects:

Qualitative assessment

DG HERA assesses the significance of any detected weakness in qualitative terms by taking into account the nature and scope of the weakness, its potential impact, and the existence of mitigating controls and/or remedial actions.

Significant deficiencies in one of the control systems

Identified weaknesses in the design or operation of DG HERA internal controls could significantly influence the appreciation of the Director's General Declaration. This could be the case notably,

- if significant conflicts of interest existed;
- if personnel were unethical or unqualified;
- if the systems failed to provide complete and accurate information due to design flaws or misapplication of procedures;
- if appropriate verifications, approvals, reviews and audits of transactions and procedures were absent or largely insufficient or inadequate;
- if duties were not separated;
- if controls were intentionally overridden and/or wilfully circumvented.

Issues outlined by auditors or OLAF

A critical observation made by the Court of Auditors, the Commission's Internal Audit Service (IAS) or OLAF could lead to a reservation,

- if the issue is not solved immediately during the reporting period, and
- if the impact is material (financial loss exceeding 2 % of the implemented budget concerned.

Significant reputational risks

Besides a possible quantitative aspect of a reputational risk, its impact on the declaration of assurance is assessed mainly on the basis of qualitative criteria, such as sensitivity of the policy area concerned, high public interest or serious legislative concerns. It encompasses issues that could cause lasting damage to the Commission's image due to, for example, financial fraud or serious breaches on provisions of legislation.

For weaknesses, which are considered significant in qualitative terms but not in quantitative terms, DG HERA takes into account the possible reputational impact they may entail to the image of DG HERA and the Commission. They are assessed according to the context and nature of the impact, awareness and duration.

Quantitative assessment

As regards legality and regularity, the proposed standard quantitative materiality threshold of 2% of the residual error rate of the payments related to budget that DG HERA implements directly (and not through partner DGs/ HaDEA), per respective programme (EU4Health, UCPM) is applied. DG HERA considers it an appropriate threshold above which weaknesses detected should be considered "material".

De minimis' threshold for financial reservations

Since 2019 ([16]), a 'de minimis' threshold for financial reservations has been introduced. Quantified annual activity report reservations related to residual error rates above the 2% materiality threshold are deemed not substantial for segments representing less than 5% of a department's total payments and with a financial impact below EUR 5 million. In such cases, quantified reservations are no longer needed. Cases where the 'de minimis' threshold applies this year are reported in annex 9.

As almost the entire HERA budget is co-delegated to partner DGs/ HaDEA, the impact of reservations in their AAR on DG HERA budget will also be taken into consideration.

([16]) Agreement of the Corporate Management Board of 30/4/2019.

ANNEX 6: Relevant Control System(s) for budget implementation (RCSs)

Annex 6 covers the relevant control systems for budget implementation in DG HERA related to the direct and indirect management.

1) Relevant control systems for Indirect Management (contribution agreements with international organizations)

Under indirect management, candidate entities to be entrusted with budget implementation tasks must demonstrate a level of financial management and protection of the EU financial interests equivalent to that required when the Commission manages European Union funds. This is verified by carrying out an ex-ante assessment ("pillar assessment") for which the entities concerned must have been assessed positively. DG HERA manages contribution agreements with international organisations that are pillar assessed and that have been chosen in accordance with the EU4Health Regulation (EU) 2021/522, Articles 7(1) and 13(1) point (b).

At the stage prior to contracting, the main control objective is to ensure that the international organisation is fully prepared to start/continue implementing the delegated funds autonomously demonstrating a level of financial management and protection of the EU financial interest equivalent to that of the Commission. The main controls at this stage include:

- ex-ante pillar assessment, conditional to granting budget autonomy. DG HERA does not conduct own pillar assessments itself but contributes to and relies on assessments conducted by other DGs.

At the stage of preparing and signing the contribution agreement with the international organisation, the main control objective is to ensure that the legal framework for the management of the relevant funds is fully compliant and regular and delegated to an appropriate entity (best value for public money, economy, efficiency), without any conflicts of interests. The main controls at this stage include:

- During the preparation of the EU4Health work programme, actions, their funding and the organisations who should implement them are identified by the policy Units and approved by the Authorising Officer responsible;
- each work programme is subject to interservice consultation for a Commission Decision;
- implementing the adopted work programme, DG HERA invites the identified organisation to submit its proposal; templates are used that comply with corporate models, and the invitation is validated by the Authorizing Officer responsible;
- DG HERA evaluates and "negotiates" the proposals (technical and financial aspects) and documents the results;
- Based on the outcome of the evaluation, and the following ex-ante checks on administrative and legal aspects of the contribution agreement, the Authorising Officer responsible approves and signs the contribution agreement;
- the contribution agreement is countersigned by the international organisation.

At the stage of monitoring the international organisation's implementation of the contribution agreement and managing the financial transactions, the main control objective is to ensure that the Commission is fully and timely informed of any relevant management issues encountered by the international organisation, to mitigate any potential financial and/or reputational impacts (legality and regularity, sound financial management, true and fair view reporting). The main controls include:

- the agreements specify the organisation's requirements on reporting issues related to control, accounting, audit, publication etc.;
- DG HERA monitors the organisation's implementation of the action, e.g. through regular monitoring meetings at operational level; review of reported control results and any underlying management/audit reports (where applicable);
- By the date stipulated in the contribution agreement, the organisation submits the final technical and financial reports;
- DG HERA assesses the technical and financial reports and documents the results;
- At this stage, DG HERA has entrusted DG SANTE with the control objective to ensure that the related financial operations comply with regulatory and contractual provisions (legality & regularity) and to ensure appropriate accounting of the operations (reliability of reporting, safeguarding of assets and information). DG SANTE carries out financial checks prior to payment according to DG SANTE's controls;
- If deemed necessary, the file is referred to OLAF.

2) Relevant control systems for Direct Management (procurement, administrative agreements, and administrative expenditure)

DG HERA transfers implementation tasks for the majority of the EU4Health programme budget to the Health and Digital Executive Agency (HaDEA), and all major procurement procedures are managed by the agency. Consequently, the number and volume of the contracts managed by DG HERA is quite limited. Almost all the procurement procedures are based on framework contracts of DG SANTE or another DG, in particular DGs DIGIT and COMM and DG HERA also uses regularly its own framework contract for legal advice. DG HERA buys mainly communication, legal advice, and IT services.

Taking into account the limited volume of procurement and the nature of the contracts (mainly specific contracts under framework contracts), DG HERA has established the following control steps.

At the stage of programming, defining the needs, and selecting the offers, the main control objective is to ensure sound financial management (i.e. effectiveness, efficiency and economy); compliance (legality & regularity); prevention of fraud (anti-fraud strategy). The main controls at this stage include:

- for operational credits, a detailed annual work programme is adopted by the Commission specifying the areas for which calls for tenders will be organised, for support credits, the Authorizing Office responsible approves the planning;

- each call for tender fixes either a maximum value or a price range for the contract based on a pricing methodology;
- timing is monitored, and planning updated through regular budget implementation reports prepared by the financial cell to the Authorizing Officer responsible,
- procurement procedures are managed through eProcurement, mainly the Public Procurement Management Tool (PPMT);
- DG HERA uses templates for terms of reference, exclusion and selection criteria that follow the Commission guidelines;
- the tender specifications, the evaluation results, and the award decision are validated by the Authorising Officer responsible.

At the stage of monitoring the implementation of the contract and the financial transactions, the main control objective is to ensure that the implementation of the contract is compliant with the signed contract and that the purchased products or services are of good quality and meet the contract's objectives and conditions (effectiveness & efficiency).

- The contract provisions follow the model contract of the Commission;
- competent staff monitors the implementation of the contract and the progress made (frequency and depth depending on the size and sensitivity of the contract);
- technical implementation reports are assessed and validated prior to initiating payments;
- DG HERA makes use of contractual provisions for refusing technical reports, cutting payments, termination of the contract, penalties etc.;
- At this stage, DG HERA has entrusted DG SANTE with the control objective to ensure that the related financial operations comply with regulatory and contractual provisions (legality & regularity) and to ensure appropriate accounting of the operations (reliability of reporting, safeguarding of assets and information). DG SANTE carries out financial checks prior to payment according to DG SANTE's controls.
- If deemed necessary, the file is referred to OLAF.

For both Direct and Indirect Management, DG HERA has established also a supervisory stage, where the main control objective is to measure the effectiveness of ex-ante controls by supervisory controls; ensure to detect and correct any error or fraud remaining undetected after the implementation ex-ante controls (legality & regularity; anti-fraud strategy); address systemic weaknesses in the ex-ante controls, based on the analysis of the findings (sound financial management); ensure appropriate accounting of the recoveries to be made (reliability of reporting, safeguarding of assets and information).

- follow-up on audit recommendations linked to procurement (ECA and IAS);
- exceptions and internal control weaknesses are reported and analysed;

This segment also includes administrative expenses for salaries and/or missions, which are reported by the service responsible for the commitment, although the payments are executed by another service, notably the PMO and/or DG HR (17). The executing service implements the necessary technical-level controls and submits a declaration to [Name of the delegating Department] on the compliance of these payments with the principle of sound financial

(17) Type III co-delegation for which these expenses were reported by the service executing the payments until 2024.

management, as well as their legality and regularity. These expenses are considered to present a low level of risk and are therefore subject to a flat rate of 0.5%, as corroborated by the control results of the executing service(s). More information on the implemented controls can be found in the [DG HR/PMO] annual activity report(s).

For the budget co-delegated for implementation outside DG HERA, DG HERA has entrusted partner DGs/HaDEA with the design of relevant control systems for budget implementation. The description of the related control strategies can be found in their respective AARs.

Being a lead parent DG for HaDEA, DG SANTE has developed the relevant control systems with regard to the budget implementation tasks delegated to HaDEA, and a description can be found in DG SANTE AAR.

In 2025, the financial initiation and verification of all DG HERA payments, both in direct and indirect management, was carried out by DG SANTE, in compliance with DG SANTE control strategy for each type of expenditure. DG SANTE relevant control systems for budget implementation can be found in DG SANTE AAR.

ANNEX 7: Specific annexes related to "financial management"

A. Free content:

Fraud risk management

Objective: The risk of fraud is minimised through the application of effective anti-fraud measures and the implementation of the Commission anti-fraud strategy ([18]) aimed at the prevention, detection and correction ([19]) of fraud		
Indicator 1: Implementation of the actions included in DG HERA's anti-fraud strategy over the whole lifetime of the strategic plan (2025-2029) **Source of data:** DG HERA's annual activity report, DG HERA's anti-fraud strategy, OLAF reporting		
Baseline (2024)	**Target** (2029)	**Latest known results** (situation on 31/12/2025)
72,7%	100% of due actions implemented each year	81,8%

Main outputs in 2025:			
Description	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
All staff participates in the 'fraud staying vigilant' course	Attendance in the course 100% of staff having attended the course	Q4 2025	Compulsory webinar on anti-fraud awareness for all DG HERA staff was organised in Q4 2025 as an equivalent training
Staff survey on the level of awareness of how to report fraud	Once a critical mass (more than 50%) of staff has attended the "Fraud staying vigilant" training	Q4 2025	Survey not launched

([18]) Communication from the Commission 'Commission Anti-Fraud Strategy: enhanced action to protect the EU budget', COM(2019) 176 of 29 April 2019 – 'the CAFS Communication'; Communication from the Commission "Commission Anti-Fraud Strategy Action plan – revision 2023" COM(2023) 405 of 11 July 2023 – "the Communication on the 2023 revision" – and the accompanying revised action plan, SWD(2023) 245– "the revised Action Plan".

([19]) Correction of fraud is an umbrella term, which refers in particular to the recovery of amounts unduly spent and to administrative sanctions.

B. Compulsory for all departments:

1. Reports and documentation considered for the assessment of the DG's functioning in view of the AOD's assurance:

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

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

- the reports from Authorising Officers in the Directorates-General/services managing budget appropriations in co-delegation. The controls cover the part of the budget entrusted to them by DG HERA;
- the reports from entrusted entities in indirect management, as well as the results of the Commission's supervisory controls on the activities of these bodies;
- the contribution by the Director in charge of Risk Management and Internal Control (RMIC) on the annual assessment of the internal control principles;
- the reports on recorded exceptions and non-compliance events;
- the observations and recommendations reported by the Internal Audit Service (IAS);
- the observations and the recommendations reported by the European Court of Auditors (ECA).

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

2. Financial Regulation: Additional reporting requirements resulting from the 2018 and 2024 revisions.

In line with the requirements of the Financial Regulation, DG HERA reports for the year 2025:

1) no cases of any in-kind donation made to the Union, for the purposes of humanitarian aid, emergency support, civil protection or crisis management aid (FR art 25.3)

2) no cases of "confirmation of instructions" (FR art 92.3)

3) no cases of financing not linked to costs (FR art 125.3)

4) no Financial Framework Partnerships >4 years (FR art 131.4)

5) no cases of flat-rates >7% for funding indirect costs (FR art 184.6)

6) no derogations from the principle of non-retroactivity pursuant to Article 196 of the Financial Regulation.

7) no cases of financial support to third parties >EUR 60 000 (FR art 207)

8) no of non-financial donations provided in the form of services, supplies or works (FR art 244.3)

3. Table Y on the estimated "cost of controls" at Commission level

Not applicable.

In 2025, administrative expenses related to salaries and/or missions are reported by the service responsible for the commitment, although the payments were executed by another service, notably the PMO and/or DG HR ([20]), which, until 2024, also reported the corresponding expenditure. This new reporting arrangement was introduced in the context of data rationalisation linked to the implementation of the Commission's new IT accounting system. In 2025, these expenses represented 4.8% of the DG HERA's total payments.

([20]) Type III co-delegation.

ANNEX 8: Reporting on the internal and external audits and assessing the effectiveness of internal control systems

Not applicable.

ANNEX 9: Specific annexes related to "Control results" and “Assurance: Reservations”

A. Annex related to "Control results" - Table X: Estimated risk at payment and at closure

Table X : Estimated risk at payment and at closure (amounts in EUR mios)

DG HERA -1	Payments made (2025;MEUR) -2	minus new prefinancing [plus retentions -3	plus cleared prefinancing [minus retentions -4	Relevant expenditure (for 2025;MEUR) -5	Detected error rate or equivalent estimates -6	Estimated risk at payment (2025;MEUR) -7	Adjusted Average Recoveries and Corrections (*adjusted* ARC; %) -8	Estimated future corrections [and deductions] (for 2025;MEUR) -9	Estimated risk at Closure (2025;MEUR) -10
RCS 1 - EU4Health programme - Contribution agreements	30.86	- 30.49	3.63	4.00	0.97% - 0.97%	0.04 - 0.04	0.00% - 0.00%	0.00 - 0.00	0.04 - 0.04
RCS 2 - EU4Health programme - Procurement	3.43	0.00	0.09	3.52	0.50% - 0.50%	0.02 - 0.02	0.00% - 0.00%	0.00 - 0.00	0.02 - 0.02
RCS 2 - EU4Health programme - Administrative agreements	3.42	0.00	0.00	3.42	0.00% - 0.00%	0.00 - 0.00	0.00% - 0.00%	0.00 - 0.00	0.00 - 0.00
RCS 2 - Administrative expenditure	1.90	0.00	0.00	1.90	0.50% - 0.50%	0.01 - 0.01	0.00% - 0.00%	0.00 - 0.00	0.01 - 0.01
DG total	**39.61**	**- 30.49**	**3.72**	**12.84**		**0.07 - 0.07**	**0.00% - *****	**0.00 - 0.00**	**0.07 - 0.07**
					Overall risk at payment in %	**0.51% - 0.51%** *(7) / (5)*		**Overall risk at closure in %**	**0.51% - 0.51%** *(10) / (5)*

Notes to the table X

(1) Relevant Control Systems differentiated per relevant portfolio segments and at a level which is lower than the total.

(2) Payments made after the preventive (ex-ante) control measures have already been implemented earlier in the cycle. For Cross-Sub Delegations (Internal Rules Article 12), the reporting remains with the Delegating departments.

In all cases of Co-Delegations (Internal Rules Article 3), "payments made" are reported by the Delegated departments. For Cross-Sub Delegations (Internal Rules Article 12), the reporting remains with the Delegating departments.

(3) New pre-financing actually paid by out by the department itself during the financial year (i.e. excluding any pre-financing received as a transfer from another department). as per note 2.5.1 to the Commission annual accounts thus excluding "Other advances to Member States" which are covered on a purely payment-made basis (note 2.5.2). Pre-financing paid/cleared" are always covered by the Delegated departments, even for Cross-Sub Delegations.

Retentions: in Cohesion, the 10% retention applied during the year.

(4) Pre-financing actually cleared during the financial year (i.e. their 'delta' in the Financial Year 'actuals', not their 'cut-off' based estimated 'consumption'). Retentions: in Cohesion, the retentions released during the year by the Commission.

(5) For the purpose of equivalence with the ECA's scope of the EC funds with potential exposure to legality & regularity errors (see the ECA's Annual Report methodological annex 1.1), our concept of "relevant expenditure" includes the payments made, subtracts the new pre-financing paid out [& adds the retentions made], and adds the pre-financing actually cleared [& subtracts the retentions released; and any deductions of expenditure made by MS] during the FY. This is a separate and 'hybrid' concept, intentionally combining elements from the budgetary accounting and from the general ledger accounting.

(6) In this column, we disclose the detected error rates or equivalent estimates.

(7) The adjusted average recovery and corrections percentage for HERA is 0% as there are no ex-post controls on the relevant expenditure in accordance with DG SANTE control strategy.

ANNEX 10: Reporting – Human resources, digital transformation and data management, and sound environmental management

Human Resource management

Objective: DG HERA employs a skilled, diverse and motivated workforce to deliver on the Commission's priorities		
Indicator 1: Percentage of female middle managers **Source of data:** SYSPER		
Baseline (2024)	**Target** (2029)	**Latest known results** (situation on 31/12/2025)
50 percent	To maintain at least 50%	50%
Indicator 2: Staff engagement index **Source of data:** Commission staff survey [data to be provided by DG HR]		
Baseline (2023)	**Target ([21])** (2029)	**Latest known results ([22])** (situation on 31/12/2025)
66%	*Increase*	*New staff engagement index (2025): 76%* *Old staff engagement index (2023): + 2 percentage points*

([21]) The Commission baseline score for the Staff Engagement Index is 73% (based on the 2023 staff survey results).

([22]) A new method of measuring staff engagement was introduced in 2025. The new Staff Engagement Index provides a more comprehensive view of staff engagement covering purpose, pride and motivation, autonomy and growth and collaboration and trust. The old Staff Engagement Index, which focused more on job content and relations with immediate colleagues and manager, will be used exclusively for comparisons with past data.

Main outputs in 2025:			
Description	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
Boost motivation of Female AD Team leaders to apply for management post by providing the appropriate training to relevant candidates	Staff participation in the career development programmes	At least 1 staff member participating in the career development programmes	1 female colleague finalised the Female Talent Development Programme in 2025

Digital transformation and data management

Objective: DG HERA is using innovative, trusted digital solutions for better policymaking, data management and administrative processes to build a digitally transformed, user-focused and data-driven Commission			
Indicator 1: Digital Culture: % of statutory staff that has completed at least one IT training course **Source of data:** Digital Commission Dashboard (data measured at DG-level)			
Baseline (2024)	**Interim milestone** (2027)	**Target** (2029)	**Latest known results** (situation on 31/12/2025)
43%	Positive trend	Positive trend	44%
Indicator 2: Seamless digital environment: cloud adoption – % of IT systems utilising cloud infrastructure services compared to the total number of IT systems **Source of data:** Digital Commission Dashboard (data measured at DG-level)			
Baseline (2024)	**Interim milestone** (2027)	**Target** (2029)	**Latest known results** (situation on 31/12/2025)
33%	Positive trend	Positive trend	67%
Indicator 3: Maturity level in implementing corporate data policies across four key areas: data management, ownership and responsibilities, data quality, and data skills (basic, developing, established, advanced, or trendsetting). **Source of data:** DG HERA			
Baseline (2024)	**Interim milestone** (2027)	**Target** (2029)	**Latest known results** (situation on 31/12/2025)
Basic	Established	Advanced	Basic

Indicator 4: Compliance indicator ([23]): percentage of staff trained on data protection compliance combined with the percentage of public records of processing operations reviewed within the last two years. **Source of data:** DG HERA			
Baseline (2024)	**Interim milestone** (2027)	**Target** (2029)	**Latest known results** (situation on 31/12/2025)
64% (100% of public records of processing operations reviewed & 28% of staff trained on data protection compliance)	>90%	100%	65,5% (100% of public records of processing operations reviewed & 31% of staff trained on data protection compliance)
Main outputs in 2025:			
Digital transformation			
Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
AI Knowledge hours	Number of sessions organised	2	5
Data management			
Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
Info and feedback sessions on the Knowledge portal	Number of sessions organised	2	1 ([24])
Data protection			
Output	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
Increased participation in the 'Introduction to data protection at the European Commission'	60% staff members participated in the course	Q4 2025	31% ([25])

([23]) The compliance indicator is calculated with a 50% weight attributed to the following two values: first, the number of public records with a publication date within the last 2 years / public records of the department. Second, the percentage of staff in the department who have attended data protection awareness-raising activities.

([24]) Instead of an additional session, targeted engagement directly through the Knowledge portal correspondents was prioritised to ensure all colleagues receive personalised support.

([25]) As it is not the course organised by DG HERA but central services, DG HERA cannot directly control the number of staff that attends this course. However, all new staff need to go through mandatory data protection onboarding and Data Protection Coordinator regularly shares information on the ongoing data protection awareness courses.

Sound environmental management

Objective: Reaching climate neutrality by 2030 and a reduced environmental footprint for the Commission.		
Indicator: % reduction in emissions from staff professional travel (t CO2eq). **Source of data:** DG/department emissions report from Mips+		
Baseline (2024 ([26]))	**Target** (2030)	**Latest known results** (situation on 31/12/2025)
378.779	50% of reduction (baseline 2024)	178.285 (47% reduction)

Main outputs in 2025:			
Description	**Indicator**	**Target**	**Latest known results** (situation on 31/12/2025)
Actions to reduce emissions from staff missions ([27])	2	Q4 2025	3 mailing campaigns completed by Q4 2025

([26]) 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.

([27]) DG/department emissions report from MIps+. Emissions from staff whose place of assignment is one of the Commission's sites: EMAS.

ANNEX 11: Implementation through non-EU entrusted entities ([28]) and/or through EU Trust Funds (if applicable)

Not applicable.

([28]) Implementing partners other than EU institutions or Union bodies.

ANNEX 12: EAMR of the Union Delegations (if applicable)

Not applicable.

ANNEX 13: Decentralised agencies and other Union bodies (if applicable)

Not applicable.