



Annual Activity Report 2023

annexes

Health Emergency Preparedness and
Response Authority

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

“As Director in charge of Risk Management and Internal Control, and as acting 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.”

Brussels, 09.04.2024

(signed)

Laurent Muschel

ANNEX 2: Performance tables

Main outputs in 2023:			
Other important outputs			
Specific objective 1: Crisis Response readiness for health emergencies			
Output	Indicator	Target	Latest known results (situation on 31/12/2023)
Preparatory work for the establishment of necessary structures under the Emergency Framework Regulation	Formal establishment	Q1 2023	The Health Crisis Implementing Committee was established in February 2023 with code C126400
Study supporting the review of HERA with regard to its operations, structure and governance	Signature of the contract	Q3 2023	Contract signed on 6 October 2023. It will run until April 2024.
Continued implementation of existing COVID-19 vaccine contracts	Completion of deliveries for all contracts running in 2023. Successful renegotiation of the contracts where required.	Throughout the year	1st Amendment to the APA with Novavax signed on 30 January 2023. 5th Amendment to the 2nd PA with BioNTech-Pfizer signed on 26 May 2023.

<p>Implementation of joint procurement contracts for COVID-19 therapeutics and new procurement contracts to increase access to additional COVID-19 therapeutics</p>	<p>Completion of deliveries scheduled for 2023 under all contracts and launch of new contracts</p>	<p>Throughout the year</p>	<p>Contracts for COVID-19 therapeutics (Remdesivir and Paxlovid) used throughout 2023. Facilitation of access to Paxlovid to countries that are not part of the JP FWC. Contract for HIPRA COVID-19 vaccine was also available during the year. Evaluating applications received for the first phase of the Dynamic purchasing System for PPE (one applicant admitted so far). Call for tender for a second mRNA C-19 vaccine prepared in 2023 and launched in January 2024 (Flexible preparedness FWC). Initiating potential JP for Remdesivir (launch will take place in 2024) Initiating JP for protein-based C-19 vaccines (launch will take place in 2024)</p>
<p>Implementation and launch of joint procurement contracts for MCMs against cross-border health threats</p>	<p>Launch and completion of Joint procurement procedures. Implementation of framework contracts.</p>	<p>Throughout the year</p>	<p>Launch of the procedure for diphtheria antitoxin, pre-pandemic zoonotic influenza vaccine, initiating JP processes for RSV vaccines and medicines. Conclusion of the FWC for Tecovirimat SIGA (mpox therapeutic) on 20/10/2023 for a ceiling of up to 100 080 Treatment courses. Implementation of the FWC for the mpox vaccine under Joint Procurement with ordering of additional quantities by participating countries in Q2 2023.</p>

Emergency communication	Number of press releases	At least one item per health emergency.	Several news items published per month in the form of press releases, daily news and website articles covering for instance COVID-19 and Mpox, amongst others.
Update communication output	Rewrite, reconfigure, replenish and publish updated HERA website	Revise, revamp and publish finished product in Q4 2023	Revamped website launched in Q4 2023
Improve awareness of HERA locally across Member States	Engage in local press and media for interviews with the Acting Director General	Throughout the year	Interviews took place in a number of Member States, including France, Estonia, Croatia and the Netherlands,
HERA sets a crisis response protocol	Protocol used as a reference for crisis response	Throughout the year	Emergency response protocol adopted in March 2023 and tested in November 2023.
Specific objective 2: Preparedness for health emergencies			
Threat assessments and intelligence gathering			
IT platform for intelligence gathering (production and availability of medical countermeasures, threat assessment and mapping medical countermeasures, stockpiling management system)	Publication of the call for tender under the 2022 EU4Health work programme (CP-p-22-01.03)	Q1 2023	The call for tender was published end of April 2023.
Strengthen Member States's IT systems ensuring interoperability with HERA's IT platform for intelligence gathering through direct grants	Grants to be signed Monitoring of progress	Q1 2023 Throughout the year	The activities kicked off in January 2023 and are slightly delayed.
Enhanced and/or improved national public health capacity in Member States for Whole Genome Sequencing and/or Reverse Transcription Polymerase Chain Reaction capacity	Number of direct grants to Member States launched	Throughout the year	21 direct grants awarded with the participation of 25 Member States, with an EC contribution of 11325 k Euros. The projects started activity in the Q3 of 2023 and started to produce first deliverables in the Q4 of 2023.
Strengthened wastewater surveillance carried out by Member States	Establishment of wastewater surveillance strategies, technical procedures, and governance framework	Q3 2023	Ongoing

Support the technological and operational development of the EIOS Platform	- Contribution agreements with WHO Hub and administrative arrangement with the Joint Research Centre to be signed and implementation to be followed-up -regular HERA Participation in Epidemic Intelligence from open source Core Group	administrative arrangement with JRC to be signed in Q2 2023 Implementation to be followed up throughout the year Q2 2023	Meeting of the EIOS coordination group, 23-24/02/2023, Berlin EIOS Technical meeting, 9-10 October, Ispra, Italy Ongoing discussions on developing specific functionalities for gathering intelligence on MCMs. Ongoing work on improving existing functionalities. Ongoing work on adapting EIOS for monitoring information supporting market intelligence.
Establish and implement procedures for the operation of the network of laboratories (HERA-Lab network)	Grants to be signed in Q4 2022	Implementation in 2023	Established formal request-reply-framework for intelligence gathering, monthly meeting between HERA coordinator and DURABLE coordination team, ad hoc threat-specific meetings
Institutional, annual update of the Threat Prioritisation exercise	Endorsement of the Threat Prioritisation Update (report) by the HERA-Advisory Forums	Q2 2023	Inclusion of two additional serious cross-border health threat dimensions to existing threat categories (environmental health threats to the first category, i.e. agents with pandemic potential) (biosecurity/emerging technologies to the second category, i.e. deliberate/accidental release of CBRN agents)
Promoting advanced R&D of medical countermeasures and related technologies			
Development of a strategic research and innovation agenda for pandemic preparedness	Cooperation with other Commission's services and Member States	Throughout the year	Ongoing
Call on sustaining established coordination mechanisms for European adaptive platform trials and/or for cohort networks	Evaluation of proposals and signature of grant agreements	Q4 2023	Call closed on 13/04/2023; 2 projects funded ⁽¹⁾

⁽¹⁾ [Funding & tenders \(europa.eu\)](https://europea.eu)

Call on broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential	Evaluation of proposals and signature of grant agreements	Q4 2023	Call closed on 13/04/2023; 6 projects funded ⁽²⁾
Call on understanding vaccine induced-immunity	Evaluation of proposals and signature of grant agreements	Q4 2023	Call closed on 13/04/2023; 2 projects funded ⁽³⁾
Call on immunogenicity of viral proteins of viruses with epidemic and pandemic potential	Evaluation of proposals and signature of grant agreements	Q4 2023	Call closed on 13/04/2023; 5 projects funded ⁽⁴⁾
Call on in vitro diagnostic devices to tackle cross-border health threats	Evaluation of proposals and signature of grant agreements	Q4 2023	Call closed on 13/04/2023; 6 projects funded ⁽⁵⁾
Direct contribution to the Coalition for Epidemics Preparedness Initiative	Allocation of the contribution	Q1/Q2 2023	Agreement was signed on 16 June 2023.
Follow-up on the study on options to bring more AMR medical countermeasures on the market	Results presented to member states and agreement on follow-up by HERA Board	Q1 2023	The study was finalized, follow-up for the implementation with actions under EU4Health
Establishment of a network of public bodies to support the Commission as regards AMR MCM	Call for tender to be launched in 2023	Throughout 2023	Not outsourced
HERA actions funded by the EU4Health work programme 2023	Call for tenders and call for proposals	Q1 – Q4 2023	Launched
HERA INVEST	Number of projects funded	Expected signatures of loans in 2024.	Bilateral discussions between EIB and potential selected companies. First loans will be signed in 2024.
Addressing market challenges and boosting the Union's strategic autonomy			

⁽²⁾ [Funding & tenders \(europa.eu\)](#)

⁽³⁾ [Funding & tenders \(europa.eu\)](#)

⁽⁴⁾ [Funding & tenders \(europa.eu\)](#)

⁽⁵⁾ [Funding & tenders \(europa.eu\)](#)

Follow-up on the study on flexible manufacturing conducted in 2022	follow up on final report	Q1 2023	Q2 2023 - The study has been accepted and presented to the Joint Industrial Cooperation Forum. On-going - the report will inform future strategic decisions on HERA manufacturing strategies and ongoing manufacturing technology watch.
Identification of bottlenecks and solutions: collaboration with Industry through (Joint Industrial Cooperation Forum) , HERA and DG GROW	Number of meetings	At least two meetings per year	Two meetings organised – in April and November 2023
Conclusion of EU FAB specific contracts	Signature	Q2 2023	Framework contracts signed, 30 June 2023
Provision of medical countermeasures			
Implementation of the medical and Chemical Biological Radiological Nuclear (CBRN) rescEU stockpiling	publication of new calls or direct grants according to the geopolitical situation	Throughout the year	Seven grants with Member States signed in December 2023.
Stockpiling Strategy	One strategy drafted and submitted to Member States	Q3 2023	Postponed to Q2 2024 because of decision at central level to publish a Communication on shortages instead
Follow-up on the feasibility study on stockpiling of medical countermeasures in the area of AMR	Results to be presented to HERA Board (positive opinion)	Q1 2023	Results of the study were presented in HERA Board on 30 January 2023
Strengthened knowledge and skills			
Develop HERA's training strategy and programme	Draft a training strategy and programme following a gap and needs analysis	Q4 2023	Postponed to Q2 2024 as a needs analysis is currently being done and the results will be fed into the strategy and programme.
Design and implement one table top exercise and one training session on relevant medical countermeasures targeting public administrations	Drafting and launching of tender	Q3 2023	Two trainings organised in October and November 2023. Internal exercise conducted in November 2023.
Governance and coordination			

Facilitation of peer-to-peer discussions among Member States with structured meetings on best practices exchange and knowledge sharing	Meetings	at least two meetings per year	Between September 2021 and December 2023 there have been 15 meetings of the HERA Board, 6 meetings of Advisory Forum, 5 meetings of the Civil Society Forum, 4 meetings of the Joint Industrial Cooperation Forum, and a large number of workshops, trainings and meetings where Member States were able to exchange best practices, experiences and lessons learned.
Specific objective 3: International resilience and appropriate response readiness for health emergencies			
Continue to work with COVAX in pursuit of global vaccination targets (strengthen the multilateral approach in pursuit of global vaccination)	COVID-19 vaccine doses shared through COVAX as a total of total donations	Delivery of donated doses	By end-2023, since the onset of the pandemic Team Europe shared 530 m doses, of which 444 m through COVAX
Structured administrative arrangements with international stakeholders	Signature	Throughout the year	Two arrangements signed (administrative arrangement with the Ministry of Health and Welfare of the Republic of Korea, working arrangement with the Japan Agency for Medical Research and Development
Contribution agreement to support WHO initiatives strengthening preparedness and response to cross-border health threats at global level	Monitoring of the implementation of agreements on antimicrobial resistance (including GARDP ⁶ and SECURE ⁷), C-TAP ⁸ , AFRO ⁹ and Hub ¹⁰	Monitoring throughout the year	Ongoing
Enhanced and/or improved national public health capacity in Africa for Whole Genome Sequencing and/or Reverse Transcription Polymerase Chain Reaction capacity	Direct grant provided under EU4Health 2023 AWP to support the Pathogen Genomics Initiative in Africa	Q3 2024	Grants signed on 15 December 2023
Study on HERA-like structures	Launch of tender	Q4 2023	Contract signed on 22 December 2023

⁶ Global Antibiotic Research & Development Partnership (GARDP)

⁷ [SECURE: The Antibiotic facility](#)

⁸ COVID-19 Technology Access Pool (C-TAP)

⁹ WHO Regional office for Africa

¹⁰ [Pandemic Hub \(who.int\)](#)

ANNEX 3: Draft annual accounts and financial reports

Annex 3 Financial Reports - DG HERA - Financial Year 2023

Table 1 : Commitments

Table 2 : Payments

Table 3 : Commitments to be settled

Table 4 : Balance Sheet

Table 5 : Statement of Financial Performance

Table 5 Bis: Off Balance Sheet

Table 6 : Average Payment Times

Table 7 : Income

Table 8 : Recovery of undue Payments

Table 9 : Ageing Balance of Recovery Orders

Table 10 : Waivers of Recovery Orders

Table 11 : Negotiated Procedures

Table 12 : Summary of Procedures

Table 13 : Building Contracts

Table 14 : Contracts declared Secret

Table 15 : FPA duration exceeds 4 years

Table 16 : Commitments co-delegation type 3 in 2022

Additional comments

TABLE 1: OUTTURN ON COMMITMENT APPROPRIATIONS IN 2023 (in Mio €) for DG HERA					
			Commitment appropriations authorised*	Commitments made	%
			1	2	3=2/1
Title 01 Research and Innovation					
01	01 01	Support administrative expenditure of the "Research and Innovation" cluster	0.00	0.00	0.00 %
Total Title 01			0.00	0.00	0.00 %
Title 06 Recovery and Resilience					
06	06 01	Support administrative expenditure of the "Recovery and Resilience" cluster	3.27	3.19	97.48 %
	06 05	Union Civil Protection Mechanism	0.00	0.00	0.00 %
	06 06	EU4Health Programme	10.74	10.74	100.00 %
	06 07	Emergency support within the Union	18.83	0.00	0.00 %
Total Title 06			32.83	13.92	42.41 %
Title 20 Administrative expenditure of the European Commission					
20	20 02	Other staff and expenditure relating to persons	0.01	0.01	100.00 %
Total Title 20			0.01	0.01	100.00 %
Total Excluding NGEU			32.84	13.93	42.43 %
Title 06 Recovery and Resilience					
06	06 05	Union Civil Protection Mechanism	0.00	0.00	0.00 %
Total Title 06			0.00	0.00	0.00 %
Total NGEU Only			0.00	0.00	0.00 %
Total DG HERA			32.84	13.93	42.43 %

* Commitment appropriations authorised include, in addition to the budget voted by the legislative authority, appropriations carried over from the previous exercise, budget amendments as well as miscellaneous commitment appropriations for the period (e.g. internal and external assigned revenue).

*Title 06 Recovery and Resilience, budget line 06 07 Emergency Support within the Union, EUR 18.83 million of commitment appropriations were co-delegated to DG INTPA in 2023 but showing on DG HERA accounts due to specificity of the carry-over procedure.

% Outturn on Commitment Appropriations in 2023 for DG HERA

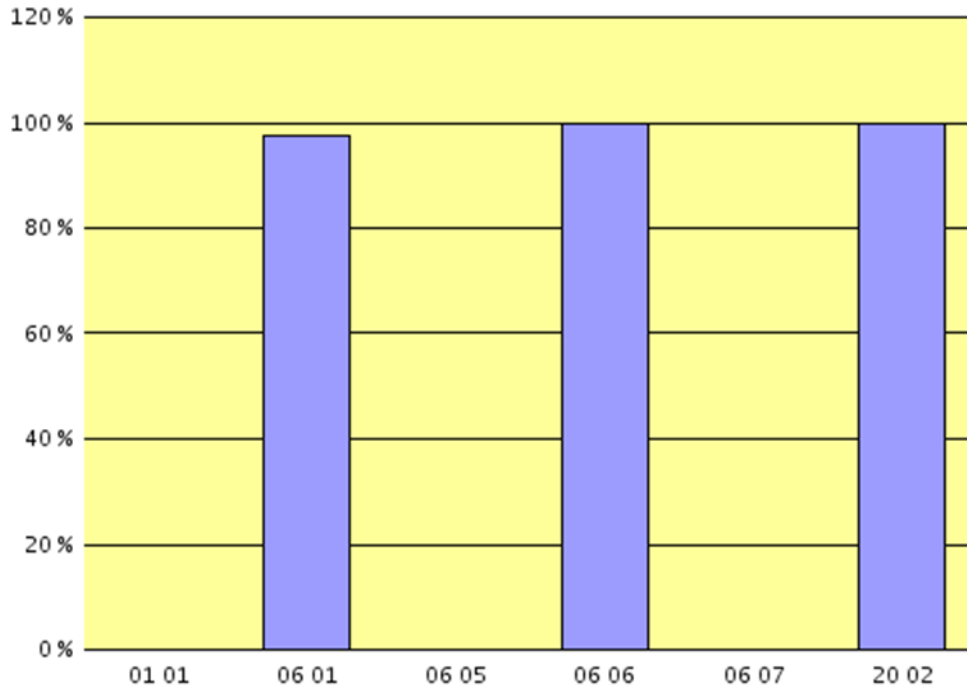


TABLE 2: OUTTURN ON PAYMENT APPROPRIATIONS in 2023 (in Mio €) for DG HERA					
			Payment appropriations authorised *	Payments made	%
			1	2	3=2/1
Title 01 Research and Innovation					
01	01 01	Support administrative expenditure of the "Research and Innovation" cluster	0.00	0.00	0.00 %
Total Title 01			0.00	0.00	0.00%
Title 06 Recovery and Resilience					
06	06 01	Support administrative expenditure of the Recovery and Resilience cluster	4.58	2.09	45.67 %
	06 05	Union Civil Protection Mechanism	0.00	0.00	0.00 %
	06 06	EU4Health Programme	6.71	6.71	100.00 %
	06 07	Emergency support within the Union	19.00	0.00	0.00 %
Total Title 06			30.29	8.80	29.05%
Title 20 Administrative expenditure of the European Commission					
20	20 02	Other staff and expenditure relating to persons	0.02	0.01	33.18 %
Total Title 20			0.02	0.01	33.18%
Total Excluding NGEU			30.31	8.80	29.05%
Title 06 Recovery and Resilience					
06	06 05	Union Civil Protection Mechanism	0.00	0.00	0.00 %
Total Title 06			0.00	0.00	0.00%
Total NGEU Only			0.00	0.00	0.00%
Total DG HERA			30.31	8.80	29.05 %

* Payment appropriations authorised include, in addition to the budget voted by the legislative authority, appropriations carried over from the previous exercise, budget amendments as well as miscellaneous payment appropriations for the period (e.g. internal and external assigned revenue).

*Title 06 Recovery and Resilience, budget line 06 07 Emergency Support within the Union, EUR 18.83 million of commitment appropriations were co-delegated to DG INTPA in 2023 but showing on DG HERA accounts due to specificity of the carry-over procedure.

% Outturn on Payment Appropriations in 2023 for DG HERA

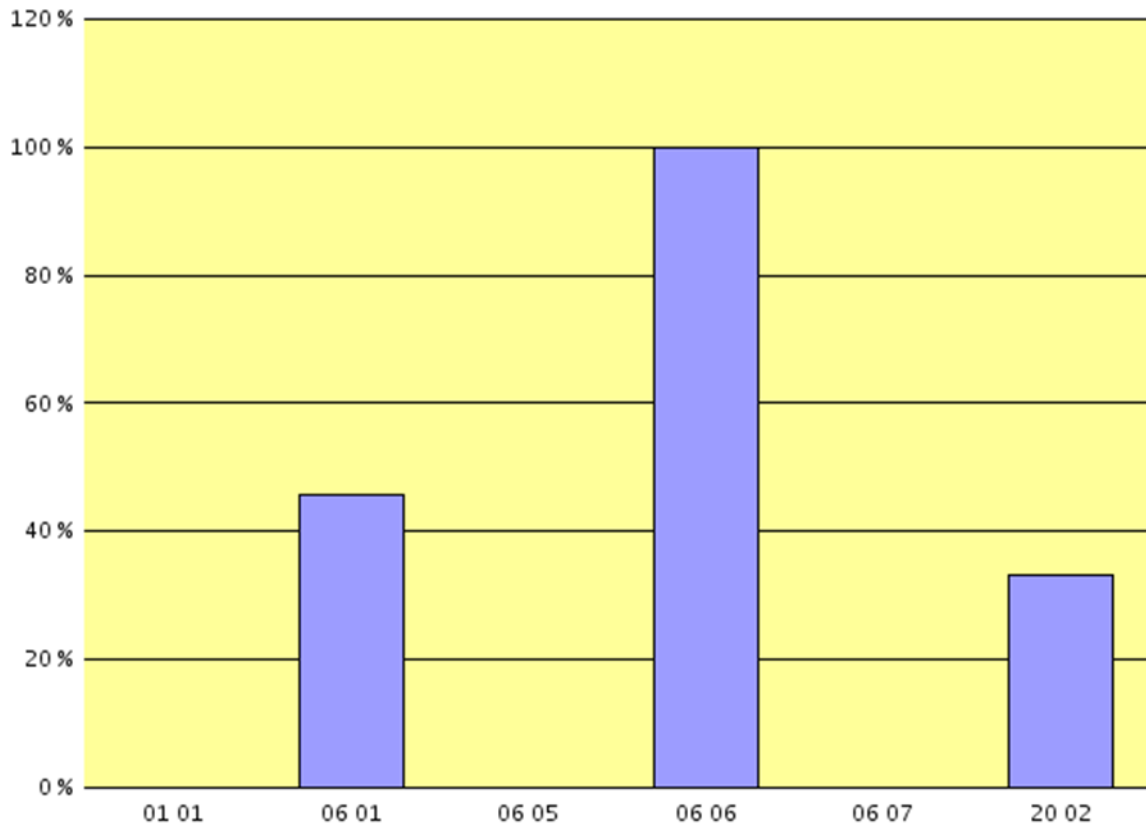


TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG HERA									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2022	Total of commitments to be settled at end of financial year 2023	Total of commitments to be settled at end of financial year 2022
			Commitments	Payments	RAL	%to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
01	01 01	Support administrative expenditure of the "Research and Innovation" cluster	0.00	0.00	0.00	0.00%	0.00	0.00	0.00
Total Title 01			0.00	0.00	0.00	0.00%	0.00	0.00	0.00

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG HERA									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2022	Total of commitments to be settled at end of financial year 2023	Total of commitments to be settled at end of financial year 2022
			Commitments	Payments	RAL	%to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
06	06 01	Support administrative expenditure of the Recovery and Resilience cluster	3.19	1.01	2.18	68.34%	0.00	2.18	1.31
	06 05	Union Civil Protection Mechanism	0.00	0.00	0.00	0.00%	0.00	0.00	0.00
	06 06	EU4Health Programme	10.74	6.71	4.03	37.54%	9.92	13.95	7.50
	06 07	Emergency support within the Union	0.00	0.00	0.00	0.00%	0.00	0.00	0.00
Total Title 06			13.92	7.71	6.21	44.59%	9.92	16.13	8.81

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG HERA									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2022	Total of commitments to be settled at end of financial year 2023	Total of commitments to be settled at end of financial year 2022
			Commitments	Payments	RAL	%to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
20	20 02	Other staff and expenditure relating to persons	0.01	0.00	0.01	66.37%	0.00	0.01	0.01
Total Title 20			0.01	0.00	0.01	66.37%	0.00	0.01	0.01
Total Excluding NGEU			13.93	7.72	6.22	44.61%	9.92	16.13	8.82

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG HERA									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2022	Total of commitments to be settled at end of financial year 2023	Total of commitments to be settled at end of financial year 2022
			Commitments	Payments	RAL	%to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
06	06 05	Union Civil Protection Mechanism	0.00	0.00	0.00	0.00%	0.00	0.00	0.00
Total Title 06			0.00	0.00	0.00	0.00%	0.00	0.00	0.00
Total NGEU Only			0.00	0.00	0.00	0.00%	0.00	0.00	0.00

Total for DG HERA			13.93	7.72	6.22	44.61 %	9.92	16.13	8.82
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Breakdown of Commitments Remaining to be Settled (in Mio EUR) in 2023 HERA

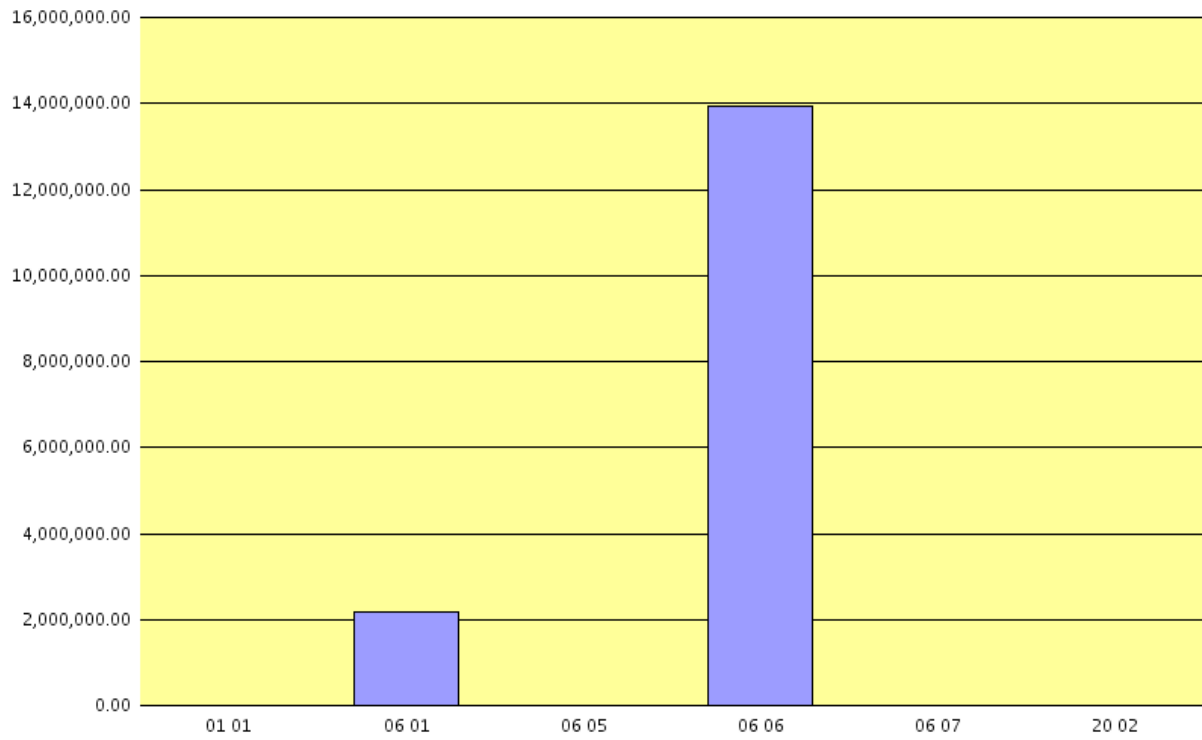


TABLE 4 : BALANCE SHEET for DG HERA

BALANCE SHEET	2023	2022
A.II. CURRENT ASSETS	12,209,000.00	7,500,000.00
A.II.2. Current Pre-Financing	12,209,000.00	7,500,000.00
ASSETS	12,209,000.00	7,500,000.00
P.II. CURRENT LIABILITIES	0.00	0.00
P.II.4. Current Payables	0.00	0.00
LIABILITIES	0.00	0.00
NET ASSETS (ASSETS less LIABILITIES)	12,209,000.00	7,500,000.00

Non-allocated central (surplus)/deficit*	-12,708,571.49	-7,500,000.00
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TOTAL DG HERA	0.00	0.00
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P.III.2. Accumulated Surplus/Deficit	499,571.49	
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It should be noted that the balance sheet and statement of financial performance presented in Annex 3 to this Annual Activity Report, represent only the assets, liabilities, expenses and revenues that are under the control of this Directorate General. Significant amounts such as own resource revenues and cash held in Commission bank accounts are not included in this Directorate General's accounts since they are managed centrally by DG Budget, on whose balance sheet and statement of financial performance they appear. Furthermore, since the accumulated result of the Commission is not split amongst the various Directorates General, it can be seen that the balance sheet presented here is not in equilibrium.

Additionally, the figures included in tables 4 and 5 are provisional since they are, at this date, still subject to audit by the Court of Auditors. It is thus possible that amounts included in these tables may have to be adjusted following this audit.

The accounting situation presented in the Balance Sheet does not include the accruals and deferrals calculated centrally by the services of the Accounting Officer.

TABLE 5 : STATEMENT OF FINANCIAL PERFORMANCE for DG HERA

STATEMENT OF FINANCIAL PERFORMANCE	2023	2022
II.1 REVENUES	1,767,344.16	
II.1.2. EXCHANGE REVENUES	1,767,344.16	
II.1.2.2. OTHER EXCHANGE REVENUE	1,767,344.16	
II.2. EXPENSES	1,428,544.59	499,571.49
II.2. EXPENSES	1,428,544.59	499,571.49
II.2.11. OTHER EXPENSES	1,108,562.98	775.00
II.2.2. EXP IMPLM BY COMMISS&EX.AGENC. (DM)	316,525.00	498,796.49
II.2.8. FINANCE COSTS	3,456.61	
STATEMENT OF FINANCIAL PERFORMANCE	3,195,888.75	499,571.49

The accounting situation presented in the Statement of Financial Performance does not include the accruals and deferrals calculated centrally by the services of the Accounting Officer.

TABLE 5bis : OFF BALANCE SHEET for DG HERA

	2023	2022

TABLE 6 PAYMENT TIMES

Legal Times									
Maximum Payment Time (Days)	Total Nbr of Payments	Nbr of Payments within Time Limit	Percentage	Average Payment Times (Days)	Nbr of Late Payments	Percentage	Average Payment Times (Days)	Late Payments Amount	Percentage
30	41	30	73.17 %	18.43	11	26.83 %	84.91	312,898.22	4. %
33	1	1	100.00 %	24.00				0.00	0. %
45	3	1	33.33 %	27.00	2	66.67 %	47.00	1,644,300.00	96. %

Total Number of Payments	45	32	71.11 %		13	28.89 %		1957198.22	22. %
Average Net Payment Time	36.26666667			18.88			79.08		
Average Gross Payment Time	37.22222222			19.40625			81.07692308		

Suspensions							
Average Report Approval Suspension	Average Payment Suspension Days	Number of Suspended Payments	% of Total Number	Total Number of Payments	Amount of Suspended Payments	% of Total Amount	Total Paid Amount
0	11	4	8.89 %	45	115,140.10	1.31 %	8,804,888.75

Late Interest paid in 2023			
DG	GL Account	Description	Amount (Eur)
HERA	65010100	Interest on late payment of charges New FR	3,456.61
			3,456.61

TABLE 7 : SITUATION ON REVENUE AND INCOME in for DG HERA							
Chapter	Revenue and income recognized			Revenue and income cashed from			Outstanding balance
	Current year RO	Carried over RO	Total	Current Year RO	Carried over RO	Total	
	1	2	3=1+2	4	5	6=4+5	
Total DG HERA							

TABLE 8 : FINANCIAL IMPACT OF EX-ANTE AND EX-POST CONTROLS in for DG HERA

EX-ANTE CONTROLS BY TRANSACTION	Irregularity	Total ex-ante amounts
NON ELIGIBLE IN COST CLAIMS		
CREDIT NOTES	11,933.33	11,933.33
RECOVERY ORDERS ON PRE-FINANCING		
Sub-Total	11,933.33	11,933.33

EX-POST CONTROLS BY TRANSACTION	Irregularity	Total ex-post amounts
RECOVERY ORDERS OTHER THAN ON PRE-FINANCING		
INCOME LINES IN INVOICES		
Sub-Total		
GRAND TOTAL (EX-ANTE + EX-POST)	11,933.33	11,933.33

TABLE 9: AGEING BALANCE OF RECOVERY ORDERS AT 12/31/2023 for DG HERA

	Number at 1/1/2023 1	Number at 12/31/2023	Evolution	Open Amount (Eur) at 1/1/2023 1	Open Amount (Eur) at 12/31/2023	Evolution

TABLE 10 :Recovery Order Waivers >= 60 000 € in 2023 for DG HERA

Waiver Central Key	Linked RO Central Key	RO Accepted Amount (Eur)	LE Account Group	Commission Decision	Comments

Total DG HERA	
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Number of RO waivers	
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There are no waivers below 60 000 €

TABLE 11 : Negotiated Procedures in 2023 for DG HERA**Internal Procedures > € 60,000**

Negotiated Procedure Legal base	Number of Procedur	Amount (€)
Annex 1 - 11.1 (c) - Extreme urgency caused by unforeseeable events not attributable to the contracting authority	1	250,000.00
Total	1	250,000.00

TABLE 12 : Summary of Procedures in 2023 for DG HERA**Internal Procedures > € 60,000**

Procedure Legal base	Number of Procedur	Amount (€)
Negotiated procedure without prior publication (Annex 1 - 11.1)	1	250,000.00
Open procedure (FR 164 (1)(a))	1	1,000,000.00
Total	2	1,250,000.00

Additional Comments:

TABLE 13 : BUILDING CONTRACTS in 2023 for DG HERA

Legal Base	Procedure subject	Contract Number	Contractor Name	Contract Subject	Contracted Amount (€)

TABLE 14 : CONTRACTS DECLARED SECRET in 2023 for DG HERA

Legal Base	LC Date	Contract Number	Contract Subject	Contracted Amount (€)

TABLE 15 : FPA duration exceeds 4 years - DG HERA

TABLE 16 : Commitments co-delegation type 3 in 2023 for DG HERA

ANNEX 4: Financial scorecard

The Annex 4 of each Commission service summarises the annual result of the standard financial indicators measurement. Annexed to the Annual Activity Report 2022, 10 standard financial indicators are presented below, each with its objective and result for the Commission service and for the EC as a whole (for benchmarking purposes)¹¹:

<ul style="list-style-type: none"> - Commitment Appropriations (CA) Implementation - CA Forecast Implementation - Payment Appropriations (PA) Implementation - PA Forecast Implementation - Global Commitment Absorption 	<ul style="list-style-type: none"> - Timely Payments - Timely Decommitments - Invoice Registration Time - Accounting Data Quality - Management Data Quality
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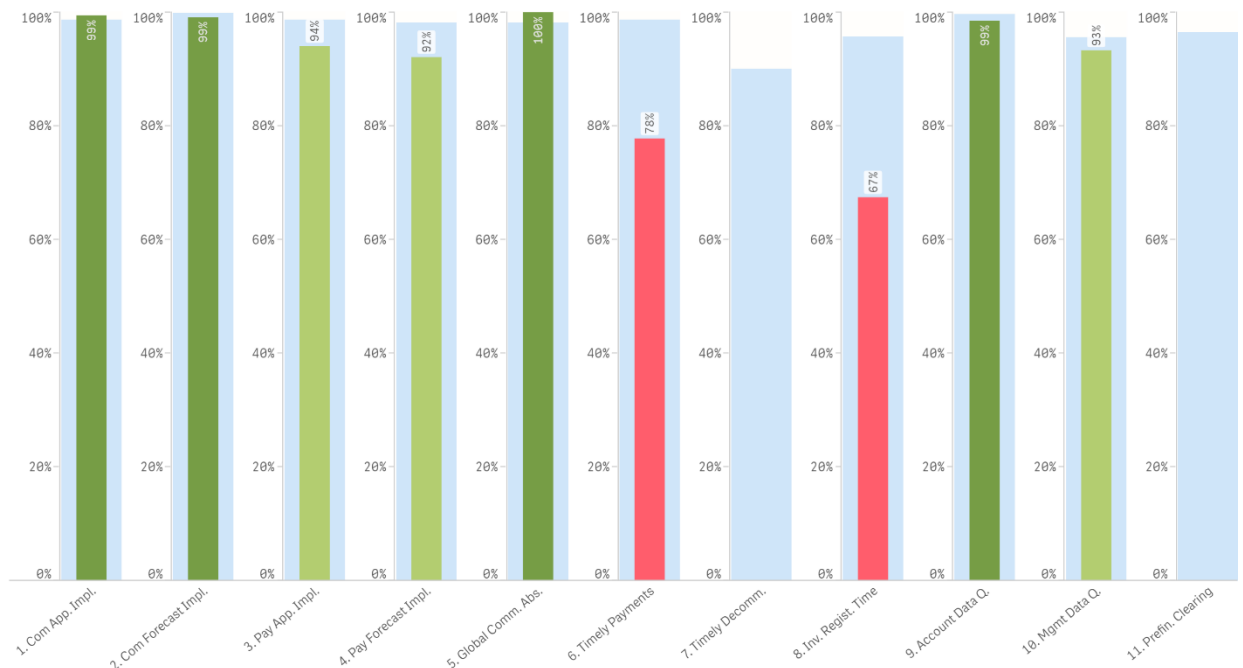
For each indicator, its value (in %) for the Commission service is compared to the common target (in %). The difference between the indicator's value and the target is colour coded as follows:

- 100 – >95% of the target: dark green
- 95 – >90% of the target: light green
- 90 – >85% of the target: yellow
- 85 – >80% of the target: light red
- 80 – 0% of the target: dark red

The Commission services are invited to provide commentary for each indicator's result in the dedicated comment section below the indicators scores as this can help the reader to understand the Commission's service context. In cases when the indicator's value achieves 80% or less of the target, the comment becomes mandatory.

The detailed definitions of the indicators are available on the internal DG BUDG site (BudgPedia) and managed by unit BUDG.C5 Financial Reporting.

HERA Indicator Scores for 2023 12



¹¹ For each indicator the light blue bar denotes the EC Score.

Indicator	Objective	Comment¹²	HERA Score	EC Score
1. Commitment Appropriations Implementation	Ensure efficient use of commitment appropriations expiring at the end of Financial Year		99%	99%
2. Commitment Forecast Implementation	Ensure the cumulative alignment of the commitment implementation with the commitment forecast in a financial year		99%	100%
3. Payment Appropriations Implementation	Ensure efficient use of payment appropriations expiring at the end of Financial Year		94%	99%
4. Payment Forecast Implementation	Ensure the cumulative alignment of the payment implementation with the payment forecast in a financial year		92%	98%
5. Global Commitment Absorption ¹³	Ensure efficient use of already earmarked commitment appropriations (at L1 level)		100%	98%
6. Timely Payments	Ensure efficient processing of	In 2023, HERA had a relatively limited number of payments,	78%	99%

¹² An explanation behind the indicator result can be provided, e.g. the comment about the achievement itself, reference to the whole Commission performance (better or worse), reasons behind this achievement. The comment is mandatory for the 'Timely payments' indicator. For the rest of indicators the comment is mandatory only if the score is equal or below the target of 80%.

¹³ Due to technical limitation: 1. the indicator does not take into account the Com L1 Consumption between the FDC ILC date and the FA FDI allowed as an exception in the external actions for Com L1 of type GF, i.e. with Financing Agreement, under the FR2018 Article 114.2. 2. it is technically not possible to exclude the decommitment of RAL (C8) which is subsequently re-committed for a new purpose. As a result, the actual Indicator score may be slightly higher than the one reported for DGs using the GF commitments.

	payments within the legal deadlines	few were late but of relatively big amounts (2 late payments to JRC out of 45 total payments for HERA in 2023 were of EUR 1.6 million). Most of the late payments came also as a result of late registration of the underlying invoices.		
7. Timely Decommitments	Ensure efficient decommitment of outstanding RAL at the end of commitment life cycle	The indicator is not applicable for HERA in 2023 due to the lack of underlying transactions recorded by HERA in 2023.	-	90%
8. Invoice Registration Time	Monitor the accounting risk stemming from late registration of invoices in the central accounting system ABAC	In 2023, HERA received a relatively limited number of invoices, few were registered late as due to the specific arrangement where DG SANTE registered the invoices for HERA, there were instances where registration took longer to coordinate.	67%	96%
9. Accounting Data Quality	Ensure the good data quality of ABAC transactions with the focus on fields having a primary impact on the accounts		99%	100%
10. Management Data Quality	Ensure the good data quality of ABAC transactions with the focus on fields having a primary impact on the management decisions		93%	96%
11. Timely Invoice PF clearing		The indicator is not applicable for DG HERA in 2023 due to the lack of underlying transactions recorded by DG HERA in 2023.		100%

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, HERA assesses both qualitative and quantitative aspects:

Qualitative assessment

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 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, HERA takes into account the possible reputational impact they may entail to the image of 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 HERA implements directly (and not through partner DGs/ HaDEA), per respective programme (EU4Health, UCPM) is applied. HERA considers it an appropriate threshold above which weaknesses detected should be considered "material".

De minimis' threshold for financial reservations

Since 2019 ⁽¹⁴⁾, 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 DG's total payments and with a financial impact below EUR 5 million. In such cases, quantified reservations are no longer needed.

The implementation of this 'de minimis' threshold applies at the level of the annual activity report reservations, i.e. not at all affecting the detailed reservations at the level of the Payment Agency(s)/Operational Programme(s).

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

⁽¹⁴⁾ Agreement of the Corporate Management Board of 30/4/2019.

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

In 2023, almost the entire HERA budget was delegated. HERA 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 2023, the financial initiation and verification of all 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"

Table Y - Overview of DG's/EA's estimated cost of controls at Commission (EC) level:

Not applicable

ANNEX 8: Specific annexes related to "assessment of the effectiveness of the internal control systems"

In line with the requirements set by HERA Internal Control Framework (ICF), HERA has carried out an annual assessment of the implementation of the Commission's Internal Control Principles (the assessment) for 2023.

The assessment has followed the methodology established in the 'Implementation Guide of the Internal Control Framework of the Commission'. It has been based on the following elements:

- Review of HERA Internal Control Monitoring Criteria;
- Exceptions to rules and procedures, including non-compliance events or cases of "confirmation of instructions";
- Issues raised by the Authorising Officers by delegation;
- HERA risk register;
- Audit observations of the IAS and the Court of Auditors.

Review of HERA Internal Control Monitoring Criteria

The assessment has checked compliance with each Principle by focusing on the review of each monitoring criterion individually.

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

Exceptions to rules and procedures, including non-compliance events or cases of "confirmation of instructions"

The assessment took into consideration that there were 5 exceptions to the rules and procedures registered in 2023. However, in 2023, HERA was still a relatively new organization, still establishing institutionally, with many processes and procedures being introduced for the first time.

Issues raised by the Authorising Officers by delegation

The assessment took into consideration that the authorising officers by delegation did not communicate any events, control results or issues which could point to control deficiencies and have a material impact on assurance.

HERA risk register

The assessment took into consideration that the risk assessment exercise carried out in 2023 identified no critical risks for HERA.

However, the risk assessment exercise has identified the complex funding structure of HERA as a risk with high potential impact on the achievement of HERA's objectives. In 2023, HERA drew funding from different programmes (EU4Health, Horizon Europe, Union Civil Protection Mechanism), and each of the programmes was governed by an individual legal base, objectives, implementing rules and procedures. Moreover, the programmes fell under the responsibility of partner lead parent DGs. It is DG SANTE for EU4Health, DG RTD for Horizon Europe, and DG ECHO for the Union Civil Protection Mechanism.

HERA is in a position where counting on its quite limited resources, it needs to seek constantly enhanced coordination with its partner DGs to ensure that its objectives are met through effective implementation of the corresponding programmes. Further, as HERA needs to co-delegate almost its entire budget to its partner DGs/ HaDEA, the budget is implemented at different management centres under the responsibility of other AOSD; The current set up requires that HERA monitors the effective programming and implementation of its budget closely to ensure its objectives are met despite the potential existence of conflicting priorities with its partners.

For each of the risks identified within HERA risk register, HERA has already set mitigating actions to be monitored on a regular basis.

Audit observations of the IAS and the Court of Auditors

HERA Internal Control Framework (ICF) and Internal Control Monitoring Criteria (ICMC) were revised in 2023 to address the Internal Audit Service's recommendations following a limited review on HERA's assessment of its Internal Control Framework for the 2022 AAR.

The assessment took into consideration that there were no other observations or recommendations reported by the Internal Audit Service in 2023, and there were no European Court of Auditors' audits in 2023 that resulted in financial management and internal control related recommendations for HERA.

HERA managed to develop well-functioning controls and to demonstrate that in 2023, it showed commitment to integrity, ethical values, and competence; exercised oversight responsibility; ; identified and analysed risks and significant changes; selected and developed control activities and general control over technology; deployed through policies and procedures; communicated internally and externally; assessed and communicated deficiencies.

HERA concluded that in 2023, 12 internal control principles were present and functioning effectively. Principles 3, 5, 8 and 13 needed minor improvements, mostly in terms of payment times and the average time to reply to requests to access to documents. Only one principle - Principle 6 - needed major improvements as in 2023, HERA recorded 3 exception reports and 2 non-compliance events (well above the target of 0); however, in 2023, HERA was still

building its teams and establishing institutionally with many processes and procedures being introduced for the first time; the procedure for recording exceptions and non-compliance events was also adopted in 2023.

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

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

Table X : Estimated risk at payment and at closure

HERA	"payments made" (FY; EUR)	minus new prefinancing [plus retentions made] (FY; EUR)	plus cleared prefinancing [minus retentions released and deductions of expenditure made by MS] (FY; EUR)	= "relevant expenditure" (FY; EUR)	Detected error rate or equivalent estimates	estimated risk at payment (FY; EUR)	Adjusted Average Recoveries and Corrections (adjusted ARC; %)	estimated future corrections (FY; EUR)	estimated risk at closure	
									(FY; EUR)	(FY; %)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
EU4Health programme contribution agreements	4.71	4.71	0.00	0.00	0.00%	0.00	0.00%	0.00	0.00	0.00%
EU4Health programme procurement	2.45	0.00	0.00	2.45	0.50%	0.01	0.00%	0.00	0.01	0.50%
EU4Health programme administrative agreements	1.64	0.00	0.00	1.64	0.50%	0.01	0.00%	0.00	0.01	0.50%
Administrative expenditure	0.01	0.00	0.00	0.01	0.00%	0.00	0.00%	0.00	0.00	0.00%
HERA total	8.80 EUR	-4.71 EUR	0 EUR	4.10 EUR	%	0.02 EUR	%	0.00 EUR	0.02 EUR	z%
Overall risk at payment in %						0.50%	Overall risk at closure in %		0.50%	%

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 or equivalent, e.g. expenditure registered in the Commission's accounting system, accepted expenditure or cleared pre-financing. In any case, this means after the preventive (ex-ante) control measures have already been implemented earlier in the cycle.

(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-SubDelegations.

(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').

(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, and adds the pre-financing actually cleared 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. HERA has low-risk types of expenditure where there are indications that the equivalent error rate might be close to 'zero', thus, the rate which should be used is 0.5% as a conservative estimate.

8) In 2023, all HERA payments were initiated and verified by DG SANTE on the basis of a Memorandum of understanding, and carried out in compliance with DG SANTE control strategy. The adjusted average recovery and corrections percentage is based on the 7-year historic Average of Recoveries and financial Corrections (ARC), which is the best available indication of the corrective measures applied over the past years as a result of ex-post controls. In accordance with the control strategy, no ex-post audits took place on procurement contracts. Thus, the future corrections are prudently estimated at 0%. This corresponds to the average amount of the implemented corrections over the past 3 years.

2. Reservations

Not applicable.

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

Main outputs in 2023:			
Description	Indicator	Target	Latest known results (31/12/2023)
HERA employs a competent and engaged workforce and contributes to gender equality at all levels of management to effectively deliver on the Commission's priorities and core business			
Recruitment of one middle manager and one senior manager	50% of female manager	At equal competence these management posts should be preferably for a female manager in view of the gender balance	One single first appointment to middle management in 2023 which was a female first appointment (100%) Female representation of 67% end of 2023
HERA is using innovative, trusted digital solutions for better policy-shaping, information management and administrative processes to forge a truly digitally transformed, user-focused and data-driven Commission			
Implementation of the corporate principles for data governance for HERA key data assets	Percentage of implementation of the corporate principles for data governance for HERA key data assets	Interim milestone by 2023: 50%	HERA has yet to identify corporate reference data assets. This activity will be completed throughout the year 2024. HERA will appoint a Local Data Correspondent (LDC) in the course of 2024.
Increase in awareness of staff on cybersecurity	Number of awareness raising activities	2 awareness raising activities (e.g. training, targeted communication, information session)	Continuous promotion to the staff of the central actions to raise awareness on cybersecurity. There are also links to the EC Cybersecurity courses on the HERA internet for the newcomers.

Description	Indicator	Target	Latest known results (31/12/2023)
Increase in awareness of staff on data protection compliance	Number of awareness raising activities	2 awareness raising activities (e.g. training, targeted communication, information session) 50% of staff should have received the awareness raising training on data protection by the end of 2023	HERA staff participated in trainings provided by SANTE DPC. There is information and links to the EC Data Protection site on the HERA intranet. Continuous targeted information in the context of concrete projects like the IT platform.
HERA takes account of its environmental impact in their actions and actively promotes measures to reduce the related day-to-day impact of the administration and its work, with the support their respective EMAS Correspondents/EMAS Site Coordinators.			
More efficient use of resources (energy, water, paper):			
Final building location of HERA	Full staff transfer to new building	Q4 2023	OIB informed HERA that the planned move to the new building has been postponed to end 2025
HERA integration into EMAS	Nomination of EMAS correspond/site coordinator	Q3 2022	HERA appointed an EMAS coordinator in 2023, who raised awareness of staff on sustainability aspects with suggestion on how to be greener on a personal level and by giving tips for greener events
Preparation of the roadmap for environmental management of HERA building	Launch	Q4 2023	HERA is not yet in its final building but in a temporary location.
Participation in the end of the year energy saving action, by closing down DG's buildings during the Christmas and New Year's holiday period.	1 building participating	% of DG buildings participating	HERA accepted to participate to the action but the building (shared with DG NEAR) remained opened at the request of DG NEAR
Reducing CO2, equivalent CO2 and other atmospheric emissions			

Description	Indicator	Target	Latest known results (31/12/2023)
Preparation of roadmap for sustainable commuting for HERA staff	Launch	Q4 2023	With the new reservation system, parking is regularly full on Tuesdays and Thursdays which oblige part of the staff to commute differently (bike, public transport, walk) to the office
Maintained use of VC meeting rooms for meetings with stakeholders (avoiding business trips) in the DG, in collaboration with DG SCIC, OIB and OIL.	Percentage of VC meeting conducted with stakeholders	> 75% of all stakeholder meetings	HERA signed the pledge for greening of mission and meetings and a majority of its meetings are held on line
Analysis of DG's missions trends /patterns (based on corporate EC-staff's professional missions,	Launch	Q3 2023	The first missions of HERA staff started in Q3 2022. HERA as a new organisation is not yet at cruise speed. The growth in staffing between beginning 2022 and end 2023 was of 300% and HERA should continue growing in 2024. Therefore, the analysis of mission trends and patterns is premature as there is not stabilised starting point for the comparison.

ANNEX 11: Implementation through national or international public-sector bodies and bodies governed by private law with a public sector mission (if applicable)

Not applicable

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

Not applicable

ANNEX 13: Decentralised agencies and/or EU Trust Funds (if applicable)

Not applicable

