



# Annual activity report 2022

## annexes

Health Emergency Preparedness and  
Response Authority (HERA)

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

***“I declare that in accordance with the Commission’s communication on the internal control framework <sup>(1)</sup>, 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.”***

***Brussels, 04.04.2023***

***(signed)***

***Laurent Muschel***

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<sup>(1)</sup> C(2017)2373 of 19.04.2017

## ANNEX 2: Performance tables

<b>Main outputs in 2022:</b>			
<b>New policy initiatives</b>			
<b>Output</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results (situation on 31/12/2022)</b>
Proposal for a Council Regulation “on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level”	Adoption	Q3 2022	Adopted on 24 October 2022  Council Regulation (EU) 2022/2372 OJ L 314, 6.12.2022, p. 64–78
Implementing Decisions and Delegated Acts necessary for the operationalisation of the Council Regulation on measures in case of a public health emergency at Union level.	At least 1 Implementing Decision or Delegated Act adopted	Q4 2022	Delayed
<b>Other important outputs</b>			
<b>Output</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results (situation on 31/12/2022)</b>
<b>Specific objective 1: Responding to crisis in case of health emergencies</b>			
Implementation of existing COVID-19 vaccine contracts and conclusion of new vaccines contracts	Completion of deliveries for all contracts running in 2022	Throughout the year	Amendments to existing BioNTech-Pfizer, Moderna and Valneva vaccine contracts. Negotiations on adaption of schedule with Sanofi and Novavax. HIPRA FWC contract signed on 1/08/2022 under Joint Procurement Agreement.

Output	Indicator	Target	Latest known results (situation on 31/12/2022)
Enhanced and/or improved national public health capacity for Whole Genome Sequencing and/or Reverse Transcription Polymerase Chain Reaction capacity, including international collaboration e.g. with African CDC	Direct grants to MS launched	Q2 2022	Implementation ongoing
Strengthened wastewater surveillance	Mapping of needs at EU level complementing activities under the HERA incubator, including ad-hoc support linked to Ukraine crisis	Throughout the year	Ongoing
Knowledge generation on need for new or adapted COVID-19 vaccines for variants: meetings of expert group on SARS CoV-2 variants	Organised (according to epidemiological events and adapted vaccine development milestones)	Throughout the year	Regular exchanges with the expert group on SARS CoV-2 variants on new variants and workshop on vaccines 2.0 organised in December 2022.
Preparation for support for characterisation of the SARS-CoV-2 variants and publication of the call: European laboratories	Launched	Q2 2022	Followed up by the publication of the call for proposals for the establishment of a laboratory network
Implementation of joint procurement contracts for COVID-19 therapeutics	Completion of deliveries scheduled for 2022 under all contracts	Throughout the year	Regular follow-up with the contractor and countries
Increased access to additional COVID-19 therapeutics: new joint procurement contracts	Launched	Throughout the year	Pfizer Paxlovid FWC signed in November 2022 Gilead Remdesivir FWC signed in July 2022 Dynamic Purchasing System pilot project for personal protective equipment launched in June 2022
<b>Specific objective 2: Preparing for health emergencies</b>			
<b>Threat assessments and intelligence gathering</b>			

Output	Indicator	Target	Latest known results (situation on 31/12/2022)
Call for a feasibility study, design and prototype development for a mapping platform on COVID-19 therapeutics in the EU	Ongoing	Throughout the year	Expected to be completed in January 2024
Preparation of IT platform for intelligence gathering (production and availability of medical countermeasures, threat assessment and mapping medical countermeasures, stockpiling management system) and publication of the call	Launched	Q4 2022	A first analysis is expected to be completed by April 2023
Strengthened Member States' IT systems ensuring interoperability with HERA's IT platform for intelligence gathering through direct grants	Launched	Q2 2022	Kick off expected in February 2023
Call for enhanced preparedness and management of High Impact Low-Probability or unexpected events	Ongoing	Throughout the year	Outcomes of the evaluations awaited
Call for improved quality assurance / quality control of data used in decision-making related to risk management of natural hazards, accidents and Chemical, Biological, Radiological and Nuclear events	Ongoing	Throughout the year	Outcomes of the evaluations awaited
Call for improved international cooperation addressing first responder capability gaps	Ongoing	Throughout the year	Outcomes of the evaluations awaited
Call for advanced materials modelling and characterisation	Ongoing	Throughout the year	Projects awarded

Output	Indicator	Target	Latest known results (situation on 31/12/2022)
Threat prioritisation and critical medical countermeasures list	Publication	Q3 2022	Press release on threat prioritisation published in July 2022 Q1 2023 the target for the first critical medical countermeasures list. Other lists throughout 2023
First edition of an annual State of Preparedness report	Publication	Q4 2022	Adopted on 30 November 2022
Study on market research and mapping of innovative diagnostic testing solutions	Signature	Q2 2022	Launched in December 2022
<b>Promoting advanced R&amp;D of medical countermeasures and related technologies</b>			
Calls (14) for research projects to improve pandemic preparedness and response	Ongoing	Throughout the year	Projects awarded
Partnership on pandemic preparedness to develop a common strategic EU research and innovation agenda for pandemic preparedness	Launched	Q3 2022	Preparatory work ongoing through the Coordination and Support Action "BE READY"
Call for long term and large scale EU platform for clinical trials and data platforms	Ongoing	Throughout the year	Ongoing
Preparation for a call for phase 3 clinical trials for certain vaccines/therapeutics	Launched	Throughout the year	Ongoing
Call for a study on options to bring more AMR medical countermeasures on the market	Study completed	December 2022	Publication of reports planned Q1 2023
Workshop on next generation vaccines under the Vaccines 2.0 Strategy	Organised	Q4 2022	9 December 2022
HERA INVEST	Preparatory actions for the establishment	Q3 and Q4 2022	ongoing



Output	Indicator	Target	Latest known results (situation on 31/12/2022)
<b>Addressing market challenges and boosting the Union's strategic autonomy</b>			
Ongoing study on options for implementing a flexible (multi-technology) EU manufacturing and innovation capacity for vaccines and therapeutics	Ongoing	Throughout the year	Contract extended to March 2023 Draft final report received in December 2022.
Preparation on rapid reconfigurable production process chains and publication of the call	Launched	Throughout the year	Projects awarded
Preparation for structured partnerships with companies and trade associations	Ongoing	Throughout the year	Joint Industrial Cooperation Forum (JICF) established in Spring 2022. Two meetings of the forum in July and November 2022.
Meeting for identification of bottlenecks and solutions: Industry (Joint Industrial Cooperation Forum) and HERA	Organised	Q4 2022	Meetings of the JICF in July and November 2022.
HERA Industry Day (Matchmaking events at EU level for critical medical countermeasures)	Organised	Q4 2022	One year of HERA Conference on 8 December 2022
HERA website (Creation of section on HERA website for industry: 'Doing Business with HERA')	Publication	Q1 2022	Delayed New target Q2 2023
Preparation for the establishment of EU FAB and publication of the call	Launched	Q2 2022	Call launched Q2 2022, Evaluation ongoing
Synergies between HERA and Important Projects of Common Interest (IPCEI) Health	Ongoing	Throughout the year	Pre-notification received by Commission in November 2022. HERA is closely following.
<b>Provision of medical countermeasures</b>			

Output	Indicator	Target	Latest known results (situation on 31/12/2022)
procurement of vaccines against infectious disease threats and publication of the call	Launched	Q3 2022	HERA purchased 334,540 doses of Mpxv vaccines between June and September 2022.
Preparation for medical and Chemical Biological Radiological Nuclear (CBRN) rescEU stockpiling and publication of the calls	Launched	Q3 2022	The calls were published in March 2022. All the proposals were evaluated and four grants have been signed in January 2023.
Call for public procurement of innovative solutions for resilience of health systems	Ongoing	Throughout the year	No project awarded
Call for pre-commercial research and innovation procurement for resilience of healthcare systems	Ongoing	Throughout the year	Project awarded
Call for a feasibility study on stockpiling of medical countermeasures in the area of AMR	Publication	21/12/2022	Study completed and report published <sup>2</sup>
<b>Strengthened knowledge and skills</b>			
Training schedule and targets based on identification of knowledge gaps	Publication	Q3 2022	Delayed to the Q1 2023

<sup>(2)</sup> Report 1 : <https://op.europa.eu/en/publication-detail/-/publication/712bbfff-801e-11ed-9887-01aa75ed71a1/language-en/format-PDF/source-278668958>

Report 2: <https://op.europa.eu/en/publication-detail/-/publication/c68221dd-80e0-11ed-9887-01aa75ed71a1/language-en/format-PDF/source-278668958>

Output	Indicator	Target	Latest known results (situation on 31/12/2022)
National/regional assessment process of public procurements in health sector	Organized	Q3 2022	Call for proposals to support structured dialogue at national or regional level on public procurement in the health sector launched on 15.09.2022 with a deadline to submit proposals by 21.02.2023
<b>Governance and coordination</b>			
Memorandum of Understanding with DG SANTE	set up	Q2 2022	Finalised
Memorandum of Understanding with DG ECHO	set up	Q3 2022	Delayed to Q1 2023
Memorandum of Understanding with DG GROW	set up	Q3 2022	Participation of HERA to the GROW Task Force for Industrial Scale-up of COVID-19 vaccines (TFIS) meetings instead, very good collaboration which does not warrant a formal MoU.
Memorandum of Understanding with DG RTD	set up	Q3 2022	Not planned
Memorandum of Understanding with HaDEA	set up	Q3 2022	Finalised
Interservice Group for partner DGs (RTD, GROW, ECHO, SANTE, INTPA, NEAR, SG, SJ, EEAS)	Creation	Q2 2022	Finalised
Memorandum of Understanding with ECDC	set up	Q2 2022	Expected to be signed Q1 in 2023
Memorandum of Understanding with EMA	set up	Q2 2022	Delayed
Creation of HERA Advisory Forum and meeting of the Forum	Organised	Q2 2022	Finalised Meetings took place on 20/04, 09/08, 09/09, 05/12 and 09/12

Output	Indicator	Target	Latest known results (situation on 31/12/2022)
Creation of Joint Industrial Cooperation Forum and meeting of the Forum	Creation	Q2 2022	Finalised Meetings took place on 13/07, 14/11, 05/12 and 09/12
Creation of Civil Society Forum and meeting of the Forum	Creation	Q2 2022	Finalised Meetings took place on 28/06, 28/11, 05/12 and 09/12
Creation of the network of national or regional HERA-like agencies/entities and meeting of the network	Creation	Q2 2022	Delayed
<b>Specific objective 3: International resilience and appropriate response readiness for health emergencies</b>			
Continue to work with COVAX in pursuit of global vaccination targets (strengthen the multilateral approach in pursuit of global vaccination)	101 m COVID-19 vaccine doses shared with COVAX, out of a total of 132 m donated doses in 2022	Throughout the year	Continuing activity
Structured administrative arrangements with international stakeholders (e.g.; U.S. Department of Health & Human services Korean Ministry of Health and Welfare; WHO Hub for Pandemic and Epidemic Intelligence	Publication	Throughout the year	Administrative Arrangement with the WHO Hub <sup>3</sup> signed on 30 November 2022
Contribution agreement to support WHO initiatives strengthening preparedness and response to cross-border health threats at global level	Signature of agreement	Q3/Q4 2022	Signed in December 2022, current follow up on the implementation

(<sup>3</sup>) [https://health.ec.europa.eu/system/files/2022-12/hera\\_adm-arrangement\\_who-hub\\_en.pdf](https://health.ec.europa.eu/system/files/2022-12/hera_adm-arrangement_who-hub_en.pdf)

## **ANNEX 3: Draft annual accounts and financial reports**

### **Annex 3 Financial Reports - DG HERA - Financial Year 2022**

**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**

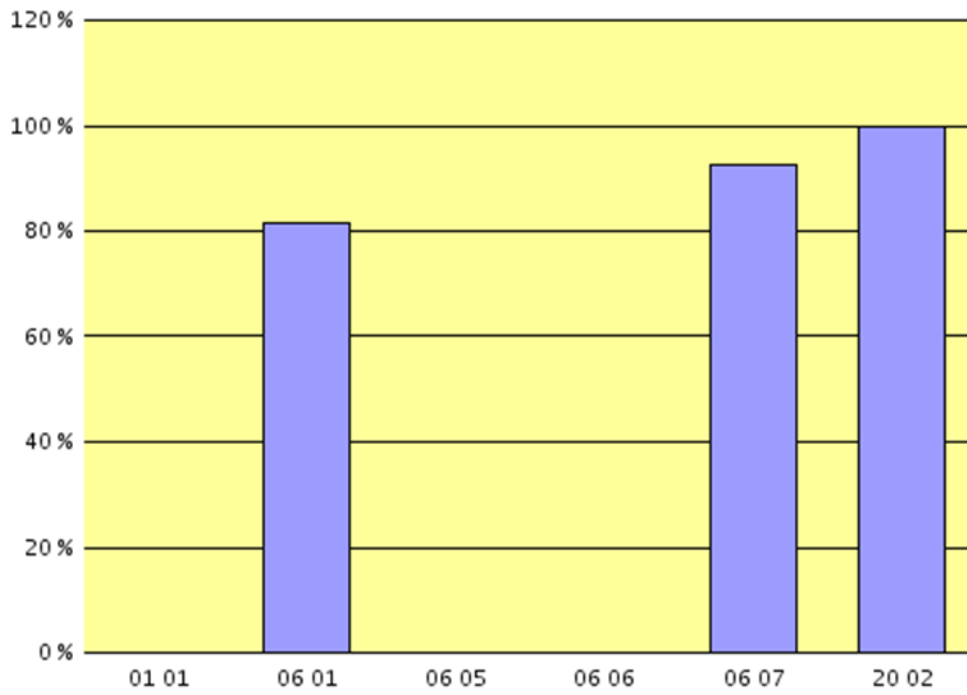
**Table 16 : Commitments co-delegation type 3 in 2022**

**Additional comments**

<b>TABLE 1: OUTTURN ON COMMITMENT APPROPRIATIONS IN 2022 (in Mio €) for DG HERA</b>					
			<b>Commitment appropriations authorised*</b>	<b>Commitments made</b>	<b>%</b>
			<b>1</b>	<b>2</b>	<b>3=2/1</b>
<b>Title 01 Research and Innovation</b>					
01	01 01	Support administrative expenditure of the "Research and Innovation" cluster	0,00	0,00	0,00 %
<b>Total Title 01</b>			<b>0,00</b>	<b>0,00</b>	<b>0,00 %</b>
<b>Title 06 Recovery and Resilience</b>					
06	06 01	Support administrative expenditure of the 'Recovery and Resilience' cluster	1,61	1,31	81,46 %
	06 06	EU4Health Programme	0,00	0,00	0,00 %
	06 07	Emergency support within the Union	369,80	342,74	92,68 %
<b>Total Title 06</b>			<b>371,41</b>	<b>344,05</b>	<b>92,63 %</b>
<b>Title 20 Administrative expenditure of the European Commission</b>					
20	20 02	Other staff and expenditure relating to persons	0,01	0,01	100,00 %
<b>Total Title 20</b>			<b>0,01</b>	<b>0,01</b>	<b>100,00 %</b>
<b>Total Excluding NGEU</b>			<b>371,42</b>	<b>344,06</b>	<b>92,63 %</b>
<b>Title 06 Recovery and Resilience</b>					
06	06 05	Union Civil Protection Mechanism (rescEU)	685,50	0,00	0,00 %
<b>Total Title 06</b>			<b>685,50</b>	<b>0,00</b>	<b>0,00 %</b>
<b>Total NGEU Only</b>			<b>685,50</b>	<b>0,00</b>	<b>0,00 %</b>
<b>Total DG HERA</b>			<b>1.056,92</b>	<b>344,06</b>	<b>32,55 %</b>

\* 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).

**% Outturn on Commitment Appropriations in 2022 for DG HERA**





<b>TABLE 2: OUTTURN ON PAYMENT APPROPRIATIONS in 2022 (in Mio €) for DG HERA</b>					
			Payment appropriations authorised *	Payments made	%
			1	2	3=2/1
<b>Title 01 Research and Innovation</b>					
01	01 01	Support administrative expenditure of the "Research and Innovation" cluster	0,00	0,00	0,00 %
<b>Total Title 01</b>			<b>0,00</b>	<b>0,00</b>	<b>0,00%</b>
<b>Title 06 Recovery and Resilience</b>					
06	06 01	Support administrative expenditure of the 'Recovery and Resilience' cluster	1,61	0,00	0,00 %
	06 06	EU4Health Programme	7,50	7,50	100,00 %
	06 07	Emergency support within the Union	476,56	430,50	90,33 %
<b>Total Title 06</b>			<b>485,68</b>	<b>438,00</b>	<b>90,18%</b>
<b>Title 20 Administrative expenditure of the European Commission</b>					
20	20 02	Other staff and expenditure relating to persons	0,01	0,00	7,75 %
<b>Total Title 20</b>			<b>0,01</b>	<b>0,00</b>	<b>7,75%</b>
<b>Total Excluding NGEU</b>			<b>485,69</b>	<b>438,00</b>	<b>90,18%</b>
<b>Title 06 Recovery and Resilience</b>					
06	06 05	Union Civil Protection Mechanism (rescEU)	0,00	0,00	0,00 %
<b>Total Title 06</b>			<b>0,00</b>	<b>0,00</b>	<b>0,00%</b>
<b>Total NGEU Only</b>			<b>0,00</b>	<b>0,00</b>	<b>0,00%</b>
<b>Total DG HERA</b>			<b>485,69</b>	<b>438,00</b>	<b>90,18 %</b>

\* 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).

**% Outturn on Payment Appropriations in 2022 for DG HERA**

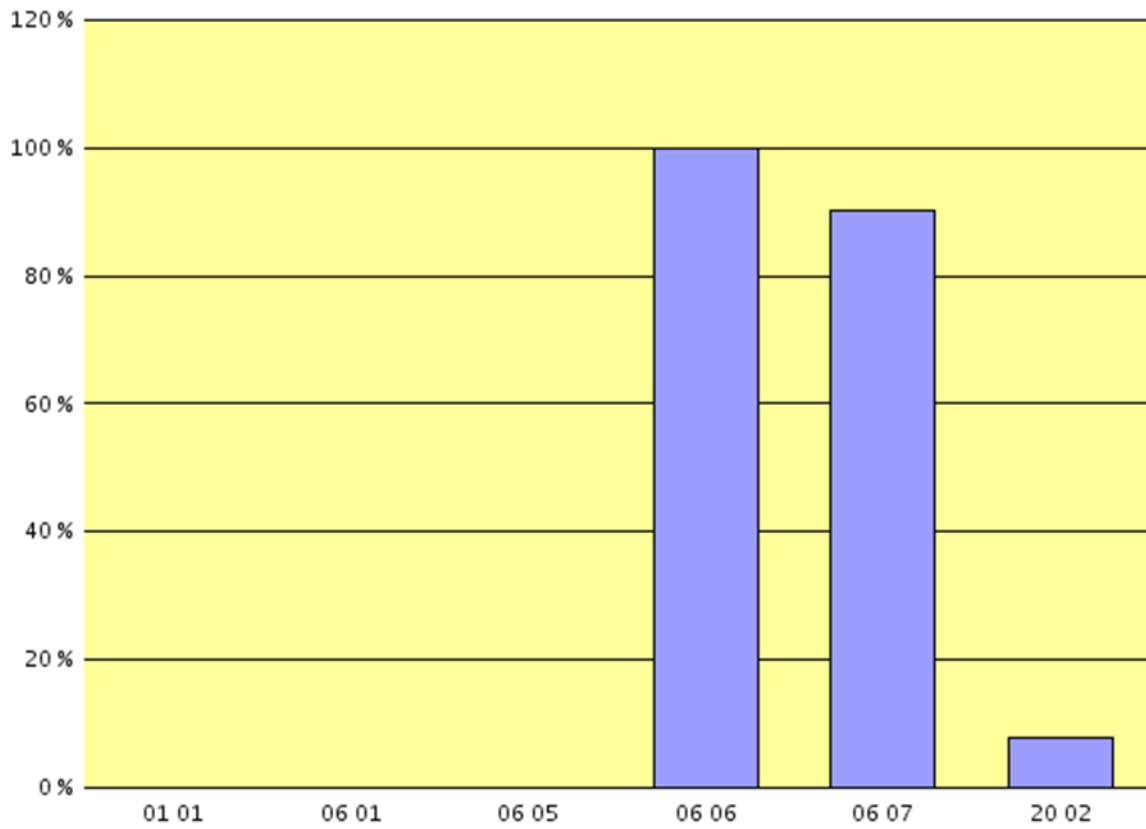
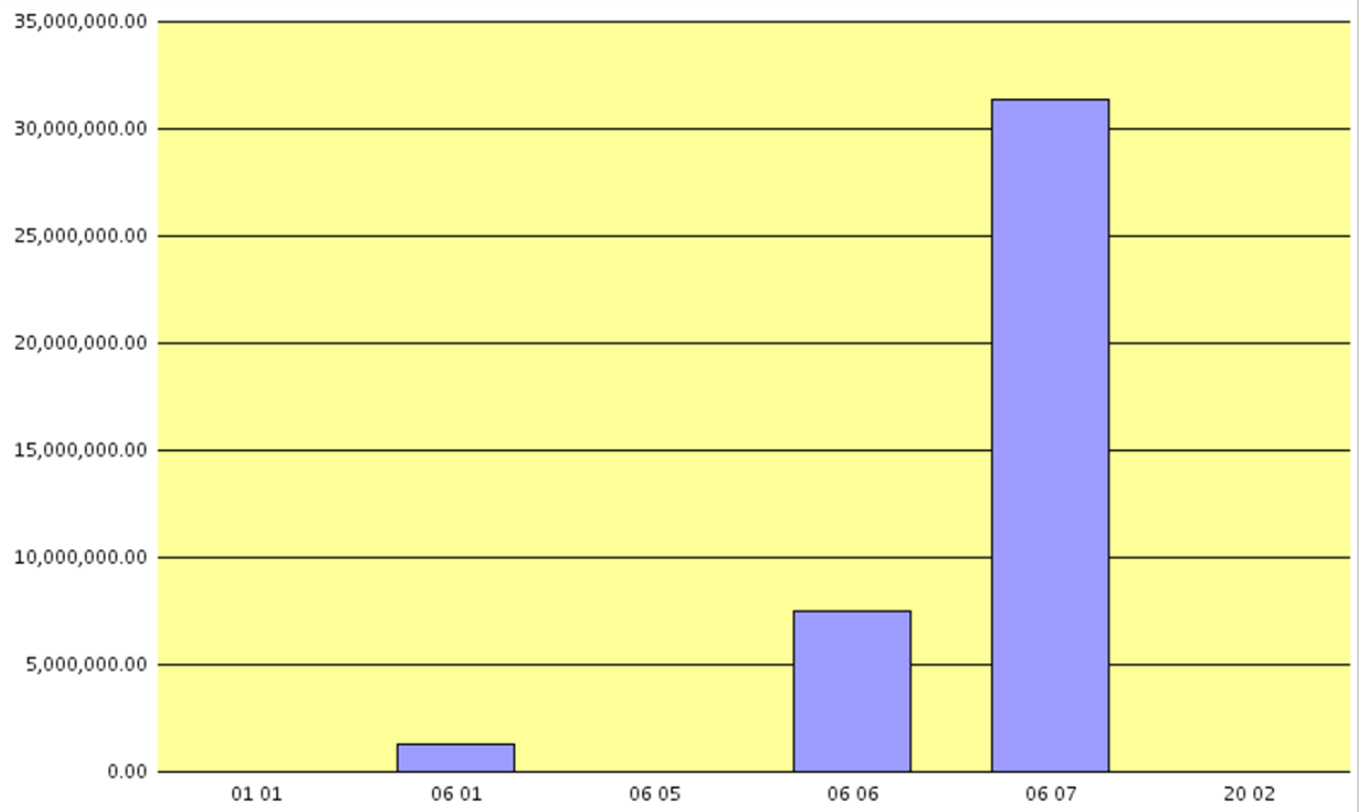


TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG HERA									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			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
<b>Total Title 01</b>			<b>0,00</b>	<b>0,00</b>	<b>0,00</b>	<b>0,00%</b>	<b>0,00</b>	<b>0,00</b>	<b>0,00</b>
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 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			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	1,31	0,00	1,31	100,00%	0,00	1,31	0,00
	06 06	EU4Health Programme	0,00	7,50	-7,50	0,00%	15,00	7,50	0,00
	06 07	Emergency support within the Union	342,74	323,73	19,00	5,54%	12,40	31,40	119,17
<b>Total Title 06</b>			<b>344,05</b>	<b>331,23</b>	<b>12,82</b>	<b>3,72%</b>	<b>27,40</b>	<b>40,22</b>	<b>119,17</b>
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 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			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	92,25%	0,00	0,01	0,00
<b>Total Title 20</b>			<b>0,01</b>	<b>0,00</b>	<b>0,01</b>	<b>92,25%</b>	<b>0,00</b>	<b>0,01</b>	<b>0,00</b>
<b>Total Excluding NGEU</b>			<b>344,06</b>	<b>331,23</b>	<b>12,82</b>	<b>3,73%</b>	<b>27,40</b>	<b>40,23</b>	<b>119,17</b>
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 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			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 (rescEU)	0,00	0,00	0,00	0,00%	0,00	0,00	0,00
<b>Total Title 06</b>			<b>0,00</b>	<b>0,00</b>	<b>0,00</b>	<b>0,00%</b>	<b>0,00</b>	<b>0,00</b>	<b>0,00</b>
<b>Total NGEU Only</b>			<b>0,00</b>	<b>0,00</b>	<b>0,00</b>	<b>0,00%</b>	<b>0,00</b>	<b>0,00</b>	<b>0,00</b>
<b>Total for DG HERA</b>			<b>344,06</b>	<b>331,23</b>	<b>12,82</b>	<b>3,73 %</b>	<b>27,40</b>	<b>40,23</b>	<b>119,17</b>

**Breakdown of Commitments Remaining to be Settled (in Mio EUR) in 2022 HERA**



**TABLE 4 : BALANCE SHEET for DG HERA**

<b>BALANCE SHEET</b>	<b>2022</b>	
A.II. CURRENT ASSETS	7.500.000,00	
A.II.2. Current Pre-Financing	7.500.000,00	
<b>ASSETS</b>	<b>7.500.000,00</b>	
P.II. CURRENT LIABILITIES	0,00	
P.II.4. Current Payables	0,00	
<b>LIABILITIES</b>	<b>0,00</b>	
<b>NET ASSETS (ASSETS less LIABILITIES)</b>	<b>7.500.000,00</b>	
P.III.2. Accumulated Surplus/Deficit		
Non-allocated central (surplus)/deficit*	-7.500.000,00	
<b>TOTAL DG HERA</b>		

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**

<b>STATEMENT OF FINANCIAL PERFORMANCE</b>	<b>2022</b>	
II.2. EXPENSES	499.571,49	
II.2. EXPENSES	499.571,49	
II.2.10.OTHER EXPENSES	775,00	
II.2.2. EXP IMPLM BY COMMISS&EX.AGENC. (DM)	498.796,49	
<b>STATEMENT OF FINANCIAL PERFORMANCE</b>	<b>499.571,49</b>	

**TABLE 5bis : OFF BALANCE SHEET for DG HERA**

	<b>2022</b>	

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 6 Payment Times

Legal Times						
Maximum Payment Time (Days)	Total Nbr of Payments	Nbr of Payments within Time Limit	Percentage	Average Payment Times (Days)	Late Payments Amount	Percentage
30	10	10	100,00 %	8,60	0,00	0, %
60	3	3	100,00 %	34,67	0,00	0, %

<b>Total Number of Payments</b>	<b>13</b>	<b>13</b>	<b>100,00 %</b>		<b>0</b>	<b>0, %</b>
<b>Average Net Payment Time</b>	<b>14,61538462</b>			<b>14,62</b>		
<b>Average Gross Payment Time</b>	<b>15,30769231</b>			<b>15,307692</b>		

Suspensions							
Average Report Approval Suspension	Average Payment Suspension Days	Number of Suspended Payments	% of Total Number	Total Number of Payments	Amount of Suspended	% of Total Amount	Total Paid Amount
0	9	1	7,69 %	13	165.464,49	0,04 %	413.000.065,44

DG	GL Account	Description	Amount (Eur)

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	7=3-6
Total DG HERA							

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

**TABLE 9: AGEING BALANCE OF RECOVERY ORDERS AT 12/31/2022 for DG HERA**

	Number at 1/1/2023 1	Number at 12/31/2022	Evolution	Open Amount (Eur) at 1/1/2023 1	Open Amount (Eur) at 12/31/2022	Evolution

**TABLE 10 :Recovery Order Waivers >= 60 000 € in 2022 for DG HERA**

Waiver Central Key	Linked RO Central Key	RO Accepted Amount (Eur)	LE Account Group	Commission Decision	Comments
<b>Total DG HERA</b>					
<b>Number of RO waivers</b>					

**TABLE 11 : Negotiated Procedures in 2022 for DG HERA**

Negotiated Procedure Legal base	Number of Procedures	Amount (€)
<b>Total</b>		



**TABLE 12 : Summary of Procedures in 2022 for DG HERA**

Procedure Legal base	Number of Procedures	Amount (€)
<b>Total</b>		

**Additional Comments:**

**TABLE 13 : BUILDING CONTRACTS in 2022 for DG HERA**

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

**TABLE 14 : CONTRACTS DECLARED SECRET in 2022 for DG HERA**

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

**TABLE 15 : FPA duration exceeds 4 years - DG HERA**

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**TABLE 16 : Commitments co-delegation type 3 in 2022 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)<sup>4</sup>:

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>- <b>Commitment Appropriations (CA) Implementation</b></li> <li>- <b>CA Forecast Implementation</b></li> <li>- <b>Payment Appropriations (PA) Implementation</b></li> <li>- <b>PA Forecast Implementation</b></li> <li>- <b>Global Commitment Absorption</b></li> </ul> | <ul style="list-style-type: none"> <li>- <b>Timely Payments</b></li> <li>- <b>Timely Decommitments</b></li> <li>- <b>Invoice Registration Time</b></li> <li>- <b>Accounting Data Quality</b></li> <li>- <b>Management Data Quality</b></li> </ul> |
|--|---|

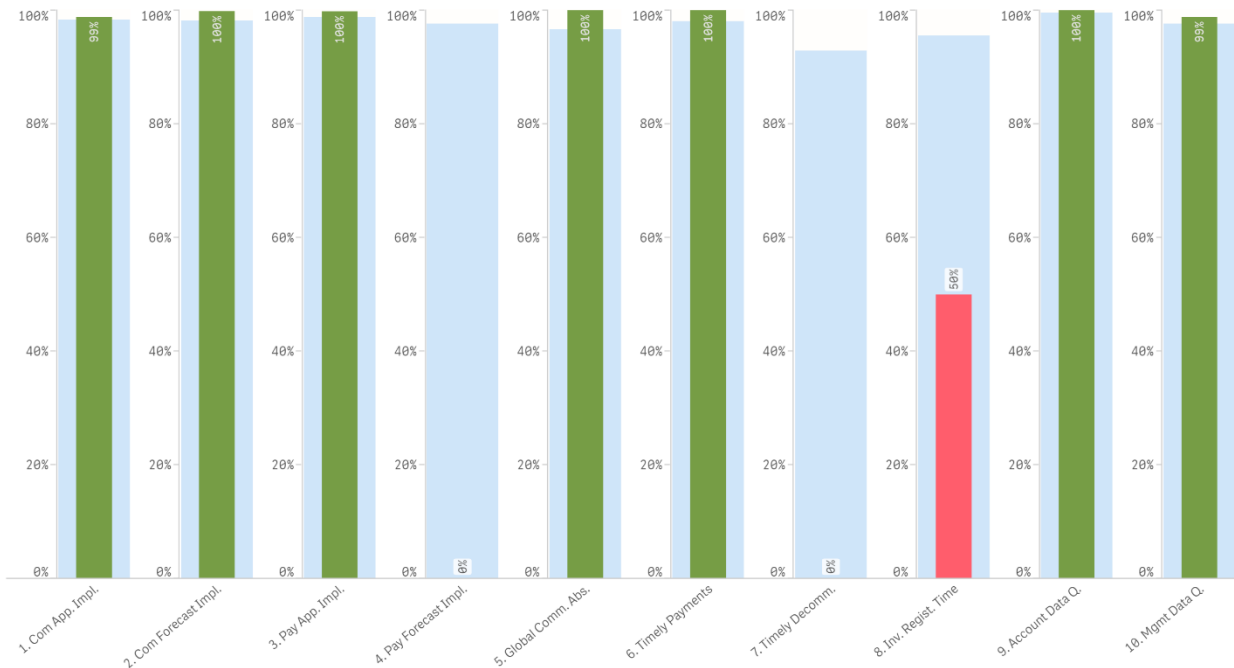
For each indicator, its value (in %) for the Commission service is compared to the common target (in %). The difference between the indicator’s value and the target is colour coded as follows:

- 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 2022 12



Indicator	Objective	Comment	HERA Score	EC Score
1. Commitment Appropriations Implementation	Ensure efficient use of commitment appropriations expiring at the end of Financial Year		99%	98%
2. Commitment Forecast Implementation	Ensure the cumulative alignment of the commitment implementation with the commitment forecast in a financial year		100%	98%
3. Payment Appropriations Implementation	Ensure efficient use of payment appropriations expiring at the end of Financial Year		100%	99%
4. Payment Forecast Implementation	Ensure the cumulative alignment of the payment implementation with the payment forecast in a financial year	Due to the handover of activities from DG SANTE to HERA and the subsequent cross-sub delegation of the payment appropriations to DG INTPA, alignment could not be ensured between the payment forecast for the payment appropriations under the Emergency Support Instrument and the pre-financings actually carried out.	0%	98%
5. Global Commitment Absorption <sup>5</sup>	Ensure efficient use of already earmarked commitment appropriations (at L1 level)		100%	97%
6. Timely	Ensure efficient		100%	98%

<sup>(5)</sup> 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	processing of payments within the legal deadlines			
7. Timely Decommitments	Ensure efficient decommitment of outstanding RAL at the end of commitment life cycle	The indicator is not applicable for HERA in 2022 due to the lack of underlying transactions recorded by HERA in 2022.	-	93%
8. Invoice Registration Time	Monitor the accounting risk stemming from late registration of invoices in the central accounting system ABAC	Due to the specific arrangement where DG SANTE registered the invoices for HERA, there were a limited number of instances where registration was late due to the time it took to coordinate between the DGs. It is important to note that the 50% indicator result is calculated on the basis of 3 late invoices out of 8 invoices registered in total in 2022.	50%	95%
9. Accounting Data Quality	Ensure the good data quality of ABAC transactions with the focus on fields having a primary impact on the accounts		100%	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		99%	98%

## 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, 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.

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.

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

In 2022, almost the entire HERA budget was delegated. 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 AAR.

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 2022, HERA executed 3 payments to grants in direct management under the Emergency Support Instrument for an amount of EUR 0.5 million. The financial initiation and verification of these 3 payments was carried out by DG SANTE, in compliance with their control strategy for this 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 2022.

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. For a number of criteria, evaluation relies on the results of a staff survey; however, the first HERA staff survey will be launched in 2023 as in 2022 HERA was still actively recruiting staff and building institutionally. The results of the 2023 staff survey will contribute to the 2023 assessment.

The identified deficiencies have been addressed in an action plan, to be implemented throughout 2023.

### **Exceptions to rules and procedures, issues raised in management reports received from the authorising officers by sub-delegation**

The assessment took into consideration that there were no exceptions to the rules and procedures registered in 2022.

### **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 2022 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.

HERA draws funding from different programmes (EU4Health, Horizon Europe, Union Civil Protection Mechanism), and each of the programmes is governed by an individual legal base, objectives, implementing rules and procedures. Moreover, the programmes fall under the responsibility of partner lead parent DGs. It is DG SANTE for EU4Health, DG RTD for Horizon Europe, and DG ECHO for the Union Civil Protection Mechanism.

HERA is in a position where counting on its quite limited resources, it needs to seek constantly enhanced coordination with its partner DGs to ensure that its objectives are met through effective implementation of the corresponding programmes. Further, as HERA needs to co-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 has to monitor the effective programming and implementation of its budget implementation 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**

The assessment took into consideration that there were no observations and recommendations reported by the Internal Audit Service in 2022, and there were no ECA audits in 2022 that resulted in financial management and internal control related recommendations for HERA.

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

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

HERA accepted the recommendations and implementation is on-going.

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

The Internal Audit Service concluded that based on HERA's internal control monitoring criteria, HERA could conclude that 8 internal control principles were present and functioning well, 5 internal control principles were present and functioning with some improvements needed, 3 internal control principles were partially present with major improvements needed, and only 1 principle was not present. Despite the very short period of existence, HERA still managed to develop well-functioning controls and to demonstrate that in 2022, it exercised oversight responsibility; established structures, authorities, and responsibilities; enforced accountability; identified and analysed risks and significant changes; used relevant information; and communicated internally and externally.

In 2022, HERA had present and functioning controls in terms of demonstrating its commitment to integrity and ethical values, specifying suitable objectives, the selection and development of general control over technology, the execution of on-going and separate assessments, and the assessment and communication of deficiencies. However, in these areas improvements are needed as more evidence for the functioning of the controls needs to be collected through a staff survey; due to the very short period of existence and the fact that by the end of 2022 HERA was still actively recruiting its staff, it was not feasible to carry out a staff survey in 2022, and it will be done in 2023. Further action is required to document procedures in the areas of exception reporting and IT security.

Due to its infant phase, and the very short period of existence (1 year), HERA could not make all of the controls fully operational in the areas of business continuity, selection and development of control activities, and deployment through policies and procedures. The Internal Audit Service has warned that the lack of a Business Continuity Plan represented a major deficiency for 2022.

Control did not function in 2022 in the area of fraud risk. HERA has not yet developed its Anti-fraud strategy. It has committed to having a fully functioning one in 2023.

Yet, in terms of financial management, the fraud risk in 2022 was controlled by DG SANTE controls as financial initiation and verification for HERA was carried out by DG SANTE. Also, HERA identified the risk of unethical behaviour in a recently set up organization during its risk assessment exercise carried out in 2022 and set up mitigating actions.

HERA made considerable progress towards establishing its Internal Control Framework in 2022. Being newly established, it is normal that in 2022 HERA could not have all the controls set and operational, work will continue to progress in 2023. Based on its own assessment of the functioning of the internal control system, and IAS observations, HERA has developed an action plan to address all deficiencies 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" (2022; MEUR)	minus new prefinancing [plus retentions made] (in 2022; MEUR)	plus cleared prefinancing [minus retentions released and deductions of expenditure made by MS] (in 2022; MEUR)	= "relevant expenditure" (for the 2022; MEUR)	Detected error rate or equivalent estimates	estimated risk at payment (2022; MEUR)	Adjusted Average Recoveries and Corrections (adjusted ARC; %)	estimated future corrections [and deductions] (for FY; EUR)	estimated risk at closure (2022; MEUR)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Emergency Support Instrument (cross subdelegation)	430	430	0	0	0	0	0	0	0
Emergency Support Instrument	0.5	0	0	0.5	2%	0.01	0	0	0.01
EU4Health	7.5	7.5	0	0	0	0	0	0	0
<b>HERA total</b>	<b>438</b>	<b>437.5</b>	<b>0</b>	<b>0.5</b>		<b>0.01</b>	<b>0</b>	<b>0</b>	<b>0.01</b>
					<b>Overall risk at payment in %</b>	<b>2%</b>		<b>Overall risk at closure in %</b>	<b>2%</b>

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.

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

(3) New pre-financing actually paid 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 [& 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.

## **2. Reservations**

Not applicable.

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

Main outputs in 2022:			
Description	Indicator	Target	Latest known results
<b>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</b>			
Recruitment of one director and 3 Heads of Unit	50% of female manager	At equal competence, 2/4 female managers should be appointed	2 heads of unit were appointed in 2022 of which one woman. The 50% target was reached. The director post and one post of Head of unit were republished and the procedure was not finalised in 2022
<b>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</b>			
Implementation of the corporate principles for data governance for HERA key data assets	Percentage of implementation of the corporate principles for data governance for HERA key data assets	Interim milestone by 2022: 50%	HERA has yet to identify corporate reference data assets. This activity will be completed throughout the year 2023. HERA also envisages to appoint a Local Data Correspondent (LDC) in the course of 2023.
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
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)	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.
Design and development of HERA internet and intranet	Launch of the intranet and internet	Q3 and Q4	HERA intranet went live in Q3, with regular news item updates, as well as key documents uploaded. HERA internet is live and is updated regularly with externally communicated published news items, key documents and events.
<b>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.</b>			
<b>More efficient use of resources (energy, water, paper):</b>			
Final building location of HERA	Full staff transfer to new building	Q4 2022	OIB informed HERA that the move could not take place as the new building foreseen is still occupied.
HERA integration into EMAS	Nomination of EMAS correspond/site coordinator	Q3 2022	HERA signed the pledge for the greening of mission and meetings. Due to the transitional situation related to the building and the priority given to achieve a critical mass of staff, the EMAS coordinator was not appointed in 2022.
Preparation of the roadmap for environmental management of HERA building	Launch	Q4 2022	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 participated to the action and the building (shared with DG NEAR) was closed until 9/01

Description	Indicator	Target	Latest known results
<b>Reducing CO2, equivalent CO2 and other atmospheric emissions</b>			
Preparation of roadmap for sustainable commuting for HERA staff	Launch	Q4 2022	HERA participated actively in the velo May action and walking challenge to raise awareness on alternative way of commuting. HERA ranked 5th for the velo May action and 1 <sup>st</sup> for the walking challenge.
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
Analysis of DG's missions trends /patterns (based on corporate EC-staff's professional missions,	Launch	Q3 2022	The fist missions of HERA staff started in Q3 2022, therefore the analysis was premature.

**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”