

5 August 2022
EMA/93616/2022
Management Board, **written procedure Friday 19 August 2022**

Decision of the Management Board

Amending budget No. 01, amending appropriations in budget 2022

THE MANAGEMENT BOARD,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council, and in particular Article 67(11) thereof,

Having regard to the Financial Regulation applying to the Agency, and in particular Articles 26, 33 and 34 thereof,

Having regard to the proposal of the Executive Director representing the Agency,

Having regard to the revised forecast of fee revenue related to scientific applications expected in 2022,

Having regard to the revised forecasts of expenditure related to staff, infrastructure and operations, and operational activities,

Whereas any amendments to the budget, including the establishment plan, shall be subject to an amending budget adopted by the same procedure as the initial budget.

HAS DECIDED

Article 1

The Agency's general budget (fund source C1) for 2022 shall be amended as detailed in Annex I below.

Article 2

The Executive Director shall implement this decision.

Amsterdam, 05 August 2022

[Signature on file]

Lorraine Nolan
Chair of the Management Board

Annex 1 to EMA/MB/93616/2022

Item	Description	Outturn as per year-end accounts	Appropriation as per adopted budget	Amending budget No. 1	Appropriations, adopted and amending budgets
		2021	2022	2022	2022
REVENUE					
Title 1	Revenue from services rendered				
1000R	Fees collected (Regulation (EU) 297/95)	€ 314,344,159	€ 327,561,000	€ 14,574,000	€ 342,135,000
Title 2	European Union and EEA contributions				
2000R	European Union and EEA contribution	€ 25,449,575	€ 40,879,000	-€ 8,754,000	€ 32,125,000
2010R	Special contribution for Orphan medicinal Products from the EU budget and EEA contribution	€ 12,187,155	€ 14,352,000	-€ 1,476,000	€ 12,876,000
Total revenue				€ 4,344,000	
EXPENDITURE					
Title 1	Staff expenditure				
Chapter 11	Staff salaries & allowances				
1100	Basic salaries	€ 51,206,866	€ 55,753,000	€ 2,000,000	€ 57,753,000
1114	Basic salaries & allowances for contract agents	€ 11,835,436	€ 11,844,000	€ 944,000	€ 12,788,000
1115	Seconded national experts and visiting experts	€ 2,428,473	€ 3,548,000	€ 188,000	€ 3,736,000
1130	Employer's social security contributions	€ 13,688,649	€ 12,120,000	€ 2,800,000	€ 14,920,000
Title 2	Infrastructure & operating expenditure				
Chapter 21	Corporate information & communication technology				
2110	Hardware & software	€ 1,809,924	€ 1,761,000	-€ 242,000	€ 1,519,000
Chapter 26	Restaurant & catering				
2600	Restaurant & catering	€ 601,622	€ 1,288,000	-€ 222,000	€ 1,066,000
Chapter 27	Information & publishing				
2700	Information & communication services	€ 2,027,511	€ 2,510,000	-€ 246,000	€ 2,264,000
Chapter 28	Business consultancy & audit services				
2800	Business consultancy	€ 2,060,396	€ 3,547,000	-€ 1,100,000	€ 2,447,000
2801	Audit services	€ 0	€ 344,000	-€ 211,000	€ 133,000
Title 3	Operational expenditure				
Chapter 30	Operational expenditure				
3000	Reimbursement of persons attending meetings	€ 138,144	€ 5,280,000	-€ 750,000	€ 4,530,000
3003	Other expenditure in relation to meetings	€ 5,250	€ 894,000	-€ 342,000	€ 552,000
3010	Evaluation of medicinal products	€ 122,826,594	€ 132,316,000	€ 3,659,000	€ 135,975,000
3020	Translation centre, Luxembourg	€ 3,236,240	€ 3,131,000	-€ 84,000	€ 3,047,000
3021	Other translations	€ 1,536,308	€ 2,349,000	-€ 413,000	€ 1,936,000
3030	Scientific studies and services	€ 9,472,602	€ 22,900,000	-€ 1,137,000	€ 21,763,000
3032	External experts	€ 0	€ 2,000,000	-€ 500,000	€ 1,500,000
Total expenditure			€ 4,344,000		

Annex 2 to EMA/MB/93616/2022

Activity Based Budget (ABB) – AB01

Work programme activities	STAFF		Staff expenditure	Infrastructure, IT and project exp.	Meeting exp. (incl. overhead)	Evaluation Service (NCAs)	Other operational expenditure	Total expenditure	
	Temporary Agent	Contract Agent & Seconded National Experts	€'000	€'000	€'000	€'000	€'000	€'000	%
			Title 1	Title 2 & Budget Item 3105	Budget item 3000 & 3003	Article 301	Articles 302 & 303		
1 Evaluation activities for human medicines	269	106	59,135	21,434	6,130	139,407	6,619	232,726	55%
1.1 Pre-authorisation activities	68	35	17,346	5,424	3,589	24,693	28	51,082	12%
1.2 Initial evaluation activities	59	15	11,787	3,532	684	17,502	1,525	35,030	8%
1.3 Post-authorisation activities	71	23	13,773	6,592	131	82,812	1,915	105,222	25%
1.4 Referrals	8	1	1,314	462	76	-	337	2,190	1%
1.5 Pharmacovigilance activities	37	23	8,635	3,218	1,138	14,399	2,805	30,194	7%
1.6 Other specialized areas and activities	27	10	6,280	2,206	512	-	9	9,008	2%
2 Evaluation activities for veterinary medicines	31	18	7,553	10,879	1,535	6,684	603	27,255	6%
2.1 Pre-authorisation activities	2	0	284	99	137	295	1	815	0%
2.2 Initial evaluation activities	8	2	1,378	494	352	2,509	294	5,028	1%
2.3 Post-authorisation activities	12	4	2,140	854	88	3,881	179	7,141	2%
2.4 Arbitrations and Referrals	0	1	160	67	108	-	122	457	0%
2.5 Pharmacovigilance activities	5	3	1,163	471	194	-	7	1,835	0%
2.6 Other specialized areas and activities	4	8	2,430	8,893	656	-	-	11,979	3%
3 Horizontal activities and other areas	208	79	43,348	45,608	7,482	4,283	24,951	125,673	30%
3.1 Committee coordination	46	15	8,314	13,002	2,413	-	14,000	37,729	9%
3.2 Inspection and Compliance	26	17	5,647	2,194	1,017	4,283	250	13,391	3%
3.3 Partners and Stakeholders	20	7	5,299	1,657	2,438	-	703	10,097	2%
3.3a Transparency and access to documents	19	11	4,192	1,837	-	-	-	6,030	1%
3.3b Information	39	16	7,781	7,186	688	-	299	15,954	4%
3.4 International activities	11	4	2,969	712	301	-	-	3,982	1%
3.5 Information Management (incl. EU Telematics)	48	10	9,145	19,020	625	-	9,700	38,491	9%
4 Corporate Governance and Support activities	141	34	25,817	9,768	570	-	6	36,161	9%
4.1 Governance, quality management and internal audit	21	8	5,145	1,493	570	-	-	7,208	2%
4.2 Finance	33	9	5,501	2,368	-	-	6	7,876	2%
4.3 Information technology	30	5	5,736	1,704	-	-	-	7,440	2%
4.4 Human resources	47	11	7,974	3,703	-	-	-	11,677	3%
4.5 Infrastructure services	10	0	1,461	499	-	-	-	1,960	0%
Total	649	237	135,854	87,689	15,718	150,374	32,180	421,815	100%

Healthcare Data Workstream

The Healthcare Data Workstream covers activities related to the EudraVigilance Data Management and the Medical Literature Monitoring service. Maintains a public inventory of healthcare data sources for the EU regulatory network and provide EMA's position on the validity of those data sources for specific regulatory use-cases. The team leads and coordinates EU regulatory efforts in data standardisation, including in industry submissions and real-world data. Coordinates and develops guidelines in data standards, terminologies, data management, etc., and participates in guideline development at an international level. [Furthermore, as a continuation to the work done in 2021, the Agency will be supporting NCAs during 2022 in performing some processing of COVID vaccine-related ICSRs in the wider context of the vaccination campaigns and to support the monitoring of vaccine safety.](#)