

15 December 2023
EMA/575753/2023
Management Board

Decision of the Management Board

Amending budget No. 01, amending appropriations in budget 2023

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 lower than expected fee revenue related to scientific applications in 2023,

Having regard to the revised forecasts of expenditure related to staff (external services), business consultancy, 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 2023 shall be amended as detailed in Annex I below.

Article 2

The Executive Director shall implement this decision.

Amsterdam, 21 December 2023

[Signature on file]

Lorraine Nolan
Chair of the Management Board

Annex 1 to EMA/MB/575753/2023

Item	Description	Outturn as per year-end accounts	Appropriation as per adopted budget (incl. transfers implemented during the year)	Amending budget No. 1	Appropriations, adopted and amending budgets
		2022	2023	2023	2023
REVENUE					
Title 1 Revenue from services rendered					
1000	Fees collected (Regulation (EU) 297/95)	€ 336,819,762	€ 376,228,000	-€ 8,400,000	€ 367,828,000
1001	Fees collected (Regulation (EU) 658/2014)	€ 28,062,282	€ 31,381,000	-€ 1,000,000	€ 30,381,000
Total revenue				-€ 9,400,000	
EXPENDITURE					
Title 1 Staff expenditure					
Chapter 16 External services					
1601	Interim services	€ 10,508,139	€ 13,497,000	-€ 500,000	€ 12,997,000
Title 2 Infrastructure & operating expenditure					
Chapter 28 Business consultancy & audit services					
2800	Business consultancy	€ 1,897,267	€ 5,000,000	-€ 1,900,000	€ 3,100,000
Title 3 Operational expenditure					
Chapter 30 Operational expenditure					
3010	Evaluation of medicinal products	€ 134,274,947	€ 150,087,000	-€ 4,900,000	€ 145,187,000
3013	Evaluation of pharmacovigilance procedures	€ 11,718,866	€ 13,261,000	-€ 500,000	€ 12,761,000
3030	Scientific studies and services	€ 22,834,042	€ 12,624,000	-€ 1,600,000	€ 11,024,000
Total expenditure			-€ 9,400,000		

Annex 2 to EMA/MB/575753/2023

Activity Based Budget (ABB)

Work programme activities	STAFF		Staff expenditure	Infrastructure, IT and project exp.	Meeting exp. (incl. overhead)	Evaluation Service (NCAs)	Other operational expenditure	Total expenditure	
			€'000	€'000	€'000	€'000	€'000	€'000	%
	Temporary Agent	Contract Agent & Seconded National Experts	Title 1	Title 2 & Budget Item 3105	Budget item 3000 & 3003	Article 301	Articles 302 & 303		
1 Evaluation activities for human medicines	279	112	67,030	34,945	6,731	145,958	6,794	261,458	58%
1.1 Pre-authorisation activities	82	30	20,263	6,328	3,191	27,009	57	56,848	13%
1.2 Initial evaluation activities	52	16	11,394	3,360	613	15,300	1,003	31,671	7%
1.3 Post-authorisation activities	76	27	18,977	14,443	222	91,187	1,885	126,715	28%
1.4 Referrals	7	2	1,236	416	213	-	258	2,123	0%
1.5 Pharmacovigilance activities	43	26	7,906	8,359	1,232	12,461	3,582	33,540	7%
1.6 Other specialized areas and activities	20	13	7,254	2,039	1,261	-	9	10,562	2%
2 Evaluation activities for veterinary medicines	39	18	12,438	7,498	1,731	6,113	614	28,393	6%
2.1 Pre-authorisation activities	2	1	1,417	626	164	353	3	2,563	1%
2.2 Initial evaluation activities	8	3	1,609	516	387	1,374	233	4,119	1%
2.3 Post-authorisation activities	10	2	3,437	1,427	79	1,890	208	7,041	2%
2.4 Arbitrations and Referrals	1	1	190	73	97	-	156	516	0%
2.5 Pharmacovigilance activities	8	5	2,390	3,901	482	2,496	14	9,284	2%
2.6 Other specialized areas and activities	11	7	3,395	953	521	-	-	4,869	1%
3 Horizontal activities and other areas	219	87	49,857	41,730	7,153	5,878	11,645	116,263	26%
3.1 Committee coordination	54	21	12,520	8,525	3,381	-	1,420	25,846	6%
3.2 Inspection and Compliance	29	18	5,497	2,529	853	5,878	30	14,786	3%
3.3 Partners and Stakeholders	27	7	6,446	1,766	1,369	-	461	10,042	2%
3.3a Transparency and access to documents	18	10	4,739	1,743	-	-	-	6,482	1%
3.3b Information	42	17	9,069	6,725	450	-	195	16,439	4%
3.4 International activities	12	3	3,191	839	521	-	-	4,552	1%
3.5 Information Management (incl. EU Telematics)	36	10	8,395	19,603	579	-	9,539	38,116	8%
4 Corporate Governance and Support activities	145	30	28,560	13,376	548	-	6	42,489	9%
4.1 Governance, quality management and internal audit	24	7	6,125	1,587	548	-	-	8,260	2%
4.2 Finance	29	9	5,741	2,871	-	-	6	8,619	2%
4.3 Information technology	24	5	5,083	2,772	-	-	-	7,855	2%
4.4 Human resources	56	9	9,930	5,495	-	-	-	15,425	3%
4.5 Infrastructure services	11	1	1,680	650	-	-	-	2,331	1%
Total	682	248	157,885	97,549	16,162	157,948	19,059	448,603	100%

FTEs are calculated as follows:	FTEs
Temporary Agents	682
Contract Agents	203
Seconded National Experts	45
Total Staff	930