

Annex to EMA/MB/379538/2019

## **Decision on amending budget No 2-2019**

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 budgetary impact of the sub-letting of the Agency's former headquarters at 30, Churchill Place, Canary Wharf, London,

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 2019 budget shall be amended as follows:

Item	tem Description		Amending Budget no. 2	Appropriation post Amending Budget							
		2019	2019	2019							
REVENUE											
Title 7	Correction of budgetary imbalances										
7000	Balance of outturn account of previous year	€ 14,468,000	€ 13,803,000	€ 28,271,000							
Total reve	nue	€ 13,803,000									
EXPENDITURE											
Title 2	Infrastructure & operating expenditure										
Chapter 20	Infrastructure & operating expenditure										
2040	Fitting-out of premises	€ 933,000	€ 13,803,000	€ 14,736,000							
Total expe	nditure		€ 13,803,000								



## Activity Based Budget 2019 - AB02

Work programme chapters	Full Time Equivalence		Staff expenditure	Infrastructure, IT and project exp.	Meeting exp. (incl. overhead)	Evaluation Service (NCAs)	Other operational expenditure	onal Total expenditure		
	* Total FTEs	Business as usual	Brexit preparedness	€'000	€'000	€'000	€'000	€'000	€'000	%
	TA, CA & National Experts		Title 1	Title 2 & Budget Item 3105	Budget item 3000	Article 301	Articles 302, 303 & Item 3003			
1 Evaluation activities for human medicines	353	351	2	45,287	20,347	5,938	115,804	6,801	194,176	68%
1.1 Pre-authorisation activities	81	80	1	10,592	2,095	2,982	20,426	7	36,102	13%
1.2 Initial evaluation activities	75	75	0	10,549	1,566	1,062	12,705	882	26,764	9%
1.3 Post-authorisation activities	79	78	1	9,558	6,067	208	70,835	1,425	88,094	31%
1.4 Referrals	6	6	0	746	125	72	-	277	1,220	0%
1.5 Pharmacovigilance activities	96	96	0	11,577	4,146	958	11,838	4,079	32,598	11%
1.6 Other specialized areas and activities	16	16	0	2,264	6,349	656	-	130	9,399	3%
2 Evaluation activities for veterinary medicines	36	35	1	4,255	1,079	715	3,687	413	10,149	4%
2.1 Pre-authorisation activities	3	3	0	363	67	67	212	-	710	0%
2.2 Initial evaluation activities	12	12	0	1,494	255	255	912	147	3,064	1%
2.3 Post-authorisation activities	10	9	1	1,164	415	74	2,562	219	4,433	2%
2.4 Arbitrations and Referrals	2	2	0	198	37	91	-	47	372	0%
2.5 Pharmacovigilance activities	5	5	0	676	236	168	-	-	1,080	0%
2.6 Other specialized areas and activities	3	3	0	360	70	61	-	-	490	0%
3 Horizontal activities and other areas	231	226	5	30,005	14,127	1,193	4,450	854	50,629	18%
3.1 Committee coordination	65	65	0	7,728	1,325	544	-	-	9,597	3%
3.2 Inspection and Compliance	34	34	0	3,638	1,111	31	4,450	-	9,230	3%
3.3 Partners and Stakeholders	40	36	4	5,990	806	503	-	605	7,904	3%
3.3a Transparency and access to documents	17	17	0	2,236	704	21	-	-	2,960	1%
3.3b Information	40	39	1	5,008	1,968	7	-	248	7,231	3%
3.4 International activities	11	11	0	2,279	222	45	-	-	2,546	1%
3.5 Information Management (incl. EU Telematics)	24	24	0	3,126	7,991	43	_	_	11,160	4%
4 Corporate Governance and Support activities	191	137		24,098	7,892	192	_	5	32,186	11%
4.1 Governance, quality management and internal audit	32	22		4,760	1,144	192	-	-	6,096	2%
4.2 Finance	27	24		2,850	542	_	-	5	3,397	1%
4.3 Information technology	58	41	17	7,949	4,382	_	-	_	12,331	4%
4.4 Human resources	60	41	19	6,809	1,515	_	_	_	8,324	3%
4.5 Infrastructure services	15	10		1,729	309	_	-	_	2,039	1%
Total	811	749		,		8,037	123,941	8,072	287,140	
* FTEs are calculated as follows:							Brexit related	ovnonditur-	59,622	
Temporary Agents	591						Budget 2019	expenditure	346,762	
Contract Agents (193 FTEs business as usual + 40 Brexit related)	233								,	
Seconded National Experts	30									
Total Staff	854									
5% vacancy rate Estimated FTEs for 2019	- 43 <b>811</b>									
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## Article 2

The Executive Director shall implement this decision. The decision shall take effect on 18 July 2019.

Done at Amsterdam, 18 July 2019

[Signature on file]
Christa Wirthumer-Hoche
Chair of the Management Board