



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

6 October 2016  
EMA/MB/572210/2015

Annex 1 to EMA/MB/572210/2015

## Decision on amending budget No 1-2016

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 27, 33 and 34 thereof,

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

Having regard to the European Commission's Paymasters Office carrying out the salary and related weighting and exchange rate adjustments with the December payroll, backdated for the months of July to December;

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.

Whereas the implementation of the amending budget needs to be carried out in two stages whereby the adjustment of budget item 1190 (weighting and exchange rate) can only be carried out once the December salary adjustment (RAPPEL) has been calculated by the European Commission's Paymasters Office and the December salaries have been paid from the EMA budget.

HAS DECIDED



## Article 1

The Agency's general budget (C1) for 2016 shall be amended as follows:

### Part I – to be implemented following adoption

Item	Description	Outturn as per year-end accounts	Appropriation pre-Amending Budget	Amending Budget no. 1	Appropriation post Amending Budget
		2015	2016	2016	2016
<b>REVENUE</b>					
<b>Title 1 Revenue from services rendered</b>					
<b>Chapter 10 Revenue from services rendered</b>					
1000R	Fees collected (Regulation (EU) 297/95)	€ 229,851,311	€ 248,716,000	-€ 4,875,000	€ 243,841,000
	<i>Fee for assessment of periodic safety update report</i>	€ 11,761,036	€ 14,686,000	-€ 815,000	€ 13,871,000
	<i>Fee for assessment of post-authorisation safety study</i>	€ 261,507	€ 1,204,000	-€ 681,000	€ 523,000
	<i>Fee for the assessment of referrals</i>	€ 998,631	€ 1,709,000	€ 0	€ 1,709,000
	<i>Pharmacovigilance annual flat fee</i>	€ 8,617,689	€ 10,646,000	€ 0	€ 10,646,000
1001R	Total fees collected (Regulation (EU) 658/2014)	€ 21,638,863	€ 28,245,000	-€ 1,496,000	€ 26,749,000
<b>Title 2 European Union contribution</b>					
<b>Chapter 20 European Union contribution</b>					
2000R	European Union contribution	€ 18,668,607	€ 11,690,000	-€ 1,986,000	€ 9,704,000
<b>Title 3 EEA contribution</b>					
<b>Chapter 30 EEA contribution</b>					
3000R	EEA contribution	€ 554,458	€ 676,000	-€ 54,000	€ 622,000
<b>Total revenue</b>				<b>-€ 8,411,000</b>	
<b>EXPENDITURE</b>					
<b>Title 1 Staff in active employment</b>					
<b>Chapter 11 Staff in active employment</b>					
1100	Basic salaries	€ 38,850,539	€ 41,477,000	-€ 369,000	€ 41,108,000
1520	Staff exchanges between EU institutions	€ 4,031,238	€ 5,660,000	-€ 810,000	€ 4,850,000
<b>Title 2 Buildings, equipment and miscellaneous operating expenditure</b>					
<b>Chapter 20 Investment in immovable property, renting of buildings &amp; associated costs</b>					
2010	Insurance	€ 626,374	€ 518,000	-€ 100,000	€ 418,000
2090	Other expenditure on buildings	€ 4,031,238	€ 4,711,000	-€ 400,000	€ 4,311,000
2203	Lease, maintenance & repair of technical equipment & installations	€ 883,182	€ 1,210,000	-€ 256,000	€ 954,000
<b>Title 3 Operating expenditure</b>					
<b>Chapter 30 Operating expenditure</b>					
3000	Reimbursement of persons attending meetings	€ 7,712,388	€ 8,780,000	-€ 808,000	€ 7,972,000
3010	Evaluation of medicinal products	€ 97,198,949	€ 107,327,000	-€ 3,570,000	€ 103,757,000
3013	Evaluation of pharmacovigilance procedures	€ 10,752,749	€ 11,815,000	-€ 1,000,000	€ 10,815,000
3020	Translation centre Luxembourg	€ 2,354,441	€ 3,610,000	-€ 835,000	€ 2,775,000
3021	Other translations	€ 1,387,235	€ 1,660,000	-€ 263,000	€ 1,397,000
<b>Total expenditure</b>				<b>-€ 8,411,000</b>	

**Part II – to be implemented following payment of the December salaries**

<b>REVENUE</b>					
<b>Title 2 European Union contribution</b>					
<b>Chapter 20 European Union contribution</b>					
2000R	European Union contribution	€ 18,668,607	€ 9,704,000	-€ 7,666,000	€ 2,038,000
3000R	EEA contribution	€ 554,458	€ 622,000	-€ 212,000	€ 410,000
<b>Total revenue</b>				<b>-€ 7,878,000</b>	
<b>EXPENDITURE</b>					
<b>Title 1 Staff in active employment</b>					
<b>Chapter 11 Staff in active employment</b>					
1190	Weightings	€ 29,860,026	€ 33,063,000	-€ 7,878,000	€ 25,185,000
<b>Total expenditure</b>				<b>-€ 7,878,000</b>	

**Article 3**

The Executive Director shall implement this decision.

Part I of the decision shall take effect on 6 October 2016 and Part II of the decision shall take effect following the processing of the December payroll, at the latest by 15 December 2016.

London, 6 October 2016

[Signature on file]

Christa Wirthumer-Hoche  
Chair of the Management Board

## Revised Activity Based Budget 2016

Chapters	Full Time Equivalence (FTEs)	Staff expenditure €'000	Infrastructure, ICT and project exp. €'000	Meeting exp. (incl. overhead) €'000	Evaluation Service (NCAs) €'000	Other operational expenditure €'000	* Total expenditure €'000	%
		Title 1	Title 2 & Budget Item 3105	Budget Item 3000, 3001 & 3003	Budget Item 3010	Remainder of Title 3		
<b>1 Evaluation activities for human medicines</b>	<b>419</b>	<b>60,389</b>	<b>28,961</b>	<b>11,749</b>	<b>104,614</b>	<b>8,600</b>	<b>214,312</b>	<b>70%</b>
1.1 Pre-authorisation activities	93	13,063	4,270	4,150	18,058	97	39,638	13%
1.2 Initial evaluation activities	79	12,525	2,910	1,511	14,594	881	32,421	11%
1.3 Post-authorisation activities	88	12,386	10,605	1,597	61,146	2,248	87,983	29%
1.4 Referrals	13	1,764	469	520	-	357	3,110	1%
1.5 Pharmacovigilance activities	114	14,994	7,126	2,287	10,815	3,324	38,545	13%
1.6 Other specialized areas and activities	32	5,657	3,580	1,684	-	1,693	12,614	4%
<b>2 Evaluation activities for veterinary medicines</b>	<b>48</b>	<b>6,747</b>	<b>2,336</b>	<b>2,466</b>	<b>3,616</b>	<b>873</b>	<b>16,039</b>	<b>5%</b>
2.1 Pre-authorisation activities	1	303	78	571	259	15	1,226	0%
2.2 Initial evaluation activities	16	2,336	586	430	1,302	130	4,784	2%
2.3 Post-authorisation activities	11	1,314	981	216	2,055	477	5,044	2%
2.4 Arbitrations and Referrals	3	498	114	193	-	165	970	0%
2.5 Pharmacovigilance activities	7	899	237	217	-	51	1,403	0%
2.6 Other specialized areas and activities	10	1,397	339	840	-	35	2,612	1%
<b>3 Horizontal activities and other areas</b>	<b>134</b>	<b>19,178</b>	<b>6,984</b>	<b>4,638</b>	<b>6,342</b>	<b>1,303</b>	<b>38,445</b>	<b>13%</b>
3.1 Committee coordination	26	3,196	886	962	-	-	5,044	2%
3.2 Inspection and Compliance	36	4,021	2,458	1,021	6,342	80	13,924	5%
3.3 Partners and Stakeholders	31	5,102	1,270	2,011	-	1,097	9,480	3%
3.3a Transparency and access to documents	23	3,596	1,767	328	-	100	5,792	2%
3.3b Information	4	802	158	315	-	25	1,299	0%
3.4 International activities	13	2,461	446	-	-	-	2,907	1%
<b>4 Corporate Governance and Support activities</b>	<b>187</b>	<b>26,633</b>	<b>7,657</b>	<b>575</b>	<b>-</b>	<b>2,513</b>	<b>37,376</b>	<b>12%</b>
4.1 Governance, quality management and internal audit	34	5,525	1,191	364	-	581	7,662	3%
4.2 Finance	27	3,550	1,653	-	-	7	5,210	2%
4.3 Information technology	44	7,385	1,548	-	-	474	9,407	3%
4.5 Human resources	41	4,967	1,841	-	-	-	6,807	2%
4.6 Infrastructure services	16	1,914	560	-	-	-	2,474	1%
4.7 Communication (corporate)	25	3,292	863	210	-	1,450	5,816	2%
<b>Total</b>	<b>787</b>	<b>112,947</b>	<b>45,937</b>	<b>19,428</b>	<b>114,572</b>	<b>13,288</b>	<b>306,172</b>	<b>100%</b>

\* It excludes exceptional investment cost for the refurbishment of the 10th floor

<b>Total Budget for 2016</b>	<b>308,422</b>
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