



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Executive Director

## Report on budgetary and financial management

Financial year 2016

### Contents

<b>1. Introduction .....</b>	<b>2</b>
<b>2. Financial management in general .....</b>	<b>3</b>
2.1. Budget overview .....	3
2.2. Revenue (income from evaluation activities and EU contribution) .....	3
2.3. Expenditure (commitments and payments) .....	6
2.4. Appropriations carried forward from 2016 to 2017 .....	8
2.5. Implementation of appropriations carried forward from 2015 to 2016 .....	8
2.6. Appropriations from external assigned revenue .....	8
2.7. Budget transfers .....	8
2.8. Cancellation of appropriations .....	9
2.9. Payment of interest on late payments .....	9
<b>3. Financial management by chapter .....</b>	<b>10</b>
3.1. Revenue .....	10
3.1.1. Stable vs. cyclical revenue .....	10
3.1.2. Cancellation of recovery orders / acceptance requests .....	10
3.2. Expenditure .....	10
3.2.1. Exchange rate impact on the budget .....	10
3.2.2. Details on expenditure items .....	11
<b>Annex I – Budget evolution .....</b>	<b>12</b>
Annex II – Detailed revenue overview, evolution .....	14
Annex III – Detailed expenditure overview, evolution .....	15
Annex IV – Amending budget .....	17
Annex V – Summary of transfers .....	18



# 1. Introduction

This report summarises the budgetary and financial management by the European Medicines Agency during the financial year 2016. It outlines the financial situation, budget evolution and the events which had a significant influence on activities during the year.

It provides qualitative information on the operational performance of the past financial year, reports in more detail on any difficulties in the implementation of the budget and provides additional, useful information for the budgetary authority and the European Court of Auditors.

It is issued in accordance with Art. 64 of Regulation (EC) No726/2004 of the European Parliament and of the Council, of 31 March 2004, and Article 93 of the EMA's Financial Regulation of 15 January 2014.

The European Medicines Agency is a fee-funded agency, with 89.34% of its 2016 revenue stemming from fees paid by the pharmaceutical industry for services provided.

EMA's 2016 budget included assigned revenue to a value of EUR 15.2 million, which originated from tenants' inducements paid by the landlord as an incentive to paid for the fit-out of and rent on the new headquarters.

## Highlights for 2016

- ✓ Following the referendum on the UK's membership of the EU, the pound weakened considerably, resulting in major exchange rate gains on payments made in Sterling, in particular salary and rent and building maintenance payments. As a consequence, the budget was reduced by EUR 16.3 million, through an amending budget adopted by the Management Board at its October 2016 meeting.
- ✓ The budgetary outturn, a surplus of approx. EUR 10.23 million, was caused in part by the continued weakening of the pound throughout the year, as well as a higher collection rate for fee income in the final weeks of December 2016.
- ✓ In order to comply with the provisions of the Financial Regulation, and in particular Arts. 69 and 70, and on the advice of the Court of Auditors, the Agency in late 2016 started committing operational expenditure (title III) fully at the point of entering into a legal commitment, even where the contract length extended beyond one year. This increased the amount of appropriations carried forward to 2017 and will also have an impact on the level of carry-forward in future years.
- ✓ The agency managed to comply fully with the ceilings/KPIs for the amounts carried forward: title I (10%), title II (20%) and title III (30%), with the following percentages achieved: title I: 0.86%, title II: 7.93%, title III: 25.86%.

This report complements other reports in conjunction with which it should be read in order to have the full picture of the agency's budgetary and financial management. For information about the agency's business objectives and the level of achievement, please refer to the Annual Activity Report and the Annual Report. For further financial information, please refer to the financial accounts.

## 2. Financial management in general

### 2.1. *Budget overview*

Authorised appropriations in the European Medicines Agency's initial budget for 2016 totalled EUR 324,711,000, representing a 7.5% increase compared to the 2015 initial budget (EUR 302,117,000).

One amending budget was processed in 2016. This addressed two general issues:

- a reduction in fee income, with a knock-on effect on payments to rapporteurs
- a considerable reduction in the euro value of expenditure incurred in Sterling, due to the weakening of the pound against the euro, in particular in the second half of the year. This impacted also staff salaries and the weighting which is paid as part thereof. The details of the amending budget can be found at Annex III.

Revenue from cash received for services rendered of was reduced by EUR 6,371,000 and the EU contribution reduced by EUR 9,918,000, bringing the budget total to EUR 308,422,000, representing a 0.1% increase over the 2015 final budget (EUR 308,097,000).

To balance the budget, expenditure appropriations related to expenditure carried out in pounds Sterling and those linked to rapporteur commitments were decreased by the same total amount.

Annexes I-III provide a detailed overview of budget evolution by chapter and selected key articles.

### 2.2. *Revenue (income from evaluation activities and EU contribution)*

As stipulated in the Financial Regulation, budget revenue is based on cash received for contributions from the European Union, fees for applications for marketing licenses for pharmaceutical products and for post-authorisation activities as well as for various administrative activities.

Revenue entered in the accounts as at 31 December 2016 amounted to a total of EUR 305,098,697.55.

Of the total revenue, 89.34% derived from the evaluation of medicines and other business related activities, 5.49% from the European Union budget to fund various public health and harmonisation activities, including positive outturn of previous year, and 5.01% from external assigned revenue as described in the work programme (2015: 83.1%/11.1%/5.8%).

The chart below provides the breakdown by type of revenue.

Chart 1: breakdown of revenue by type/title

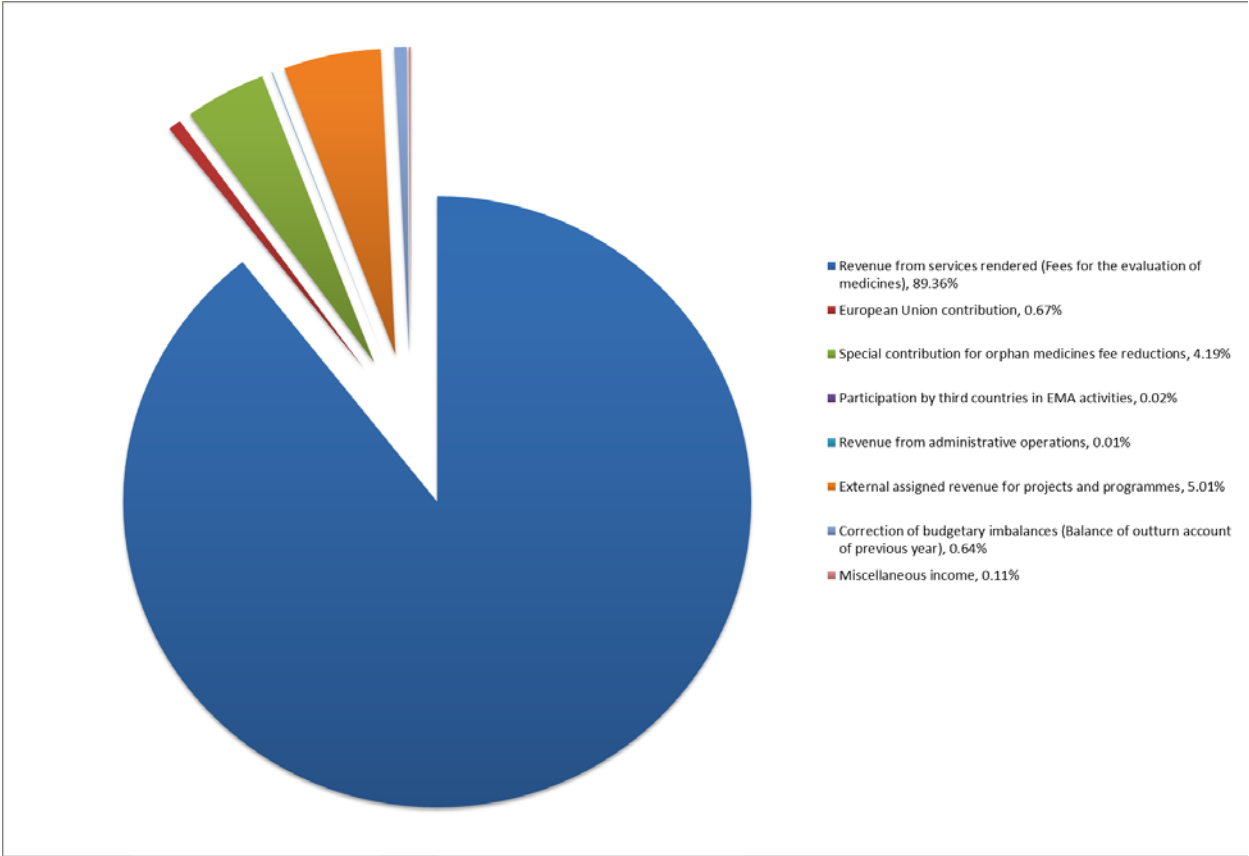


Table 1 below presents the implementation of the revenue budget of the European Medicines Agency.

**Table 1 Implementation of 2016 revenue appropriations**

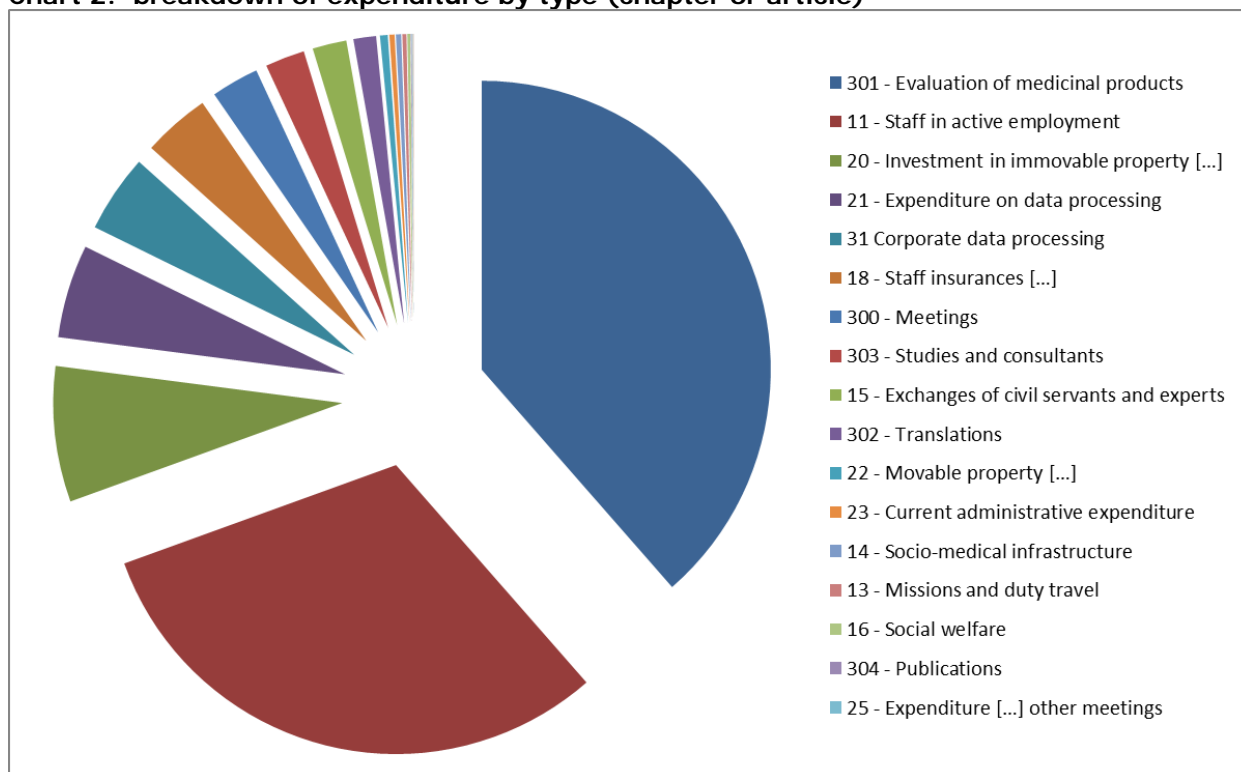
<b>Appropriation type</b>	<b>EUR or %</b>
<b>I. Appropriations in general</b>	
Initial appropriations	324,711,000.00
Amending budget	-16,289,000.00
Final appropriations	308,422,000.00
<b>II. Use of appropriations</b>	
Recovery orders 2016 and earlier	350,008,264.34
Representing in % of final appropriations	113.48%
Cash-receipts against recovery orders 2016 and earlier	305,098,697.55
Representing in % of final recovery orders	87.17%
<b>III. Amounts established in 2016</b>	
Recovery orders 2016 only	289,280,395.70
Representing in % of final appropriations	93.79%
Cash-receipts against recovery orders 2016 only	262,098,200.56
Representing in % of final recovery orders	90.60%
<b>IV. Amounts unpaid from 2016 to be paid in 2017 or later</b>	
Recovery orders for the evaluation of medicinal products (fees)	44,863,540.72
Other recovery orders	46,026.07
<b>V. Amounts unpaid in 2015 or earlier, paid in 2016</b>	
Recovery orders for the evaluation of medicinal products (fees)	42,945,620.53
Recovery orders for EU contribution	0.00
Other recovery orders	54,876.46
<b>VI. Waivers and cancellations of amounts receivable</b>	
Recovery orders waived or cancelled by the authorising officer in accordance with Article 62 Financial Regulation	0.00
<b>VII. Waivers of fees and charges (excluding waivers for orphan medicines )</b>	
Reductions deriving from paediatric or micro, small- and medium sized enterprises, advanced therapies and variations legislation	13,723,291.04
Other reductions in accordance with Article 9 of the Fee Regulation	3,824,301.20

### 2.3. Expenditure (commitments and payments)

Commitments totalled EUR 297,012,705.56 or 96.30% of final appropriations (2015: 94.05%). Payments totalled EUR 253,980,400.73 or 85.51% of commitments entered into (2015: 87.09%). For details on the implementation of expenditure see Table 2.

Chart 2 below provides a breakdown of types of expenditure by chapter and selected key articles.

**Chart 2: breakdown of expenditure by type (chapter or article)**



**Table 2 Implementation of 2016 expenditure appropriations**

Appropriation type	EUR or %
<b>I. Appropriations in general</b>	
Initial appropriations	324,711,000.00
Amending budget	-16,289,000.00
Final appropriations	308,422,000.00
<b>II. Use of 2016 appropriations</b>	
Commitments*	297,012,705.56
Representing of final appropriations	96.30%
Payments	253,980,400.73
Representing of final commitments	85.51%
<b>III. Carry-over from 2016 to 2017</b>	
<i>Carry-over of administrative appropriations</i>	4,161,798.37
<i>Carry-over of operational appropriations</i>	38,870,506.46
Total automatic carry-over	43,032,304.83
Representing of final appropriations	13.95%
Representing of final commitments	14.49%
<b>IV. Cancellation of 2016 appropriations</b>	
Appropriations cancelled	11,409,294.44
Representing of final appropriations	3.70%
<b>V. Carry-over from 2015 to 2016</b>	
<b>Automatic carry-over, C8</b>	
<i>Carry-over of administrative appropriations</i>	4,644,241.17
<i>Carry-over of operational appropriations</i>	32,776,728.97
Total automatic carry-over	37,420,970.14
Payment against carry-over	35,753,697.89
Total automatic carry-over unused	1,667,272.25
Representing of carry-over	95.54%
<b>Non-automatic carry-over, C2</b>	
Non-automatic carry-over to 2016	5,398,000.00
Payment against carry-over	4,417,680.00
Carry-over to 2017, C8	115,974.90
Amount cancelled	980,320.00
Representing of carry-over	81.84%
* note that the figure reported to the budget authority includes EUR 115,974.90 which in this table are reported under C2, as per SAP.	

## 2.4. Appropriations carried forward from 2016 to 2017

Automatic carry-forward to financial year 2017 totalled EUR 43,032,304.83 or 13.71% of appropriations (total carried forward from 2015 to 2016, both automatically and non-automatically: EUR 48,818,970.14 or 13.90%).

There was no non-automatic carry-forward to 2017.

**Table 3** Automatic carry-over from 2016 to 2017, per title

automatic carry-forward to 2017, originally C1 and C2			
Title	Total commitments	of which carried over	
	EUR	EUR	%
1 : Staff	110,729,047.31	957,021.58	0.86%
2 : Building and equipment	40,406,994.08	3,204,776.79	7.93%
3 : Operational expenditure*	150,294,344.17	38,870,506.46	25.86%
<b>Total</b>	<b>301,430,385.56</b>	<b>43,032,304.83</b>	<b>14.28%</b>

\* includes a total of EUR 115,974.90 on budget items 3030 and 3105 booked as C2 appropriations in 2016

## 2.5. Implementation of appropriations carried forward from 2015 to 2016

Automatic carry-forward from financial year 2015 to 2016, *i.e.*, fund source C8, totalled EUR 37,420,970.14. Payments against the C8 appropriations equalled EUR 35,753,697.89 or 95.54% (2015: 93.95%) and EUR 1,667,272.25 were cancelled.

Non-automatic carry-forward from financial year 2015 to 2016, *i.e.*, fund source C2, totalled EUR 5,398,000.00. A total of EUR 4,301,705.10 was paid in 2016 and EUR 115,974.90 carried forward for payment in 2017, resulting in the cancellation of appropriations totalling EUR 980,320.00. The cancellation was mainly due to the fact that, despite our best efforts, some of the contracts were not ready for signature and commitment by the end of March 2016, the final date for commitment under the Financial Regulation.

## 2.6. Appropriations from external assigned revenue

The Agency introduced assigned revenue, fund source R0, in 2014 in order to manage the inducements received in the context of the project to construct, fit-out and occupy its new headquarters.

In 2016, an amount of EUR 15,230,149.24 was recognised as assigned revenue, from landlord inducements related to the project for the new headquarters. This amount covered all rent cost incurred in 2016. The remainder of the inducements will cover rent cost for most of 2017, depending on the strength of Sterling against the euro.

## 2.7. Budget transfers

In line with Article 27(1) of the Financial Regulation, the Executive Director may make unlimited transfers within a title and of up to 10% of appropriations from one title to another. Transfers *per se* are not an indicator of deficiencies in financial management but are a necessary tool to adjust the budget in a changing environment, as illustrated, *e.g.*, by the use of interim staff instead of contract staff, increased expenditure due to exchange rate fluctuation, etc. Only if and when the changes also relate to changes in the work programme might they indicate shortcomings in the planning process.



During 2016 twelve transfers were made. All were adjustments within the limits of Article 27(1) of the Financial Regulation, *i.e.*, transfers within titles, and therefor approved by the Executive Director. They totalled EUR 9,268,000 or 3.00% of final appropriations. All involved expenditure appropriations.

The transferred expenditure appropriations were primarily needed to cover increased expenditure on business IT development, increased appropriations for rapporteurs and pharmacovigilance services and reduction of appropriations where expenditure is mainly paid in pound Sterling.

Annex V provides details of all transfers carried out in 2016.

## 2.8. Cancellation of appropriations

Expenditure appropriations should be understood as estimates of requirements, and not as an entitlement to create the corresponding commitments. Being reliant on fee income, as the agency is, means that the level of cancelled expenditure appropriations does not indicate delays in the implementation of the work programme but should be considered rather as the result of stringent monitoring of actual revenue and adjustments to the expenditure.

In budget 2016, expenditure appropriations totalling EUR 11,409,294.44 remained unused, corresponding to 3.70% of final appropriations (2015: EUR 12,927,191.98, 4.20%).

This unused amount must be seen in conjunction with collected revenue being EUR 3,323,302.45 (1.08%) below budget revenue appropriations, while still resulting in a positive overall outturn balance (before adjustments for exchange rate, cancellations of carry-over, etc.) of EUR 7,970,017.09 or 2.58% of final appropriations (2015: 8,964,611.10, 2.9%).

## 2.9. Payment of interest on late payments

In compliance with the agency's standard contract, established in accordance with Article 77 of the Financial Regulation, the terms of payment are 30 days upon receipt of a valid invoice. If these terms are not respected, from day 31 until the actual day of payment, the payment accrues default interest at the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of the Official Journal of the European Union, increased by 8%<sup>1</sup>. The default interest accrued is paid automatically to the supplier/contractor if it amounts to more than EUR 200 at the time of payment of the valid invoice.

In 2016, 466 payments out of a total of 57,738, *i.e.* 0.81% of all payments, were made later than 30 days after receipt of a valid invoice (2015: 0.27% of all payments). This resulted in default interest of EUR 1,208.00 being paid to suppliers and contractors.

**Table 4** Breakdown of late payments and default interest

	Payments		Of which late payments		Interest accrued	Interest => EUR 200
	Number	EUR	Number	EUR	EUR	EUR
Supply and other services	43,964	188,712,761	466	5,049,072	6,141	1,208
Evaluation services (NCAs)	13,774	114,507,874	0	0	0	0
(*) gross amounts paid to third parties, including VAT and taxes						

<sup>1</sup> in accordance with Article 92 of the Financial Regulation applicable to the Budget of the Union and Articles 83(2) and 111 of its Rules of Application

### 3. Financial management by chapter

Hereafter follows an analysis of the evolution of revenue (based on cash collected) and expenditure (based on commitments) in 2016. It contains information at title level for revenue and expenditure. Detailed information per chapter, of both revenue and expenditure, can be found at Annexes I-III.

#### 3.1. Revenue

##### 3.1.1. Stable vs. cyclical revenue

In budgetary terms, EUR 115.6 million (37.89% of total 2016 revenues) represent the proportion which can be considered stable, since it relates to annual product maintenance fees received for both human and veterinary medicines activities, EU and EEA contributions as well as externally assigned revenue. In 2016, 62.11% of total revenue thus depended on cyclical business activities.

**Table 5** Stable and cyclical sources of revenue

	2015 Actual	% of total	2016 Actual	% of total
Stable revenue for the Agency	126,541,607	41.61%	115,597,939	37.89%
<i>EU subsidies and contributions</i>	33,934,672	11.16%	14,862,990	4.87%
<i>External assigned revenue</i>	17,558,761	5.77%	15,276,322	5.01%
<i>Annual fees</i>	75,048,174	24.68%	85,458,627	28.01%
Cyclical business revenue	176,441,999	58.02%	187,129,585	61.33%
Revenue from miscellaneous activities	1,134,625	0.37%	2,371,174	0.78%
Total revenue	304,118,230	100.00%	305,098,698	100.00%

##### 3.1.2. Cancellation of recovery orders / acceptance requests

Article 62(5) of the Financial Regulation stipulates that recovery orders which have been issued can, under certain, well-defined circumstances, be cancelled by the authorising officer.

In 2016, no recovery orders were issued and subsequently cancelled.

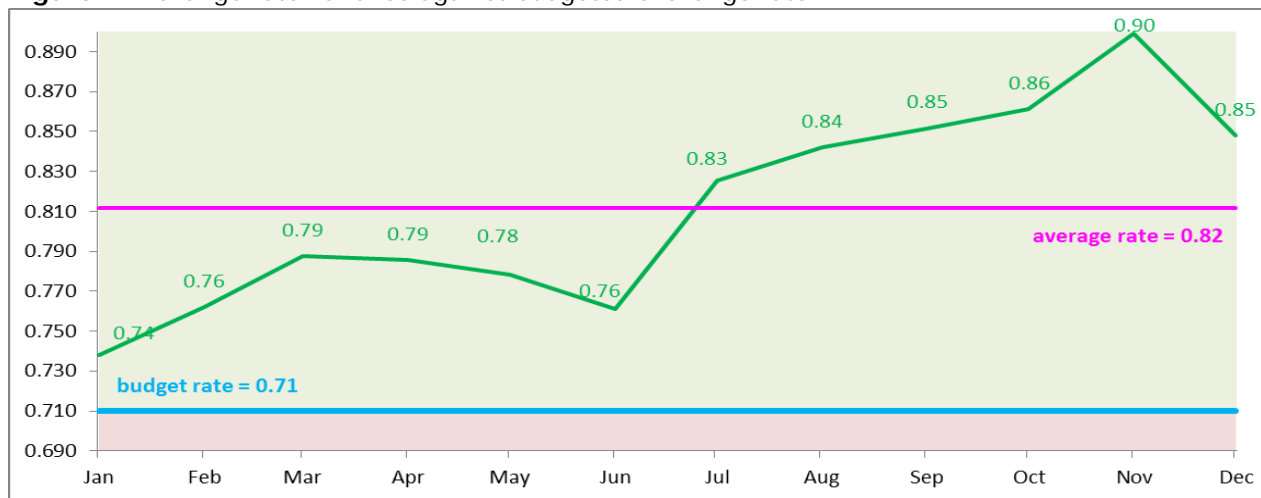
#### 3.2. Expenditure

##### 3.2.1. Exchange rate impact on the budget

Whereas the revenue of the agency is in Euro (EUR), administrative expenditure is mainly paid in Pounds Sterling (GBP). Throughout 2016 there was an overall decrease in the value of Sterling expressed in Euro, compared to the exchange rate used for the establishment of the budget. This resulted in decreased EUR expenditure, in particular in titles 1 and 2 of the budget.

The weakening of Sterling and the reduced estimate of fee applications were the main justification for one Amending Budget in 2016, which decreased expenditure appropriations on budget items 1190 (weighting on salaries) and 2000 (rent) as well as on items 3010 and 3013 (evaluation activities).

**Figure 1** Exchange rate variance against budgeted exchange rate



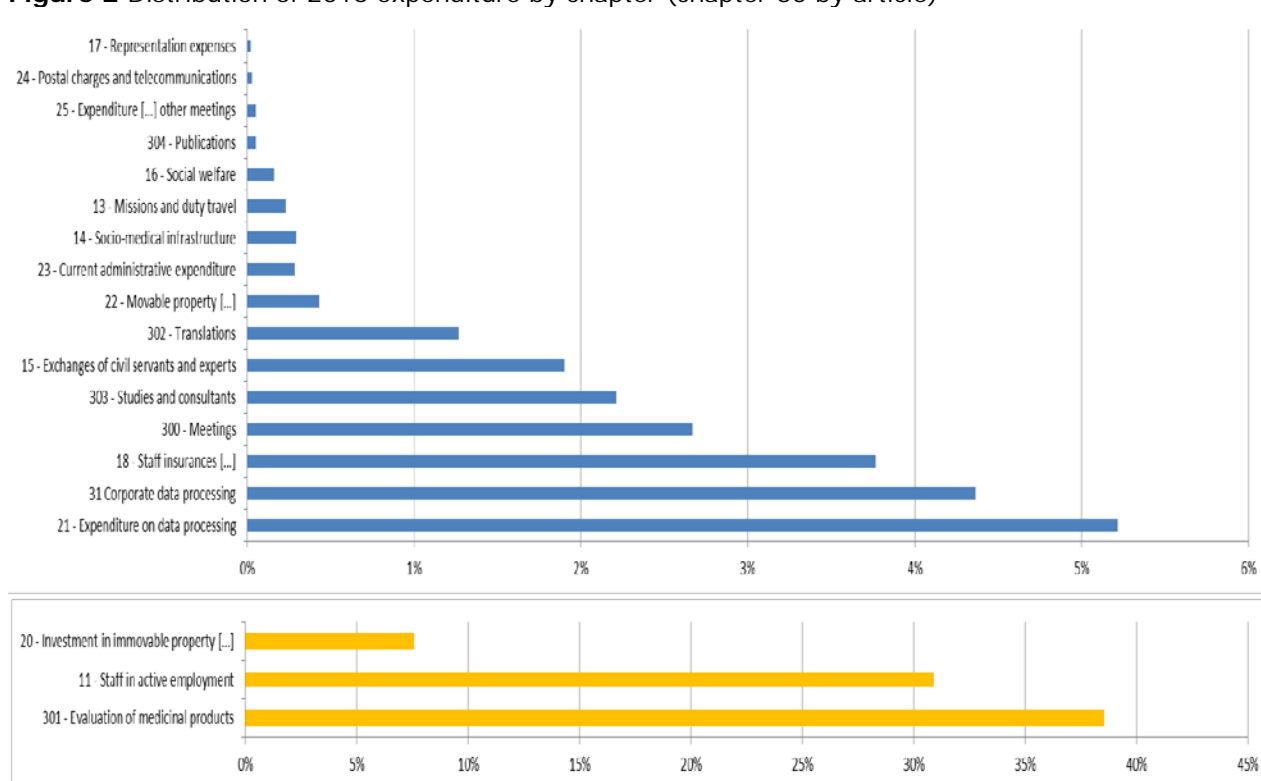
### 3.2.2. Details on expenditure items

In 2016 the four chapters and articles with the highest amounts committed accounted for 82.27% of total commitments (2015: 84.30% of total commitments). They were:

- Chapter 11 'Staff in active employment' (2016: 30.91%)
- Chapter 20 'Investments in immovable property, renting of buildings and associated costs' (2016: 7.59%)
- Chapter 21 'Expenditure for corporate data processing' (2016: 5.22%) and
- Article 301 'Evaluation of medicinal products' (2016: 38.55%).

Detailed information at chapter and article level can be found at Annex II.

**Figure 2** Distribution of 2016 expenditure by chapter (chapter 30 by article)



## Annex I – Budget evolution

Title Chapter/Article /Item	Heading	VOTED BUDGET (Dec 2015)		AMENDMENTS/TRANSFERS		DIFFERENCE	DESCRIPTION	FINAL BUDGET	
		Commitment appropriations (in EUR)	Payment appropriations (in EUR)	Commitment appropriations (in EUR)	Payment appropriations (in EUR)	%		Commitment appropriations (in EUR)	Payment appropriations (in EUR)
<b>REVENUE</b>									
100	FEES COLLECTED	248,716,000	248,716,000	-4,875,000	-4,875,000	-1.96%	Reduced following review of expected numbers of applications to be submitted.	243,841,000	243,841,000
101	FEES COLLECTED, PHV	28,245,000	28,245,000	-1,496,000	-1,496,000	-5.30%	Reduced following review of expected numbers of applications to be submitted.	26,749,000	26,749,000
200	EU CONTRIBUTION ORPHAN MEDICINAL PRODUCTS	11,690,000	11,690,000	-9,652,000	-9,652,000	-82.57%	Less balancing contribution needed in view of lower expenditure on rapporteurs and Sterling based expenditure.	2,038,000	2,038,000
201	CONTRIBUTION	12,785,000	12,785,000	0	0	0.00%	No change.	12,785,000	12,785,000
30	EEA CONTRIBUTION	676,000	676,000	-266,000	-266,000	-39.35%	EEA contributions are calculated as a percentage of general EU contribution (2.74% in 2016) and was reduced as a consequence of the lower balancing contribution received.	410,000	410,000
50	REVENUE FROM ADMIN. ACTIVITIES & ANCILLARY SERVICES	90,000	90,000	0	0	0.00%	No change.	90,000	90,000
60	EXTERNAL ASSIGNED REVENUE FOR PROJECTS & PROGRAMMES	19,559,000	19,559,000	0	0	0.00%	No change.	19,559,000	19,559,000
70	BALANCE OF OUTTURN ACCOUNT OF PREVIOUS YEARS	1,950,000	1,950,000	0	0	0.00%	No change.	1,950,000	1,950,000
90	MISCELLANEOUS REVENUE	1,000,000	1,000,000	0	0	0.00%	No change.	1,000,000	1,000,000
<b>TOTAL</b>		<b>324,711,000</b>	<b>324,711,000</b>	<b>-16,289,000</b>	<b>-16,289,000</b>	<b>-5.02%</b>		<b>308,422,000</b>	<b>308,422,000</b>

Title Chapter/Article /Item	Heading	VOTED BUDGET (Dec 2015)		AMENDMENTS/TRANSFERS		DIFFERENCE	DESCRIPTION	FINAL BUDGET	
		Commitment appropriations (in EUR)	Payment appropriations (in EUR)	Commitment appropriations (in EUR)	Payment appropriations (in EUR)	%		Commitment appropriations (in EUR)	Payment appropriations (in EUR)
<b>EXPENDITURE</b>									
11	STAFF IN ACTIVE EMPLOYMENT	102,365,000	102,365,000	-9,346,000	-9,346,000	-9.13%	Lower Sterling expenditure due to the weakening pound.	93,019,000	93,019,000
13	DUTY TRAVEL	640,000	640,000	70,000	70,000	10.94%	More duty travel undertaken than initially planned.	710,000	710,000
14	SOCIO-MEDICAL INFRASTRUCTURE	870,000	870,000	11,000	11,000	1.26%	To cover an increased number of medicals.	881,000	881,000
15	EXCHANGE OF CIVIL SERVANTS AND EXPERTS	6,962,000	6,962,000	-810,000	-810,000	-11.63%	Fewer than planned SNEs.	6,152,000	6,152,000
16	SOCIAL WELFARE	483,000	483,000	20,000	20,000	4.14%		503,000	503,000
17	REPRESENTATION EXPENSES	40,000	40,000	60,000	60,000	150.00%		100,000	100,000
18	SOCIAL SECURITY FOR STAFF	11,314,000	11,314,000	-62,000	-62,000	-0.55%		11,252,000	11,252,000
<b>TITLE I</b>		<b>122,674,000</b>	<b>122,674,000</b>	<b>-10,057,000</b>	<b>-10,057,000</b>	<b>-8.20%</b>		<b>112,617,000</b>	<b>112,617,000</b>
20	INVESTMENT IN IMMOVABLE PROPERTY, RENTING OF BUILDINGS & ASSOC. COST	28,244,000	28,244,000	-867,000	-867,000	-3.07%	Lower cost due to falling value of Sterling.	27,377,000	27,377,000
21	CORPORATE DATA PROCESSING & TELECOMMUNICATIONS	18,023,000	18,023,000	-1,799,000	-1,799,000	-9.98%		16,224,000	16,224,000
22	MOVABLE PROPERTY & ASSOC. COST	1,785,000	1,785,000	24,000	24,000	1.34%		1,809,000	1,809,000
23	CURRENT ADMIN. EXPENDITURE	1,288,000	1,288,000	-160,000	-160,000	-12.42%		1,128,000	1,128,000
24	POSTAL CHARGES	183,000	183,000	0	0	0.00%		183,000	183,000
25	FORMAL & OTHER MEETINGS	54,000	54,000	117,000	117,000	216.67%		171,000	171,000
<b>TITLE II</b>		<b>49,577,000</b>	<b>49,577,000</b>	<b>-2,685,000</b>	<b>-2,685,000</b>	<b>-5.42%</b>		<b>46,892,000</b>	<b>46,892,000</b>
300	MEETINGS	9,435,000	9,435,000	-1,498,200	-1,498,200	-15.88%	Lower cost due to fallings value of Sterling	7,936,800	7,936,800
3010	EVALUATION OF MEDICINAL PRODUCTS	107,327,000	107,327,000	-1,070,000	-1,070,000	-1.00%	Fewer applications, requiring less appropriation to pay rapporteurs	106,257,000	106,257,000
3013	EVALUATION OF PHV PROCEDURES	11,815,000	11,815,000	-570,000	-570,000	-4.82%	Fewer applications, requiring less appropriation to pay rapporteurs	11,245,000	11,245,000
302	TRANSLATION EXPENDITURE	5,270,000	5,270,000	-1,499,900	-1,499,900	-28.46%	Few applications to be translated, more cost-effective requests for translation.	3,770,100	3,770,100
303	STUDIES & CONSULTANTS	7,862,000	7,862,000	-1,273,900	-1,273,900	-16.20%	Less expenditure on business consultants and postponement of some scientific studies.	6,588,100	6,588,100
304	INFORMATION & PUBLICATION	274,000	274,000	-120,000	-120,000	-43.80%		154,000	154,000
31	BUSINESS RELATED IT PROJECTS	10,477,000	10,477,000	2,485,000	2,485,000	23.72%	To prepare for full commitment up-front of fixed price contracts extending into 2017.	12,962,000	12,962,000
<b>TITLE III</b>		<b>152,460,000</b>	<b>152,460,000</b>	<b>-3,547,000</b>	<b>-3,547,000</b>	<b>-2.33%</b>		<b>148,913,000</b>	<b>148,913,000</b>
<b>TOTAL</b>		<b>324,711,000</b>	<b>324,711,000</b>	<b>-16,289,000</b>	<b>-16,289,000</b>	<b>-5.02%</b>		<b>308,422,000</b>	<b>308,422,000</b>

## Annex II – Detailed revenue overview, evolution

Item	Heading	2015	2016	Change		Comment
		EUR	EUR	EUR	%	
1000	Fees collected (Regulation (EU) 297/95)	229,851,310.88	244,748,932.04	14,897,621.16	6.48%	Fee income from evaluation services is the main source of revenue for the agency, representing 80.23% of 2016 revenue (2015: 75.58%). The value of recovery orders / invoices for fees, reflecting the level of activities, rose by 6.48% when compared to 2015, whereas the value of cash-receipts was stable, increasing by only 0.3%. The difference between the value of fee-related cash receipts and recovery orders is due to the decrease in the value of recovery orders raised in 2016 for which revenue will only be cashed in the following years (from EUR 45.5 mio. in 2015 to EUR 44.9 mio. in 2016). Appropriations were reduced by EUR 4,875,000 through an amending budget.
1001	Fees collected (Regulation (EU) 658/2014)	21,638,861.94	27,839,279.42	6,200,417.48	28.65%	Fees are charged for PSUR, PASS and referral procedures and involve more than approx. 4,000 companies across Europe. The chapter accounted for 9.13% in 2016 (2015: 7.12%). Appropriations were reduced by EUR 1,936,000 through an amending budget.
2000	European Union contribution	18,668,607.31	2,037,869.78	-16,630,737.53	-89.08%	This article accounted for 0.67% of 2016 revenues (2015: 6.14%). The contribution from the European Union budget decreased by 89.08% between 2015 and 2016.
2010	Special contribution for orphan medicinal products	13,212,250.00	12,768,875.00	-443,375.00	-3.36%	This article accounted for 4.19% of 2016 revenue (2015: 4.34%). EUR 369,125 (2.81%) remained uncollected.
3000	EEA contribution	554,457.69	56,245.22	-498,212.47	-89.86%	This chapter covers the compensation received for the participation of EEA countries in the agency's activities. It accounted for 0.02% of 2016 revenue (2015: 0.18%). The actual amount receivable is calculated as a percentage of the general contribution, i.e. the EU contributions excluding EU contribution derived from agency surplus and EU contribution earmarked for compensation of orphan fee reductions. The percentage used for 2016 was 2.76%.
5200	Revenue from administrative operations and ancillary services	107,548.90	72,541.06	-35,007.84	-32.55%	Chapter 52 includes the income from administrative charges as well as bank interest. The chapter accounted for 0.01% of 2016 revenues (2015: 0.04%).
6000	External assigned revenue for projects and programmes	17,558,760.53	15,276,321.70	-2,282,438.83	-13.00%	This chapter accounted for 5.017% of 2016 revenues (2015: 5.77%). The bulk of the revenue, EUR 15,230,149.24 relates to the inducement paid by the landlord. Grant related revenue, constituting 0.30% of total assigned revenue, was received from the IMI FluCop programme via IMI-JU (Innovative Medicines Initiative Joint Undertaking), an Executive Office of the European Union, and from the grant manager for the FP7-GRIP programme.
7000	Balance of outturn account of previous year	1,499,357.43	1,949,934.18	450,576.75	30.05%	This chapter accounted for 0.64% of 2016 revenues (2015: 0.49%). Any surplus (positive outturn) from the previous budget year is posted here.
9000	Miscellaneous revenue	1,027,075.81	348,699.15	-678,376.66	-66.05%	This chapter accounted for 0.11% of 2016 revenues (2015: 0.34%). The bulk of the appropriations relates to refunds related to corrections of rapporteur payments and a reduction of building service charges.
<b>Total</b>		<b>304,118,230.49</b>	<b>305,098,697.55</b>	<b>980,467.06</b>	<b>0.32%</b>	

## Annex III – Detailed expenditure overview, evolution

Chapter	Heading	2015	2016	2016	Change 2015-2016		2016 budget v/commitments		Comment
		EUR commitments	EUR final budget	EUR commitments	EUR	%	EUR	%	
11	Staff in active employment	94,091,430.58	93,019,000.00	91,820,944.70	-2,270,485.88	-2.41%	-1,198,055.30	-1.29%	Chapter 11 accounted for 30.91% of 2016 expenditure (2015: 31.88%), constituting the second largest share of expenditure. 44.37% of chapter 11 expenditure related to item 1100 'basic salaries' and 31.75% to 1190 'weightings' (2015: 41.32% and 31.75%). For these two items commitments amounted to EUR 68,799,926.63. A net total of EUR 1,099,000.00 was transferred out of the chapter. Appropriations were reduced by EUR 8,247,000.00 through an amending budget.
13	Missions and duty travel	623,414.45	710,000.00	682,607.16	59,192.71	9.49%	-27,392.84	-3.86%	This chapter accounted for 0.23% of 2016 expenditure with a total of 700 duty trips carried out (2015: 0.21% and 829 trips). The chapter was reinforced by a net amount of EUR 70,000 through transfer.
14	Socio-medical infrastructure	782,736.37	881,000.00	865,421.56	82,685.19	10.56%	-15,578.44	-1.77%	This chapter accounted for 0.29% of 2016 expenditure. While expenditure on catering decreased, socio-medical expenditure increased by The chapter was reinforced by a total of EUR 11,000 through transfer.
15	Exchanges of civil servants and experts	5,105,419.71	6,152,000.00	5,646,529.71	541,110.00	10.60%	-505,470.29	-8.22%	This chapter accounted for 1.90% of 2016 expenditure (2015: 1.73%). Compared to 2015 there was an increase in the number of national experts on secondment on a full-time equivalent (FTE) basis, up from 32.5 in 2015 to 38. The number of trainees increased from 46.4 to 64 (FTE) with the length of traineeships being 12 months. Appropriations were reduced by EUR 810,000 through an amending budget.
16	Social welfare	528,382.75	503,000.00	471,675.28	-56,707.47	-10.73%	-31,324.72	-6.23%	Chapter 16 accounted for 0.16% of 2016 expenditure (2015: 0.18%). The decrease in expenditure is due to the weakening of Sterling against the Euro during 2016. The chapter was reinforced by EUR 20,000 through transfer.
17	Representation expenses	137,166.58	100,000.00	55,535.04	-81,631.54	-59.51%	-44,464.96	-44.46%	Chapter 17 accounted for 0.02% of 2016 expenditure (2015: 0.05%). The decrease was caused by the expenditure reverting to its longer-term level, after the additional activities related to the Agency's anniversary celebrations in 2015. The chapter was reinforced by EUR 60,000 through transfer.
18	Staff insurances [...]	2,382,121.09	11,252,000.00	11,186,333.86	8,804,212.77	369.60%	-65,666.14	-0.58%	Chapter 18 accounted for 3.77% of 2016 expenditure (2015: 0.81%). Compared to 2015, expenditure increased by 369.6% in 2016. This considerable increase was mainly caused by the payment of employer's pension contributions to the European Commission's pension office, as required by the Staff Regulations. A net amount of EUR 62,000.000 was transferred out of the chapter.
<b>Title I</b>		<b>103,650,671.53</b>	<b>112,617,000.00</b>	<b>110,729,047.31</b>	<b>7,078,375.78</b>	<b>6.83%</b>	<b>-1,887,952.69</b>	<b>-1.68%</b>	

Chapter	Heading	2015		2016	Change 2015-2016		2016 budget v/commitments		Comment
		EUR		EUR	EUR	%	EUR	%	
20	Investment in immovable property, renting of buildings [...]	30,262,654.48	27,377,000.00	22,529,081.41	-7,733,573.07	-25.55%	-4,847,918.59	-17.71%	to 10.26% in 2015. The decreased expenditure is due to the fit-out the agency's new headquarters almost being fully paid. The final payment will now only take place in 2017. Appropriations were reduced by EUR 500,000 through an amending budget and a further net total of EUR 367,000 was transferred out of the chapter.
21	Expenditure on data processing	16,522,168.87	16,224,000.00	15,502,356.07	-1,019,812.80	-6.17%	-721,643.93	-4.45%	Chapter 21 accounted for 5.22% of 2016 expenditure (2015: 5.60%). The decrease in IT expenditure in chapter 21 was mainly due to lower than expected expenditure on hardware and software. A net total of EUR 1,799,000 was transferred out of the chapter.
22	Movable property [...]	1,337,401.81	1,809,000.00	1,284,231.46	-53,170.35	-3.98%	-524,768.54	-29.01%	Chapter 22 accounted for 0.29% of 2016 expenditure (2015: 0.45%). The decrease in expenditure in 2016 was due to no further investment in furniture taking place. The chapter was reinforced by a net total of EUR 280,000 through transfer. Appropriations were reduced by EUR 256,000 through an amending budget.
23	Current administrative expenditure	1,144,954.07	1,128,000.00	846,907.38	-298,046.69	-26.03%	-281,092.62	-24.92%	This chapter accounted for 0.29% of 2016 expenditure (2015: 0.39%). The decrease in expenditure was mainly due to a decrease in expenditure on damages. A net total of EUR 160,000 was transferred out of the chapter.
24	Postal charges and telecommunications	108,228.18	183,000.00	92,711.23	-15,516.95	-14.34%	-90,288.77	-49.34%	This chapter accounted for 0.03% of 2016 expenditure (2015: 0.04%). The decrease in expenditure was due to lower consumption as well as exchange rate gains.
25	Expenditure on formal and other meetings	46,478.34	171,000.00	151,706.53	105,228.19	226.40%	-19,293.47	-11.28%	This chapter accounted for 0.05% of 2016 expenditure (2015: 0.02%). The increase was due to an increase in the cost of memberships to fora. The chapter was reinforced by EUR 117,000 through transfer.
<b>Title II</b>		<b>49,421,885.75</b>	<b>46,892,000.00</b>	<b>40,406,994.08</b>	<b>-9,014,891.67</b>	<b>-18.24%</b>	<b>-6,485,005.92</b>	<b>-13.83%</b>	
Chapter	Heading	2015	2016	2016	Change 2015-2016		2016 budget v/commitments		Comment
		EUR commitments	EUR final budget	EUR commitments	EUR	%	EUR	%	
300	Meetings	7,993,129.98	7,936,800.00	7,924,059.03	-69,070.95	-0.86%	-12,740.97	-0.16%	Article 3000 accounted for 2.67% of 2016 expenditure (2015: 2.71%). Compared to 2015, expenditure decreased by 0.86%. A total of EUR 690,200 was transferred away from the article. Appropriations were reduced by EUR 808,000 through an amending budget.
301	Evaluation of medicinal products	107,951,698.35	117,502,000.00	114,508,871.21	6,557,172.86	6.07%	-2,993,128.79	-2.55%	Article 301 accounted for 38.55% of 2016 expenditure (2015: 36.58%). Between 2015 and 2016 expenditure in absolute terms increased by approx. EUR 6.5 million, with approx. EUR 6 million for evaluations and EUR 0.5 million for pharmacovigilance services). competent authorities. The chapter was reinforced by EUR 2,930,000 through transfer. Appropriations were reduced by EUR 4,570,000 through an amending budget.
302	Translations	3,741,676.40	3,770,100.00	3,759,288.00	17,611.60	0.47%	-10,812.00	-0.29%	Article 302 accounted for 1.27% of 2016 expenditure (2015: 1.27%). A total of EUR 401,900 was transferred away from the article, with a further reduction of appropriations by EUR 1,098,000 through an amending budget.
303	Studies and consultants	8,150,847.87	6,588,100.00	6,570,331.47	-1,580,516.40	-19.39%	-17,768.53	-0.27%	This article accounted for 2.21% of 2016 expenditure (2015: 2.76%). The decrease in expenditure is due to reduced business consultancy expenditure on projects which were delayed or postponed. A total of EUR 1,273,900 was transferred away from the article.
304	Publications	138,289.73	154,000.00	152,114.46	13,824.73	10.00%	-1,885.54	-1.22%	This article accounted for 0.05% of 2016 expenditure (2015: 0.05%). The decrease in expenditure is mainly due to the weakening of Sterling against the Euro 1 2016. A total amount of EUR 120,000 was transferred away from the article.
31	Business related IT projects	14,105,977.89	12,962,000.00	12,962,000.00	-1,143,977.89	-8.11%	0.00	0.00%	This article accounted for 4.36% of 2016 expenditure (2015: 4.78%). The decrease in expenditure can be explained by a number of projects being delayed during the year. Overall IT expenditure (chapters 21 and 31) decreased by 7.06%, compared to 2015. The chapter was reinforced by a total of EUR 2,485,000 to allow for a number of fixed-price contract to be put in place before the end of the year.
<b>Title III</b>		<b>142,081,620.22</b>	<b>148,913,000.00</b>	<b>145,876,664.17</b>	<b>3,795,043.95</b>	<b>2.67%</b>	<b>-3,036,335.83</b>	<b>-2.04%</b>	
	<b>Total</b>	<b>295,154,177.50</b>	<b>308,422,000.00</b>	<b>297,012,705.56</b>	<b>1,858,528.06</b>	<b>0.63%</b>	<b>-11,409,294.44</b>	<b>-3.70%</b>	



## Annex IV – Amending budget

<b>Part I</b>					
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</b>	<b>Revenue from services rendered</b>				
<b>Chapter 10</b>	<b>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</b>	<b>European Union contribution</b>				
<b>Chapter 20</b>	<b>European Union contribution</b>				
2000R	European Union contribution	€ 18,668,607	€ 11,690,000	-€ 1,986,000	€ 9,704,000
<b>Title 3</b>	<b>EEA contribution</b>				
<b>Chapter 30</b>	<b>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</b>	<b>Staff in active employment</b>				
<b>Chapter 11</b>	<b>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</b>	<b>Buildings, equipment and miscellaneous operating expenditure</b>				
<b>Chapter 20</b>	<b>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</b>	<b>Operating expenditure</b>				
<b>Chapter 30</b>	<b>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>	
<b>Part II</b>					
<b>REVENUE</b>					
<b>Title 2</b>	<b>European Union contribution</b>				
<b>Chapter 20</b>	<b>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</b>	<b>Staff in active employment</b>				
<b>Chapter 11</b>	<b>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>	

## Annex V – Summary of transfers

Transfers carried out in accordance with Article 27(1) and (2) of the Financial Regulation.

Annex III Summary of transfers in accordance with Art. 23 (1) and (2) of the Financial Regulation					
No.	From/To item	Item No.	Item Heading	Amount of receiving item	Amount of donating item
01	from	2330	Legal expenses	0	90,000
	to	2340	Damages	90,000	0
02	from	2090	Other expenditure on buildings	0	437,000
	to	2080	Other expenditure related to construction or fitting out of a building	320,000	0
	to	2501	Membership to for a	117,000	0
03	from	2000	Rent		995,000
	to	2080	Other expenditure related to construction or fitting out of a building	995,000	0
04	from	1101	Family allowances	0	318,000
	from	1830	Insurance against sickness, accidents & occupational disease, unemployment insurance & pension	0	322,000
	to	1120	Further training, language courses and re-training	120,000	0
	to	1175	Interim services	520,000	0
05	from	1102	Expatriation and foreign residence allowance	0	20,000
	to	1172	Miscellaneous insurances relating to staff activities	20,000	0
06	from	1100	Basic salaries	0	40,000
	from	2203	Lease, maintenance & repair of technical equipment & installations	0	10,000
	to	1410	Medical service	40,000	0
	to	2210	Furniture	10,000	0
07	from	2114	Maintenance & support of corporate applications	0	650,000
	to	2110	Hardware & software for corporate processes	650,000	
08	from	1101	Family allowances	0	121,000
	from	1400	Restaurant & canteens	0	60,000
	from	2020	Water, gas, electricity & heating	0	120,000
	from	2300	Stationery & office supplies	0	60,000
	from	2359	Other operating expenditure	0	100,000
	to	1300	Duty travel	70,000	0
	to	1410	Medical service	31,000	0
	to	1610	Social contact between staff	20,000	0
	to	1700	Representation expenses	60,000	0
	to	2210	Furniture	280,000	0

No.	From/To item	Item No.	Item Heading	Amount of receiving item	Amount of donating item
09	from	1100	Basic salaries	0	250,000
	to	1114	Basic salaries & allowances for contract agents	250,000	0
10	from	1101	Family allowances	0	260,000
	from	3030	Studies & consultants	0	430,000
	to	1830	Insurance against sickness, accidents & occupational disease, unemployment insurance & pension	260,000	0
	to	3013	Evaluation of pharmacovigilance procedures	430,000	0
11	from	2110	Hardware & software for corporate processes	0	130,000
	from	2114	Maintenance & support of corporate applications	0	1,669,000
	from	3000	Reimbursement of persons attending meetings	0	200,300
	from	3002	Catering	0	39,900
	from	3020	Translation Centre, Luxembourg	0	116,800
	from	3021	Other translations	0	25,100
	from	3030	Studies & consultants	0	47,700
	from	3031	Subscriptions to specialised research	0	186,200
	from	3040	Information & publications	0	70,000
	to	3105	Business IT development	2,485,000	0
12	from	1190	Weightings	0	1,000,000
	from	2030	Maintenance & cleaning	0	130,000
	from	3000	Reimbursement of persons attending meetings	0	330,000
	from	3003	Other expenditure in relation to meetings	0	120,000
	from	3020	Translation Centre, Luxembourg	0	220,000
	from	3021	Other translations	0	40,000
	from	3030	Studies & consultants	0	610,000
	from	3040	Information & publications	0	50,000
	to	3010	Evaluation of medicinal products	2,500,000	0
			<b>Total amount of transfers</b>	<b>9,268,000</b>	<b>9,268,000</b>