

27 March 2019 EMA/871245/2018 Executive Director

# Report on budgetary and financial management

Financial year 2018

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## 1. Introduction

This report summarises the outcomes of the budgetary and financial management carried out by the European Medicines Agency during the financial year 2018. It outlines the financial situation, budget evolution and the events which had a significant influence on activities during the year.

It provides qualitative and quantitative 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 89.62% of its 2018 revenue stemming from fees paid by the pharmaceutical industry, for services provided.

#### Highlights for 2018

- ✓ The financial consequences of Brexit, i.e. the Agency's departure from the UK and move to the Netherlands began to be felt in 2018, with reported expenditure amounting to EUR 25.9 million. A reporting mechanism was put in place to enable close monitoring. Point 3.2.1 below provides more detailed information.
- ✓ The budgetary outturn, a surplus of approx. EUR 13.80 million, was caused mainly by lower than budgeted staff expenditure (contract agent recruitments not materialising and over-estimated cost of national experts on secondment, interim services and relocation visits), reduced payments to national competent authorities (NCAs), reduced expenditure as a result of the business continuity plan (BCP), which was put in place to prepare for the agency's departure from the UK (Brexit), and some major IT projects being postponed or delayed.
- ✓ In order to comply with the provisions of the Financial Regulation, and in particular its 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. As a result, commitments made in 2017 totalling EUR 2.4 million expired in 2018 and had to be re-committed on new appropriations. It is expected that there could be a similar impact in future years, increasing the amount of cancellation of carry-forward.
- ✓ The agency managed to comply with the ceilings/KPIs for the amounts carried forward: title I (10%), title II (20%) and title III (30%), with the following percentages achieved for the automatic carry-forward: title I: 1.23%, title II: 16.31%, title III: 31.25% (title III includes non-automatic carry-forward).

This report should be read in conjunction with other reports 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 2018 totalled EUR 337,761,000, representing a 4.9% increase compared to the 2017 initial budget (EUR 322,103,000).

No amending budgets were processed in 2018, so the final budget remained at EUR 337,761,000.

A summary table of the evolution of the budget can be found at Annex I, while Annexes II and III provide detailed information and Annex IV details of transfers carried out in 2018.

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

As stipulated in the Financial Regulation, budget revenue is based on cash received in terms of 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 2018 amounted to a total of EUR 317,081,125.07.

Of the total income, 89.69% derived from the evaluation of medicines and other business related activities, 10.28% from the European Union budget to fund various public health and harmonisation activities, including positive outturn of previous year, and 0.03% from external assigned revenue as described in the work programme (2017: 87.96%/8.99%/3.05%).

The chart below provides the breakdown by type of revenue.

Figure 1: breakdown of revenue by type/title

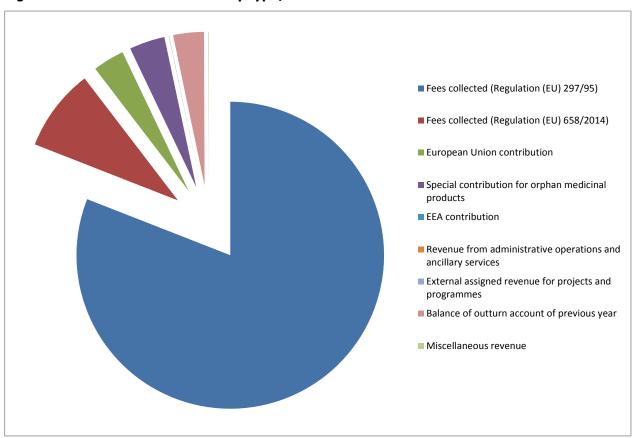


Table 1 below presents the implementation of the revenue budget of the European Medicines Agency.

Table 1: Implementation of 2018 revenue appropriations

Appropriation type	EUR or %
I. Appropriations in general	
Initial appropriations	337,761,000.00
Amending budget	0.00
Final appropriations	337,761,000.00
II. Use of appropriations	
Recovery orders 2018 and earlier	349,027,420.27
Representing in % of final appropriations	103.34%
Cash-receipts against recovery orders 2018 and earlier	317,081,125.07
Representing in % of final recovery orders	90.85%
III. Amounts established in 2018	
Recovery orders 2018 only	309,693,964.99
Representing in % of final appropriations	91.69%
Cash-receipts against recovery orders 2018 only	280,402,077.27
Representing in % of final recovery orders	90.54%
IV. Amounts unpaid from 2018 to be paid in 2019 or later	
Recovery orders for the evaluation of medicinal products (fees)	31,776,622.94
Other recovery orders	169,672.26
V. Amounts unpaid in 2017 or earlier, paid in 2018	
Recovery orders for the evaluation of medicinal products (fees)	36,647,776.73
Recovery orders for EU contribution	0.00
Other recovery orders	31,271.07
VI. Waivers and cancellations of amounts receivable	
Recovery orders waived or cancelled by the authorising officer in accordance with Article 62 Financial Regulation	226,560.00
VII. Waivers of fees and charges (excluding waivers for orphan medicines )	
Reductions deriving from paediatric or micro, small- and medium sized enterprises, advanced therapies and variations legislation	13,099,627.45
Other reductions in accordance with Article 9 of the Fee Regulation	5,539,195.40

## 2.3. Expenditure (commitments and payments)

Commitments on fund source C1 totalled EUR 306,602,880.05 or 90.78% of final appropriations (2017: 92.92%). Payments totalled EUR 251,781,077.78 or 82.12% of commitments entered into (2017: 84.46%). For details on the implementation of expenditure see Table 2.

The chart below provides a breakdown of types of expenditure by chapter and selected key articles.

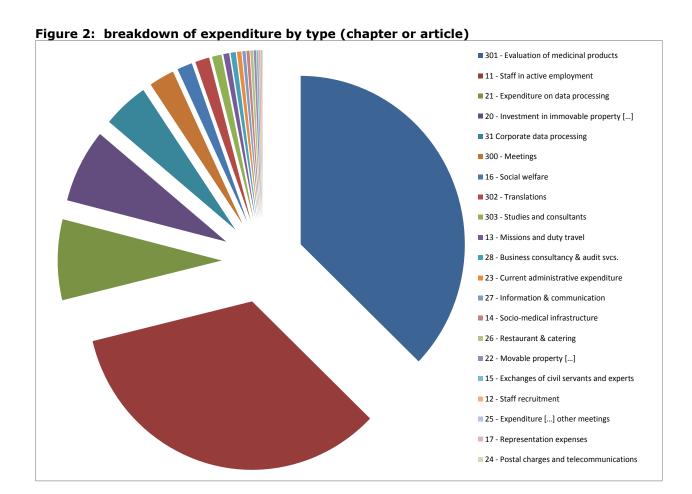


Table 2: Implementation of 2018 expenditure appropriations

Appropriation type	EUR or %
I. Appropriations in general	
Initial appropriations	337,761,000.00
Amending budget	0.00
Final appropriations	337,761,000.00
II. Use of 2018 appropriations	
Commitments	306,602,880.05
Representing of final appropriations	90.78%
Payments	251,781,077.78
Representing of final commitments	82.12%
III. Carry-over from 2018 to 2019	
Carry-over of administrative appropriations	9,749,205.10
Carry-over of operational appropriations	43,572,597.17
Total automatic carry-over	53,321,802.27
Representing of final appropriations	15.79%
Representing of final commitments	17.39%
IV. Cancellation of 2018 appropriations	
Appropriations cancelled	31,158,119.95
Representing of final appropriations	9.22%
V. Carry-over from 2017 to 2018	
Automatic carry-over, C8	
Carry-over of administrative appropriations	6,931,023.43
Carry-over of operational appropriations	40,905,047.27
Total automatic carry-over	47,836,070.70
Payment against carry-over	43,322,944.21
Total automatic carry-over unused	4,513,126.49
Representing of carry-over	90.57%
Non-automatic carry-over, C2	
Non-automatic carry-over to 2018	6,181,000.00
Payment against carry-over	5,712,041.60
Amount cancelled	468,958.40
Representing of carry-over	92.41%
Non-automatic carry-over to 2019	1,500,000.00

## Appropriations carried forward from 2018 to 2019

#### 2.4.1 Automatic carry-forward

Automatic carry-forward to financial year 2019 totalled EUR 53,321,802.27 or 17.39% of appropriations (total carried forward from 2017 to 2018: EUR 47,836,070.70 or 14.44%).

Table 3: Automatic carry-over from 2018 to 2019, per title

Title	Total commitments of which carri		ried over
Title	EUR	EUR	%
1 : Staff	112,584,216.61	1,381,902.98	1.23%
2 : Building and equipment	51,297,559.72	8,367,302.12	16.31%
3 : Operational expenditure*	142,721,103.72	43,572,597.17	30.53%
Total	306,602,880.05	53,321,802.27	17.39%

Non-automatic carry-forward

The Management Board was requested to approve a non-automatic carry-forward to 2019 of EUR 1,500,000.00 to cover the cost related to a key IT project, which saw contract delays for reasons outside the Agency's control.

Table 4: Non-automatic carry-over from 2018 to 2019, per title

Title	Total commitments	of which carried over			
Title	EUR	EUR	%		
1 : Staff	0.00	0.00	n/a		
2 : Building and equipment	0.00	0.00	n/a		
3 : Operational expenditure	1,500,000.00	1,500,000.00	100.00%		
Total	1,500,000.00	1,500,000.00	100.00%		

### 2.4. Implementation of appropriations carried forward from 2017 to 2018

Automatic carry-forward from financial year 2017 to 2018, *i.e.*, fund source C8, totalled EUR 47,836,070.70. Payments against these appropriations equalled EUR 43,322,944.21 or 90.57% of appropriations (2017: 89.89%) and EUR 4,513,126.49 were cancelled.

Non-automatic carry-forward, *i.e.*, fund source C2, from financial year 2017 to 2018 amounted to EUR 6,181,000.00. Payments against the C2 appropriations amounted to EUR 5,712,041.60 or 92.41% of appropriations (there was no non-automatic carry-forward in 2017) and EUR 468,958.40 were cancelled; due to overall delays in the implementation of the Clinical Trial and Database programme, part of the work was not able to commence as planned. This resulted in underspending of the committed C2 funds.

#### 2.5. Appropriations from external assigned revenue

The Agency's 2018 budget included no appropriations from external assigned revenue.

### 2.6. 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 2018 six transfers were made. They all involved adjustments within the limits of Article 27(1) of the Financial Regulation, *i.e.*, transfers within titles, and were therefore approved by the Executive Director. Six transfers involved expenditure appropriations and one also revenue appropriations.

The transferred expenditure appropriations were primarily needed to cover increased expenditure on business IT development and to provide appropriations for re-commitment of expiring commitments on C8.

Additional appropriations were also required to cover an increase in the Agency's social security contributions, as well as expenditure related to the Agency's departure from its Canary Wharf headquarters.

Annex IV provides details of all transfers carried out in 2018.

## 2.7. 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 2018, expenditure appropriations, i.e. fund source C1, totalling EUR31,158,119.96 remained unused, corresponding to 9.22% of final appropriations (2017: EUR 23,441,414.26, 7.08%).

The underuse of commitment appropriations can be explained by:

#### Title I

- lower expenditure on salaries, mainly due to delays in recruitment and staff attrition, in addition to uncertainty related to 'Brexit', which resulted in budget estimates intended to cover the 'worst case' scenario, i.e. the highest realistic level of expenditure;
- lower expenditure on national experts, trainees and interim staff, due to uncertainty related to 'Brexit'.

#### Title II

- lower than estimated cost related to the relocation of the data centre;
- lower activities and revised priorities as a result of the implementation of the business continuity plan (BCP) imposed on the Agency's activities in preparation for its departure from the UK (Brexit').

#### Title III

- lower expenditure on rapporteurs due to a decrease in the number of scientific applications received;
- lower IT development expenditure due to delays incurred in various projects.

This unused amount must be seen in conjunction with collected revenue being EUR 20,679,874.93 (6.12%) 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 8,978,245.03 or 2.66% of final appropriations (2017: 13,905,574.70, 4.20%).

## 2.8. 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%¹. 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 2018, 1,714 payments out of a total of 57,822, i.e. 2.96% of all payments, were made later than 30 days after receipt of a valid invoice (2017: 0.39% of all payments). This resulted in default interest of EUR 3,291.10 being paid to suppliers and contractors (2017: EUR 2,805.00).

Table 5: Breakdown of late payments and default interest

	Pay	ments	_	ich late nents	Interest accrued	Interest => EUR 200
	Number	EUR	Number	EUR	EUR	EUR
Supply and other services	44,845	301,952,930	1.714	20,792,916	7,970	2 201
Evaluation services (NCAs)	13,774	11,400,876	1,/14	20,792,910	7,970	3,291

## 3. Financial management by chapter

Hereafter follows an analysis of the evolution of revenue (based on cash collected) and expenditure (based on commitments) in 2018. In contains information at title level for revenue and expenditure. Detailed information per chapter, for both revenue and expenditure, can be found in Annexes I-III.

#### 3.1. Revenue

#### 3.1.1. Stable vs. cyclical revenue

In budgetary terms, EUR 119.0 million (37.53% of total 2018 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 2018, 62.47% of total revenue thus depended on cyclical business activities.

Table 6: Stable and cyclical sources of revenue

	2017 Actual	% of total	2018 Actual	% of total
Stable revenue for the Agency	126,102,349	39.73%	118,995,786	37.53%
EU subsidies and contributions	28,533,369	8.99%	22,360,145	7.05%
External assigned revenue	9,665,942	3.05%	91,994	0.03%
Annual fees	87,903,038	27.70%	96,543,646	30.45%
Cyclical business revenue	190,910,291	60.16%	187,613,707	59.17%
Revenue from miscellaneous activities	347,786	0.11%	10,471,632	3.30%
Total revenue	317,360,425	100.00%	317,081,125	100.00%

<sup>&</sup>lt;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

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

Article 62(4) of the Financial Regulation stipulates that recoveries established can, under certain, well-defined circumstances, be partly or fully waived by the authorising officer.

In 2018, recovery orders for a total of EUR 226,560.00 were waived. Recovery orders for a total of EUR 32,000 were waived due to the companies having gone into liquidation, while recovery order for a total of EUR 194,560 related to fees for parallel distribution applications were cancelled since the legal basis in place at the time was deemed too weak to guarantee recovery of the debts through legal proceedings.

#### 3.2. Expenditure

#### 3.2.1. Brexit-related expenditure

Financial planning for 2018 included Brexit expenditure amounting to EUR 18,639,000, additional income amounting to EUR 1,215,000 and savings amounting to EUR 3,877,000, resulting in a nett cost of EUR 14,762,000. Key expenditure items include the cost of transferring the Agency's data centre to its new location in Hamburg and the cost related to staff's relocation to Amsterdam. At the end of the year, expenditure amounting to EUR 15.5 million had been incurred.

Planning for 2018 also included an estimated 82.4 FTEs (full-time equivalent) dedicated to Brexit-related activities. The hours recorded for the year amounted to 88.6 FTEs.

The tables below provide details of actual expenditure incurred in 2018, as well as the estimated cost of the staff resources dedicated to working on Brexit activities.

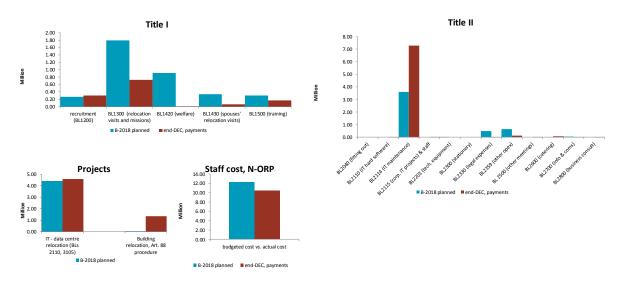


Figure 3: Brexit-related expenditure

#### 3.2.2. 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 2018 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, resulting in a drop by 1.77% in Euro terms for expenditure incurred in Sterling, when comparing the average exchange rate for 2018 (0.885) against the rate applied for the establishment of the budget (0.87).

Figure 4 below provides details of the evolution throughout 2018. The decrease in EUR expenditure affected in particular titles 1 and 2 of the budget (salaries and building/facilities) and contributed to a considerable degree to the underuse of appropriations, cf. pt. 2.8 above.

0.9000 0.89758 0.8950 0.8900 age exchange rate Jan-Dec 2018: 0.8854 0.8850 0.887 0.8800 0.8750 echange rate gain 0.8700 exchange rate loss 0.8650 0.8600 0.8550 Jan-18 Feb-18 Jun-18 Jul-18 Dec-18 Mar-18 Nov-18

Figure 4: Exchange rate variance against budget exchange rate

#### 3.2.3. Details on expenditure items

In 2018 the four chapters and articles with the highest amounts committed accounted for 86.03% of total commitments (2017: 83.99% of total commitments). They were:

- Chapter 11 'Staff in active employment', 33.97% (2017: 32.45%)
- Chapter 20 'Investments in immovable property, renting of buildings and associated costs', 7.09% (2017: 7.39%)
- Chapter 21 'Expenditure for corporate data processing', 7.74% (2017: 6.89%) and
- Article 301 'Evaluation of medicinal products', 37.24% (2017: 37.27%).

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

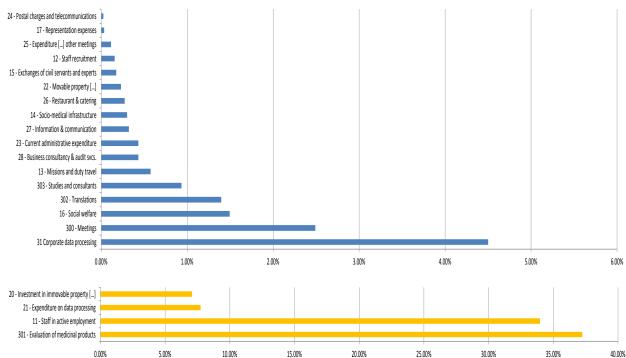


Figure 5: Distribution of 2018 expenditure by chapter (chapter 30 by article)

# Annex I – Budget evolution

		OPTED BUDGET	2018 (Dec 201	AMENDMENTS	/TRANSFERS	DIFFERENCE	DESCRIPTION	FINAL	BUDGET
Title Chapter/Article /Item	Heading	Commitment appropriations (in EUR)	Payment appropriations (in EUR)	Commitment appropriations (in EUR)	Payment appropriations (in EUR)	%		Commitment appropriations (in EUR)	Payment appropriations (in EUR)
REVENUE									
100	FEES COLLECTED (Regulation (EU) 297/95)	275,342,000	275,342,000	0	0	0.00%	No change.	275,342,000	275,342,000
	FEES COLLECTED PhV (Regulation (EU) 658/2014)	29,166,000	29,166,000	0	0	0.00%	No change.	29,166,000	29,166,000
200	EU & EEA CONTRIBUTION	8,989,000	8,989,000	1,416,000	1,416,000	15.75%	Increased in order to enable full consumption of EU/EEA contributions	10,405,000	10,405,000
201	ORPHAN & EEA CONTRIBUTION	13,416,000	13,416,000	-1,416,000	-1,416,000	-10.55%	Decreased to match lower number of OMP applications submitted	12,000,000	12,000,000
50	REVENUE FROM ADMIN. ACTIVITIES	84,000	84,000	0	0		No change.	84,000	
	EXTERNAL ASSIGNED REVENUE FOR PROJECTS & PROGRAMMES	148,000	148,000	0	0	0.00%	No change.	148,000	148,000
	BALANCE OF OUTTURN ACCOUNT FROM PREVIOUS YEARS	10,116,000	10,116,000	0	0	0.00%	No change.	10,116,000	10,116,000
90	MISCELLANEOUS REVENUE	500,000	500,000	0	0	0.00%	No change.	500,000	500,000
TOTAL		337,761,000	337,761,000	0	0	0.00%		337,761,000	337,761,000

		DOPTED BUDGET	2018 (Dec 201)	AMENDMENT	S/TRANSFERS	DIFFERENCE	DESCRIPTION	FINAL I	BUDGET
Title Chapter/Article /Item	Heading	Commitment appropriations (in EUR)	Payment appropriations (in EUR)	Commitment appropriations (in EUR)	Payment appropriations (in EUR)	%		Commitment appropriations (in EUR)	Payment appropriation (in EUR)
EXPENDITURE									
							Increased in order to enable payment of		
	STAFF HOLDING A POST IN THE LIST OF						an increased number of famility		
	POSTS	113,256,000	113,256,000	215,000	215,000	0.19%	allowances	113,471,000	113,471,00
	STAFF RECRUITMENT	500,000	500,000				procedures	545,000	
	DUTY TRAVEL	2,712,000	2,712,000				No change	2,712,000	
14	SOCIO-MEDICAL INFRASTRUCTURE	2,243,000	2,243,000		-260,000		Less expenditure on staff removal service	1,983,000	1,983,00
15	STAFF TRAINING	900,000	900,000	0	0	0.00%	No change	900,000	900,00
	EXTERNAL SERVICES	5,844,000	5,844,000				No change	5,844,000	
	RECEPTIONS & EVENTS	95,000	95,000		-		Increased cost of internal functions	131,000	
	RECEITIONS & EVENTS	·		•					
TITLE I		125,550,000	125,550,000	36,000	36,000	0.03%		125,586,000	125,586,000
	INVESTMENT IN IMMOVABLE PROPERTY,						Increased cost of maintenance & cleaning,		
20	RENTING OF BUILDINGS & ASSOC. COST	21,797,000	21,797,000	181,540	181,540	0.83%	utilities, fitting-out	21,978,540	21,978,54
	INFORMATION & COMMUNICATION								
21	TECHNOLOGY	26,555,000	26,555,000	0	0	0.00%	No change	26,555,000	26,555,000
22	MOVABLE PROPERTY & ACCOR COST	==		47.600	47.600		Less expenditure on furniture and	706 400	706.40
22	MOVABLE PROPERTY & ASSOC. COST	774,000	774,000	-47,600	-47,600	-6.15%	technical equipment Less expenditure on archive streamlining	726,400	726,400
23	CURRENT ADMIN. EXPENDITURE	2,142,000	2,142,000	-143,940	-143,940	6 700/	and business continuity	1,998,060	1,998,060
	POSTAGE	112,000	112,000				Less expenditure on postal charges	1,998,000	
2.7	1001/102	112,000	112,000	3,000	3,000	7.70/0	Savings achieved on memberships to	107,000	107,000
25	OTHER MEETINGS	390,000	390,000	-15,000	-15,000	-3.85%	professional bodies	375,000	375,000
		,	, , , , , , , , , , , , , , , , , , , ,		,		To cover the cost of catering equipment	,,,,,,	,
	RESTAURANT & CATERING	777,000	777,000	100,000	100,000		for temporary building in Amsterdam	877,000	877,000
	INFORMATION & PUBLISHING	1,288,000	1,288,000	0	0	0.00%	No change	1,288,000	1,288,000
	BUSINESS CONSULTANCY & AUDIT SERVICES	2,432,000	2,432,000	0	0	0.00%	No change	2,432,000	2,432,000
TITLE II		56,267,000	56,267,000	70,000	70,000	0.12%		56,337,000	56,337,000
200	MEETINGS	0.217.000	0.217.000		,	0.000/	No shange	0.217.000	0.217.00
300	MEETINGS	8,317,000	8,317,000	0	0	0.00%	No change Fewer applications, requiring less	8,317,000	8,317,000
3010	EVALUATION OF MEDICINAL PRODUCTS	114,382,000	114,382,000	-3,719,500	-3,719,500	-3 25%	appropriation to pay rapporteurs	110,662,500	110,662,500
	EVALUATION OF PHV PROCEDURES	13,238,000	13,238,000				No change	13,238,000	
302	TRANSLATION EXPENDITURE	4,994,000	4,994,000				No change	4,994,000	
	STUDIES & CONSULTANTS	3,170,000	3,170,000				No change	3,170,000	
		1, 1,000	., .,				To cover increased cost related to various	., .,	., ,,,
31	BUSINESS RELATED IT PROJECTS	11,843,000	11,843,000	3,613,500	3,613,500	30.51%	IT projects	15,456,500	15,456,50
TITLE III		155,944,000	155,944,000	-106,000	-106,000	-0.07%		155,838,000	155,838,00
TOTAL		337,761,000	337,761,000	0	0	0.00%		337,761,000	337,761,000

## Annex II – Detailed revenue overview, evolution

		2017	2018	Change		
Item	Heading	EUR	EUR	EUR	%	Comment
1000	Fees collected (Regulation (EU) 297/95)	251,217,555.08	256,676,368.94	5,458,813.86	2.17%	Fee income from evaluation services is the main source of revenue for the agency, representing 80.95% of 2018 revenue (2017: 79.16%). The value of recovery orders / invoices for fees, reflecting the level of activities, decreased by 10.04% when compared to 2017, whereas the value of cash receipts increased by 2.17%. The difference between the value of fee-related cash receipts and recovery orders is due to the increase in the value of recovery orders raised in 2018 for which revenue will only be cashed in the following years (from EUR 30.4 mio. in 2017 to EUR 31.9 mio. in 2018).
1001	Fees collected (Regulation (EU) 658/2014)	27,595,774.15	27,480,984.59	-114,789.56	-0.42%	Fees are charged for PSUR, PASS and referral procedures and involve around 4,000 companies across Europe. The item accounted for 8.67% in 2018 (2017: 8.70%).
2000	European Union contribution	2,438,000.00	10,503,205.00	8,065,205.00	330.81%	This item accounted for 3.319% of 2018 revenues (2017: 0.77%). The contribution from the European Union budget increased by 331% between 2017 and 2018.
2010	Special contribution for orphan medicinal products	13,268,470.00	11,856,940.00	-1,411,530.00		This article accounted for 3.74% of 2018 revenue (2017: 4.18%). EUR 1,416,000.000 were transferred to item 2000R.
3000	EEA contribution	60,219.00	0.00	-60,219.00	-100.00%	This chapter covered the compensation received for the participation of EEA countries in the agency's activities and in 2018 amounted to 2.37% of the EU contributions. They are now incorporated into item 2000R and 2010R.
5200	Revenue from administrative operations and ancillary services	217,323.25	40,050.00	-177,273.25	-81.57%	Chapter 52 includes the income from administrative charges as well as bank interest. The chapter accounted for 0.01% of 2018 revenues (2017: 0.07%).
	External assigned revenue for projects and programmes	9,665,941.77	91,994.36	-9,573,947.41		This chapter accounted for 0.03% of 2018 revenues (2017: 3.05%) and was made up of grants received from the EU budget for the Agency's participation in various projects under the IMI programme.
7000	Balance of outturn account of previous year	12,766,679.69	10,231,434.65	-2,535,245.04		(positive outturn) from the previous budget year is posted here.
	Miscellaneous revenue	130,462.36	200,147.53	69,685.17		This chapter accounted for 0.06% of 2018 revenues (2017: 0.04%). The bulk of the appropriations relates to refunds linked to corrections of rapporteur payments, recoveries from suppliers and interest charged on late payments by customers.
Total		317,360,425.30	317,081,125.07	-279,300.23	-0.09%	

## Annex III - Detailed expenditure overview, evolution

		2017	2018	2018	Change 201	7-2018	2018 budget v/co	mmitments	
Chapter	Heading	EUR commitments	EUR final budget	EUR commitments	EUR	%	EUR	%	Comment
11	Salaries and allowances	99,891,783.21	113,471,000.00	104,196,331.03	4,304,547.82	4.31%	-9,274,668.97	-8.17%	Chapter 11 accounted for 33.97% of 2018 expenditure (2017: 32.45%), constituting the second largest share of expenditure. 48.96% of chapter 11 expenditure related to items 1100 'basic salaries' and 1114 'CA salaries' and 17.64% to 1190 'weightings' (2017: 41.32% and 31.75%). For these three items commitments amounted to EUR 69,348,099.81. The chapter was reinforced by a total of EUR 215,000.
12	Staff recruitment	119,768.30	545,000.00	479,809.62	360,041.32	300.61%	-65,190.38	-11.96%	This chapter accounted for 0.16% of 2018 expenditure (2017: 0.04%). The chapter was reinforced by a total of €45,000.
13	Duty travel	860,824.00	2,712,000.00	1,761,233.06	900,409.06	104.60%	-950,766.94	-35.06%	This chapter accounted for 0.57% of 2018 expenditure (2017:
14	Social contacts between staff	717,430.56	1,983,000.00	923,499.58	206,069.02	28.72%	-1,059,500.42	-53.43%	This chapter accounted for 0.30% of 2018 expenditure (2017: 0.23%). A total of EUR 260,000.00 was transferred out of the chapter. The increase in expenditure is due to the Agency's contribution to European schools in the Netherlands for children of staff members enrolled from September 2018.
15	Staff training	740,652.28	900,000.00	537,099.28	-203,553.00	-27.48%	-362,900.72	-40.32%	This chapter accounted for 0.18% of 2018 expenditure (2017: 0.24%). Access to training was reduced due to the BCP invoked during 2018.
16	External services	4,365,059.77	5,844,000.00	4,580,646.69	215,586.92	4.94%	-1,263,353.31	-21.62%	Chapter 16 accounted for 1.49% of 2018 expenditure (2017: 1.42%). Compared to 2017 there was a decrease in the number of national experts on secondment on a full-time equivalent (FTE) basis, down from 36 to 32. The number of trainees increased from 46.4??? to 64??? (FTE).
17	Receptions and events	97,237.00	131,000.00	105,597.35	8,360.35	8.60%	-25,402.65	-19.39%	Chapter 17 accounted for 0.03% of 2018 expenditure (2017: 0.03%). The chapter was reinforced by EUR 36,000 through transfer.
Title I		106,792,755.12	125,586,000.00	112,584,216.61	5,791,461.49	5.42%	-13,001,783.39	-10.35%	

Chapter	Heading	2017	2018	2018	Change 201		2018 budget v/cd		Comment
Chapter	rieadilig	EUR	EUR	EUR	EUR	%	EUR	%	
20	Investment in immovable property, renting of buildings []	22,736,332.25	21,978,540.00	21,722,612.22	-1,013,720.03	-4.46%	-255,927.78	-1.16%	Chapter 20 accounted for 7.09% of 2018 expenditure, compared to 7.39% in 2017. The decreased expenditure is due to exchange rate gains realised between Sterling and the Euro. Appropriations were reinforced by EUR 181,540 through transfer, to provide funds for expenditure related to the Agency's new headquarters in Amsterdam.
21	Information and communication technology	21,200,860.22	26,555,000.00	23,731,230.20	2,530,369.98	11.94%	-2,823,769.80	-10.63%	Chapter 21 accounted for 7.74% of 2018 expenditure (2017: $6.89\%$ ). The increase in IT expenditure in chapter 21 was mainly due to expenditure related to the relocation of the Agency's data centre.
22	Movable property and associated costs	746,492.87	726,400.00	704,620.76	-41,872.11	-5.61%	-21,779.24	-3.00%	Chapter 22 accounted for 0.23% of 2018 expenditure (2017: 0.24%). The stable expenditure in 2018 was due to no further investment in the current building taking place. A total of EUR 47,600 was transferred out of the chapter.
23	Current administrative expenditure	594,398.72	1,998,060.00	1,324,821.24	730,422.52	122.88%	-673,238.76	-33.69%	This chapter accounted for 0.43% of 2018 expenditure (2017: 0.19%). The increase was mainly due to expenditure related to the Agency's move to Amsterdam. A net total of EUR 143,940 was transferred out of the chapter.
24	Postal and delivery services	65,163.05	107,000.00	78,384.22	13,221.17	20.29%	-28,615.78	-26.74%	This chapter accounted for 0.03% of 2018 expenditure (2017: 0.02%). A total of EUR 5,000 as transferred out of the chapter.
25	Other meetings and memberships	340,034.13	375,000.00	349,324.23	9,290.10	2.73%	-25,675.77	-6.85%	This chapter accounted for 0.11% of 2018 expenditure (2017: 0.11%). A net total of EUR 15,000 was transferred out of the chapter.
26	Restaurant and catering	753,347.97	877,000.00	837,582.98	84,235.01	11.18%	-39,417.02	-4.49%	This chapter accounted for 0.27% of 2018 expenditure (2017: 0.24%). The increase in expenditure was mainly related to the Agency's new building in Amsterdam. The chapter was reinforced by EUR 100,000.
27	Information and communication services	881,934.09	1,288,000.00	986,819.17	104,885.08	11.89%	-301,180.83	-23.38%	This chapter accounted for 0.32% of 2018 expenditure (2017: 0.29%). The increase was linked to the alignment of commitments with the budget year.
28	Business consultancy and audit services	2,045,565.66	, ,	1,562,164.70	-483,400.96	-23.63%	-869,835.30		This chapter accounted for 0.51% of 2018 expenditure (2017: 0.66%). The bulk of expenditure was on business consultancy, with approx. 10% spent on audit services.
Title II		49,364,128.96		51,297,559.72		3.92%	-5,039,440.28	-8.95%	
Chapter	Heading	2017 EUR	2018	2018 EUR	Change 201	7-2018	2018 budget v/co	ommitments	Comment
Спарсег	Heading	commitments	EUR final budget	commitments	EUR	%	EUR	%	
									Article 3000 accounted for 2.49% of 2018 expenditure (2017:
300	Meetings	8,654,838.95	8,317,000.00	7,635,327.48	-1,019,511.47	-11.78%	-681,672.52	-8.20%	2.81%). Compared to 2017, expenditure decreased by approx. EUR 1 million. Lower meeting activities were partly caused by the business continuity situation.
300	Meetings  Evaluation of medicinal products	8,654,838.95 114,724,839.97	, ,	7,635,327.48 114,143,745.60	-1,019,511.47 -581,094.37	-0.51%	-681,672.52 -9,756,754.40	-8.20% -7.87%	2.81%). Compared to 2017, expenditure decreased by approx. EUR 1 million. Lower meeting activities were partly caused by the business continuity situation.  Article 301 accounted for 37.24% of 2018 expenditure (2017: 37.27%). Between 2017 and 2018 expenditure in absolute terms decreased by approx. EUR 0.6 million, with pharmacovigilance services decreasing by approx. EUR 1 million and payments to rapporteurs increasing by around €400,000. Appropriations were reduced by a total of EUR 3,719,500 through transfer.
		, ,	123,900,500.00	, ,	, ,		ŕ	-7.87%	2.81%). Compared to 2017, expenditure decreased by approx. EUR 1 million. Lower meeting activities were partly caused by the business continuity situation.  Article 301 accounted for 37.24% of 2018 expenditure (2017: 37.27%). Between 2017 and 2018 expenditure in absolute terms decreased by approx. EUR 0.6 million, with pharmacovigilance services decreasing by approx. EUR 1 million and payments to rapporteurs increasing by around €400,000. Appropriations were reduced by a total of EUR 3,719,500 through transfer.  Article 302 accounted for 1.40% of 2018 expenditure (2017: 1.54%). The decrease in expenditure in absolute terms was linked to the lower number of scientific applications received in 2018.
301	Evaluation of medicinal products	114,724,839.97	123,900,500.00	114,143,745.60	-581,094.37	-0.51%	-9,756,754.40	-7.87% -14.30%	2.81%). Compared to 2017, expenditure decreased by approx. EUR 1 million. Lower meeting activities were partly caused by the business continuity situation.  Article 301 accounted for 37.24% of 2018 expenditure (2017: 37.27%). Between 2017 and 2018 expenditure in absolute terms decreased by approx. EUR 0.6 million, with pharmacovigilance services decreasing by approx. EUR 1 million and payments to rapporteurs increasing by around €400,000. Appropriations were reduced by a total of EUR 3,719,500 through transfer.  Article 302 accounted for 1.40% of 2018 expenditure (2017: 1.54%). The decrease in expenditure in absolute terms was linked to
301 302 303	Evaluation of medicinal products  Translations  Scientific studies  Business related IT projects*	114,724,839.97 4,752,224.00 3,471,375.45 20,064,422.39	123,900,500.00 4,994,000.00 3,170,000.00 15,456,500.00	114,143,745.60 4,279,634.10 2,863,988.67 13,798,407.87	-581,094.37 -472,589.90 -607,386.78 -6,266,014.52	-0.51% -9.94% -17.50%	-9,756,754.40 -714,365.90 -306,011.33 -1,658,092.13	-7.87% -14.30% -9.65% -10.73%	2.81%). Compared to 2017, expenditure decreased by approx. EUR 1 million. Lower meeting activities were partly caused by the business continuity situation.  Article 301 accounted for 37.24% of 2018 expenditure (2017: 37.27%). Between 2017 and 2018 expenditure in absolute terms decreased by approx. EUR 0.6 million, with pharmacovigilance services decreasing by approx. EUR 1 million and payments to rapporteurs increasing by around €400,000. Appropriations were reduced by a total of EUR 3,719,500 through transfer. Article 302 accounted for 1.40% of 2018 expenditure (2017: 1.54%). The decrease in expenditure in absolute terms was linked to the lower number of scientific applications received in 2018. This article accounted for 0.93% of 2018 expenditure (2017: 1.13%). The decrease in expenditure is due to reduced expenditure
301 302 303 31	Evaluation of medicinal products  Translations  Scientific studies  Business related IT projects*	114,724,839.97 4,752,224.00 3,471,375.45 20,064,422.39	123,900,500.00 4,994,000.00 3,170,000.00	114,143,745.60 4,279,634.10 2,863,988.67 13,798,407.87	-581,094.37 -472,589.90 -607,386.78 -6,266,014.52	-0.51% -9.94% -17.50%	-9,756,754.40 -714,365.90 -306,011.33 -1,658,092.13	-7.87% -14.30% -9.65%	2.81%). Compared to 2017, expenditure decreased by approx. EUR 1 million. Lower meeting activities were partly caused by the business continuity situation.  Article 301 accounted for 37.24% of 2018 expenditure (2017: 37.27%). Between 2017 and 2018 expenditure in absolute terms decreased by approx. EUR 0.6 million, with pharmacovigilance services decreasing by approx. EUR 1 million and payments to rapporteurs increasing by approx. EUR 1 million and payments to rapporteurs increasing by approx. EUR 1 million and payments to rapporteurs increasing by approx. EUR 1 million and payments to rapporteurs increasing by approx. EUR 1 million and symmetric services decreasing by approx. EUR 1 million and payments to rapporteurs increasing by approx. EUR 1 million and payments to rapporteurs increasing by approx. EUR 1 million and payments to rapporteurs increasing by approx. EUR 1 million and payments to rapporteurs increased by a counted for 1.40% of 2018 expenditure (2017: 1.13%). The decrease in expenditure is due to reduced expenditure on encepp studies in 2018.  This article accounted for 4.50% of 2018 expenditure (2017: 6.52%). 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 9.05%, compared to 2017. The chapter was reinforced through transfer by a total of EUR 3,616,500 to allow for recommitment of expiring C8 appropriations and in

<sup>\* 2018</sup> commitments do not include EUR1,500,000 which were carried forward non-automatically, i.e. C2

# **Annex IV – Summary of transfers**

No.	From/To item	Item No.	Fund source	Item Heading	Amount of receiving item	Amount of donating item
01	from	2114	C1	Maintenance & support of applications	0	38,000
	to	2115	C1	IT development related to corporate processes	38,000	0
02	from	3010	C1	Evaluation of medicinal products	0	106,000
	to	2040	C1	Fitting-out of premises	106,000	0
03	from	2000	C1	Rent	0	311,000
	to	1700	C1	Receptions & events	36,000	0
	to	2030	C1	Maintenance & cleaning	80,000	0
	to	2090	C1	Utilities & other building charges	95,000	0
	to	2600	C1	Restaurant & catering	100,000	0
	from	3010	C1	Evaluation of medicinal products	0	2,400,000
	to	3105	C1	Business IT development	2,400,000	0
04	from	1420	C1	Miscellaneous welfare expenditure	0	260,000
	to	1101	C1	Family allowances	213,000	0
	to	1143	C1	Fixed specific allowances	2,000	0
	to	1200	C1	Staff recruitment	45,000	0
	from	2000	C1	Rent	0	22,000
	to	2300	C1	Stationery & office supplies	22,000	0
05	from	1181	C1	Allowances on entering & leaving the service & on transfer	0	370,000
	to	1130	C1	Employer's social security contribution	370,000	0
	from	2000	C1	Rent	0	100,000
	to	2030	C1	Maintenance & cleaning	100,000	
	from	2400	C1	Postal & delivery services	0	5,000
	to	2500	C1	Other meetings	5,000	0
06	from	2010R	C1	Special contribution for OMP from the EU	0	1,416,000
	to	2000R	C1	budget & EEA contribution  European Union & EEA contribution	1,416,000	0
	from	1181	C1	Allowances on entering & leaving the	0	600,000
	to	1130	C1	service & on transfer  Employer's social security contribution	600,000	0
	from	2000	C1	Rent	0	227,460
	from	2050	C1	Security	0	47,000
	from	2090	C1	Utilities & other building charges	0	74,000
	from	2203	C1	Technical equipment & installations	0	42,000
	from	2210	C1	Furniture	0	5,600
	from	2358	C1	Business continuity	0	65,600
	from	2359	C1	Other operating expenditure	0	100,340
	from	2501	C1	Memberships with professional bodies &	0	20,000
	to	2040	C1	organisations Fitting-out of premises	582,000	20,000
	from	3010	C1	Evaluation of medicinal products	382,000	1,213,500
	to	3105	C1	Business IT development	1,213,500	1,213,300
	10	3103	CI	,	7,423,500	
				Total amount of transfers	7,423,500	7,423,500