



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/301708/2017  
Administration and Corporate Management Division

## Annual accounts

Financial year 2016



## Accounting Officer's certificate on the annual accounts for the financial year 2016

The annual accounts of the European Medicines Agency for the year 2016 have been prepared in accordance with Title IX the Financial Regulation applicable to the general budget of the European Union, the accounting rules adopted by the Commission's Accounting Officer and the accounting principles and methods adopted by myself.

I acknowledge my responsibility for the preparation and presentation of the annual accounts of the European Medicines Agency in accordance with Art.50 of the Agency Financial Regulation.

I have obtained from the authorising officer, who certified its reliability, all the information necessary for the production of the accounts that show the European Medicines Agency's assets and liabilities and the budgetary implementation.

I hereby certify that based on this information, and on such checks as I deemed necessary to sign off the accounts, I have a reasonable assurance that the accounts present fairly, in all material aspects, the financial position, the result of the operations and the cash-flow of the European Medicines Agency as at December 31, 2016.



Paola Samassa

Accounting Officer  
London, 01 June 2017

## Table of contents

<b>Accounting Officer's certificate on the annual accounts for the financial year 2016 .....</b>	<b>2</b>
<b>Part I: Financial statements and explanatory notes.....</b>	<b>5</b>
<b>1. Legal role.....</b>	<b>5</b>
<b>2. Principal activities of the Agency .....</b>	<b>5</b>
<b>3. Introduction and legal basis .....</b>	<b>5</b>
<b>4. Accounting principles.....</b>	<b>6</b>
<b>5. Accounting policies .....</b>	<b>8</b>
5.1. Recognition of fees revenue and associated evaluation expenditure.....	8
5.1.1. Fees levied in accordance with Council Regulation (EC) 297/95 of 10 <sup>th</sup> February 1995, as amended.....	8
5.1.2. Fees levied in accordance with Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014.....	9
5.2. Bases for conversion of currencies.....	9
5.3. Tangible and intangible fixed assets .....	9
5.4. Leases .....	10
5.5. Receivables .....	10
5.6. Cash & cash equivalents .....	10
5.7. Current payables, accrued and deferred charges.....	10
5.8. Pension obligations.....	11
5.9. Financial instruments.....	11
<b>6. Balance sheet as at 31 December 2016 .....</b>	<b>12</b>
<b>7. Statement of financial performance for the year ended December 31, 2016 .....</b>	<b>13</b>
<b>8. Cash flow statement for the year ended December 31, 2016 .....</b>	<b>14</b>
<b>9. Statement of changes in net assets .....</b>	<b>15</b>
<b>10. Notes to the financial statements .....</b>	<b>16</b>
10.1. Intangible fixed assets .....	16
10.2. Tangible fixed assets .....	17
10.3. Current receivable .....	18
10.4. VAT recoverable from member states .....	18
10.5. Sundry receivables and prepaid expenses.....	18
10.6. Cash and cash equivalents .....	19
10.7. Non-current liabilities.....	19
10.8. Current payables.....	20
10.9. Non-budgetary commitments and contingent liabilities.....	20
10.10. Fees and charges relating to marketing authorisations .....	21

10.11. Contribution from EU entities and budgetary outturn balance.....	22
10.11.1. Other consolidated entities.....	23
10.12. External assigned revenue for projects.....	23
10.13. Sundry revenue.....	23
10.14. Staff expenses .....	23
10.15. Administrative expenditure .....	24
10.16. Operating expenditure .....	24
10.17. Non-operating activities .....	25
10.17.1. Differences on exchange.....	25
<b>11. Financial assets and financial liabilities risk analysis.....</b>	<b>26</b>
11.1. Credit quality of financial assets .....	26
11.2. Analysis of the age and impairment of financial assets .....	27
11.3. Liquidity risk.....	27
11.4. Market risk disclosures.....	28
<b>Part II: Aggregated reports on the implementation of the budget and explanatory notes.....</b>	<b>29</b>
<b>12. Establishment of the budget and budget principles .....</b>	<b>29</b>
<b>13. Implementation of the 2016 budget .....</b>	<b>30</b>
13.1. Budgetary result account for the year ended December 31, 2016.....	31
13.2. Reconciliation of economic result with budget result .....	33
13.3. Summary of the implementation of income appropriations .....	34
13.4. Summary of the implementation of commitment appropriations.....	34
13.5. Summary of the implementation of payment appropriations .....	35
13.6. Summary of the implementation of appropriations carried over by decision .....	35
13.7. Summary of the implementation of appropriations carried over automatically .....	35
<b>Annex I – Details of the implementation of budget revenue 2016 .....</b>	<b>36</b>
<b>Annex II – Details of the implementation of budget expenditure 2016 .....</b>	<b>37</b>

# Part I: Financial statements and explanatory notes

## 1. Legal role

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

The Agency provides the Member States and the institutions of the European Union (EU) the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

## 2. Principal activities of the Agency

Working with the Member States and the European Commission as partners in a European medicines network, the European Medicines Agency:

- provides independent, science-based recommendations on the quality, safety and efficacy of medicines, and on more general issues relevant to public and animal health that involve medicines;
- applies efficient and transparent evaluation procedures to help bring new medicines to the market by means of a single, EU-wide marketing authorisation granted by the European Commission;
- implements measures for continuously supervising the quality, safety and efficacy of authorised medicines to ensure that their benefits outweigh their risks;
- provides scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;
- recommends safe limits for residues of veterinary medicines used in food-producing animals, for the establishment of maximum residue limits by the European Commission;
- involves representatives of patients, healthcare professionals and other stakeholders in its work, to facilitate dialogue on issues of common interest;
- publishes impartial and comprehensible information about medicines and their use;
- develops best practice for medicines evaluation and supervision in Europe, and contributes alongside the Member States and the European Commission to the harmonisation of regulatory standards at the international level.

## 3. Introduction and legal basis

The accounts are kept in accordance with the provisions of Title IX of the Commission Delegated Regulation (EC, Euratom) No 1271/2013 of 30 September 2013 on the framework Financial Regulation for the bodies referred to in Article 208 of Regulation (EC, Euratom) No 966/2012 of the European Parliament on the Financial Regulation applicable to the general budget of the European Communities and the internationally accepted accounting standards for the public sector (IPSAS) as outlined in the accounting rules referred to in Article 94.

As required by Article 92 of the framework Financial Regulation the Agency annual accounts for 2016 comprise:

- The financial statements, comprising the balance sheet, the statement of financial performance, the cash flow statement, the statement of changes in net assets and relevant annexes which supplement the information contained in the financial statements
- The reports on the implementation of the budget of the Agency

## 4. Accounting principles

The objectives of financial statements are to provide information about the financial position, performance and cash flows of an entity that is useful to a wide range of users. For a public sector entity such as the Agency, the objectives are more specifically to provide information useful for decision making, and to demonstrate the accountability of the entity for the resources entrusted to it.

If they are to present a true and fair view, financial statements must not only supply relevant information to describe the nature and range of an Agency's activities, explain how it is financed and supply definitive information on its operations, but do so in a clear and comprehensible manner which allows comparisons between financial years. It is with these goals in mind that the present report has been drawn up.

The accounting system of the Agency, in common with all European Institutions, comprises general accounts prepared on the accrual basis and budget accounts prepared on the modified cash accounting basis. The application of accrual accounting principles essentially means that income is recorded in the accounts when it is earned and expenditure when it is incurred and not just when cash is received or paid. The biggest impact of applying the accrual basis in the Agency financial statements relates to:

Item	Accrual	Budget
Fee revenue	Based on invoices raised/revenue recognised	Cash received by the Agency during the year
Community contribution	Net amount due after deduction of budget result for the year	Cash received by the Agency during the year
Fixed assets	Purchases of fixed assets are capitalised and their cost depreciated over the useful life of the assets	Total amount purchased during the year charged to the budget
Expenditure	Actual amounts paid plus accrued liabilities at year end	Actual amounts paid plus budgetary carry over

As the economic result and the budget result both cover the same underlying transactions, it is a useful control to ensure that they are reconcilable. The reconciliation between the budget result and the economic outturn is presented in Part II, Aggregated reports on the implementation of the budget and explanatory notes.

The financial statements referred to in Article 92 shall present information, including information on accounting policies, in a manner that ensures it is relevant, reliable, comparable and understandable. The financial statements shall be drawn up in accordance with generally accepted accounting principles as outlined in the accounting rules referred to in Article 143 of Regulation (EU, Euratom) No 966/2012, namely:

- **Going-concern principle**

The going concern principle means that for the purposes of preparing the financial statements, the Agency is deemed to be established for an indefinite duration;

- **Principle of prudence**

The principle of prudence means that assets and income shall not be overstated and liabilities and charges shall not be understated. However, the principle of prudence does not allow the creation of hidden reserves or undue provisions;

- **Principle of consistent accounting methods**

The consistent accounting methods means that the structure of the components of the financial statements and the accounting methods and valuation rules may not be changed from one year to the next;

- **Principle of comparability of information**

The comparability of information means that for each item the financial statements shall also show the amount of the corresponding item for the previous year;

- **Materiality principle**

The materiality principle means that all operations which are of significance for the information sought shall be taken into account in the financial statements. Materiality shall be assessed in particular by reference to the nature of the transaction or the amount;

- **No-netting principle**

The no-netting principle means that receivables and debts may not be offset against each other, nor may charges and income, save where charges and income derive from the same transaction, from similar transactions and provided that they are not individually material;

- **Principle of substance over form**

The principle of reality over appearance means that accounting events recorded in the financial statements shall be presented by reference to their economic nature;

- **Accrual-based accounting principle**

The accrual-based accounting principle means that transactions and events shall be entered in the accounts when they occur and not when amounts are actually paid or recovered. They shall be booked to the financial years to which they relate.

## 5. Accounting policies

These accounts have been prepared following, in all material respects, the accounting rules adopted by the Accountant of the European Commission in accordance with Article 143 of Regulation (EU, Euratom) No 966/2012 of the European Parliament on the Financial Regulation applicable to the general budget of the European Communities.

The following are the accounting policies applied in the preparation of these accounts.

### ***5.1. Recognition of fees revenue and associated evaluation expenditure***

#### **5.1.1. Fees levied in accordance with Council Regulation (EC) 297/95 of 10<sup>th</sup> February 1995, as amended**

The Agency charges a fee to applicants for services rendered in accordance with Council Regulation EC No 1905/2005 of 14<sup>th</sup> December 2005 amending Council Regulation (EC) 297/95 of 10<sup>th</sup> February 1995 for the evaluation of medicinal products, as amended by Commission Regulation (EU) No 2016/461 of 30 March 2016 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate.

Recovery orders (invoices) are processed on administrative validation at the start of the procedure to which the service relates. The evaluation service is subcontracted to the national competent authorities (NCAs) of the Member States who receive a fixed percentage of the fee, generally 50% except for annual fees, which is 30%.

#### **Initial applications, variations and scientific advice and associated national competent authorities expenditure**

The Agency recognises revenue for each of the following application types on a straight-line basis over a set time period. The set time period is the average number of days taken for each application to be evaluated, from submission to opinion, as follows:

Full application: 330 days; extensions: 250 days; type II variations major: 90 days; type II variations minor: 30 days; scientific advice: 70 days. Revenue for other application types is recognized when the associated invoices are processed.

Expenditure for evaluation of applications by the NCAs is accrued in line with the matching principle.

#### **Annual fees**

In addition to procedures validated during the year an annual maintenance fee is charged to marketing authorisation holders in respect of post authorisation monitoring activities required by legislation. These fees, which account for approximately 30% of total fees revenue, are due on the first and each subsequent anniversary of the notification of the marketing authorisation decision and revenue is accrued as a pro rata basis in relation to the time passed since the previous anniversary date.

The amounts due to the NCAs for evaluation services are accrued at the same time as the revenue is recognised.



### **5.1.2. Fees levied in accordance with Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014**

The Agency charges a fee to the marketing authorisation holders for the conduct of pharmacovigilance activities in respect of medicinal products for human use in accordance with Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014 on fees payable to the European Medicines Agency.

#### **Pharmacovigilance procedures**

For fees levied for the assessment of pharmacovigilance procedures, i.e. periodic safety update reports (PSURs), post-authorisation safety studies (PASS) and referrals initiated as a result of the evaluation of pharmacovigilance data, recovery orders (invoices) are processed at the start of the procedure to which the service relates. The level of fee charged for each type of procedure is prescribed by the Regulation and the cost is apportioned between the marketing authorisation holders involved in each procedure. The scientific assessment is subcontracted to the national competent authorities (NCAs) of the Member States, who receive a fixed remuneration in accordance with Part I – III of the Annex to Regulation (EU) No 658/2014.

Revenue for pharmacovigilance procedures is recognized when the associated invoices are processed. Expenditure for evaluation of applications by the NCAs is accrued in line with the matching principle.

#### **Pharmacovigilance annual fees**

Annual fees are levied on 1<sup>st</sup> July of each calendar year to support the Agency activities with regard to the provision of pharmacovigilance-related services in the areas of information technology systems and literature monitoring. The amounts charged cover the period from 1<sup>st</sup> January to 31<sup>st</sup> December of the year concerned.

### **5.2. Bases for conversion of currencies**

The accounts are presented in Euro (EUR). Assets and liabilities are converted into Euro on the basis of the exchange rate ruling at 31<sup>st</sup> December (2016: 0.85618), except for tangible and intangible fixed assets, which retain their value in Euro at the rate that applied when they were purchased. During the year revenue and expenditure incurred in currencies other than the Euro, mainly Pounds Sterling (GBP) are converted to Euro based on the monthly exchange rates published by the European Commission.

### **5.3. Tangible and intangible fixed assets**

Tangible and intangible fixed assets are valued at their acquisition price converted into Euro at the rate applying when they are purchased. The book value of a fixed asset is equal to its acquisition price or production cost, plus or minus revaluations, depreciation and other amounts written off. Depreciation rates are reported below. The threshold for the recording of tangible assets is fixed at € 420.

Development costs for internally generated intangible assets, i.e. computer software, paid to third party consultants as well as internal staff costs, if above the Agency's threshold of € 1,000,000 are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Agency and the cost of the item can be measured reliably. All projects for which the overall estimated expenditure exceeds € 1,000,000 are the subject of an ex ante evaluation, in compliance with Article 29.5 of the Agency Financial Regulation and Article 11 of the implementing rules. Development costs below the threshold

and all other repairs and maintenance costs are charged to the economic outturn account during the financial period in which they are incurred.

Depreciation on assets is calculated using the straight-line method to allocate their cost over their estimated useful lives, as follows:

Asset class description	Years	%
Internally generated computer software	4	25%
Other computer software	4	25%
Building and fitting out costs	4	25%
Computer hardware	4	25%
Office furniture	10	10%
Technical equipment	8	12.5%
Technical equipment (shorter useful life)	4	25%

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each balance sheet date. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing proceeds with carrying amount. These are included in the economic outturn account.

#### **5.4. Leases**

Leases where the lessor retains a significant portion of the risks and rewards of ownership are classified as operating leases. Payments made under operating leases are charged to the economic outturn account on a straight-line basis over the period of the lease.

The Agency has not entered into financing leases (i.e. where the lessee holds substantially all the risks and rewards of ownership).

#### **5.5. Receivables**

Receivables are carried at original invoice amount less write-down for impairment. A write-down for impairment of receivables is established when there is objective evidence that the Agency will not be able to collect all amounts due. The amount of the write-down is the difference between the asset's carrying amount and the recoverable amount.

#### **5.6. Cash & cash equivalents**

Cash and cash equivalents are carried in the balance sheet at cost. They include cash in hand, deposits held at call and short term deposits with banks.

#### **5.7. Current payables, accrued and deferred charges**

Current payables arising from the purchase of goods and services other than expenditure for evaluation of applications by the NCAs, for which the accounting policy is outlined in section 5.1, are

recognised at invoice reception for the original amount. The corresponding expenses are recognised in the financial statements in the period to which they relate and are entered in the accounts when the supplies or services are delivered and accepted by the Agency.

In accordance with EU accounting rule 12 a liability for employees accumulated compensated absences (untaken leave) at year-end is included on the balance sheet under current payables (accrued charges). The amount is calculated as the additional amount that the Agency expects to pay as a result of the unused entitlement that has accumulated at the reporting date, applying the staff average cost based on the Agency's population and the specific country correction coefficient.

### **5.8. Pension obligations**

Agency's staff are members of the European Union Pension Scheme which is a defined benefit pension plan. A defined benefit plan is a pension plan that generally defines an amount of pension benefit that an employee will receive on retirement, usually dependent on one or more factors such as age, years of service and compensation.

In accordance with Article 83 of the Staff Regulations, the payment of the benefits provided for in the pension scheme constitutes a charge on the European Union's budget. The provision for this charge is not funded, but the Member States guarantee the payment of these benefits collectively according to the scale fixed for the financing of this expenditure.

Staff contribute one third of the cost of this pension scheme, currently 9.8%<sup>1</sup> of their basic salaries.

In accordance with Article 83a of the Staff Regulations, agencies which are partly financed from the general budget of the European Union shall pay the part of the employers' contributions which corresponds to the proportion between the Agency's revenues without the subsidy from the general budget of the European Union and its total revenues.

Future benefits payable to Agency's staff under the EU pension scheme are accounted for in the consolidated accounts of the European Union as they are the responsibility of the Member States. Accordingly, no provisions for pension payments or any pension fund deficits are required to be included in these accounts.

### **5.9. Financial instruments**

EU accounting rule 11 requires the Agency to disclose information that enables users of its financial statements to evaluate the nature and the extent of risks arising from financial instruments, i.e. financial assets and financial liabilities, to which the entity is exposed at the end of the reporting period.

The financial assets and financial liabilities concerning the Agency are: cash and cash equivalents, receivables and payables. The analysis of the credit risk, the liquidity risk and the market risk of the Agency's financial instruments is presented in section 11 of this report.

---

<sup>1</sup> updated rate as of July 2016; the weightings not being taken into account

## 6. Balance sheet as at 31 December 2016

Amounts in EUR

	Note	31.12.2016 Final	31.12.2015 Final
<b>NON-CURRENT ASSETS</b>			
Intangible fixed assets	10.1	27,431,359.55	14,308,036.16
Tangible fixed assets	10.2	39,694,088.19	53,804,246.58
<b>TOTAL NON CURRENT ASSETS</b>		<b>67,125,447.74</b>	<b>68,112,282.74</b>
<b>CURRENT ASSETS</b>			
Current receivable	10.3	44,421,606.66	45,357,069.79
Provision for doubtful debts	10.3	- 1,772,944.89	- 1,152,939.15
Receivables from consolidated EU entities	10.11.1	33,321.28	-
VAT recoverable from member states	10.4	3,629,852.81	1,916,252.65
Sundry Receivables	10.5	-	7,003.34
Accrued marketing authorisation fees		39,800,540.40	38,023,938.91
Prepaid expenses	10.5	9,513,430.86	9,765,259.24
Cash and cash equivalents	10.6	62,753,616.31	80,197,286.80
<b>TOTAL CURRENT ASSETS</b>		<b>158,379,423.43</b>	<b>174,113,871.58</b>
<b>TOTAL ASSETS</b>		<b>225,504,871.17</b>	<b>242,226,154.32</b>
<b>NON-CURRENT LIABILITIES</b>			
	10.7		
Provision for risk and charges		13,600,317.85	13,140,403.72
Deferred revenue		49,013,019.58	54,697,248.73
<b>TOTAL NON CURRENT LIABILITIES</b>		<b>62,613,337.43</b>	<b>67,837,652.45</b>
<b>CURRENT LIABILITIES</b>			
Deferred revenue within 1 year		5,684,229.15	5,684,229.15
Deferred marketing authorisation fees		29,659,047.60	24,961,407.81
Current payables	10.8	42,069,751.81	38,014,086.75
Sundry payables		4,325.07	10,061.57
Payables to consolidated EU entities	10.11.1	436,642.94	540,062.98
Budgetary result payable to European Commission	10.11	10,231,434.65	12,766,679.69
<b>TOTAL CURRENT LIABILITIES</b>		<b>88,085,431.22</b>	<b>81,976,527.95</b>
<b>TOTAL LIABILITIES</b>		<b>150,698,768.65</b>	<b>149,814,180.40</b>
<b>NET ASSETS</b>		<b>74,806,102.52</b>	<b>92,411,973.92</b>
<b>NET ASSETS</b>			
Accumulated surplus/deficit		92,411,973.92	101,881,400.70
Economic result of the year		- 17,605,871.40	- 9,469,426.78
<b>NET ASSETS</b>		<b>74,806,102.52</b>	<b>92,411,973.92</b>

## 7. Statement of financial performance for the year ended December 31, 2016

Amounts in EUR

	Note	31.12.2016 Final	31.12.2015 Final
<b>OPERATING REVENUE</b>			
Fees and charges related to marketing authorisations	10.10	270,368,167.88	254,954,239.30
Contribution from EU entities	10.11	5,332,463.66	21,463,930.99
External assigned revenue for projects	10.12	5,334,407.79	5,641,388.25
Sundry revenue	10.13	348,699.15	1,024,379.49
<b>TOTAL OPERATING REVENUE</b>		<b>281,383,738.48</b>	<b>283,083,938.03</b>
<b>OPERATING EXPENDITURE</b>			
Staff expenses	10.14	113,060,038.51	101,271,678.85
Administrative expenditure	10.15	37,023,514.07	38,671,790.00
Operating expenditure	10.16	130,328,177.97	129,982,925.94
Depreciation		19,930,833.63	21,138,745.88
Disposal and derecognition of assets		174,505.58	154,256.65
Other expenditure		1,079,919.87	1,199,720.08
<b>TOTAL OPERATING EXPENDITURE</b>		<b>301,596,989.63</b>	<b>292,419,117.40</b>
<b>SURPLUS (DEFICIT) FROM OPERATING ACTIVITIES</b>		<b>- 20,213,251.15</b>	<b>- 9,335,179.37</b>
SURPLUS (DEFICIT) FROM NON-OPERATING ACTIVITIES	10.17	2,607,379.75	- 134,247.41
<b>SURPLUS (DEFICIT) FROM ORDINARY ACTIVITIES</b>		<b>- 17,605,871.40</b>	<b>- 9,469,426.78</b>
SURPLUS (DEFICIT) FROM EXTRAORDINARY ITEMS		-	-
<b>ECONOMIC RESULT OF THE YEAR</b>		<b>- 17,605,871.40</b>	<b>- 9,469,426.78</b>

## 8. Cash flow statement for the year ended December 31, 2016

Amounts in EUR

	<b>2016</b>	<b>2015</b>
	<b>Final</b>	<b>Final</b>
<b>Economic result of the year</b>	<b>- 17,605,871.40</b>	<b>- 9,469,426.78</b>
<b>OPERATING ACTIVITIES</b>		
Amortization (intangible fixed assets)	4,086,108.58	6,709,892.87
Depreciation (tangible fixed assets)	15,844,725.05	14,428,853.01
(Increase)/decrease in current receivable and accrued fees	- 841,138.36	- 9,886,311.08
(Increase)/decrease in other receivables	- 1,454,768.44	- 1,450,675.68
(Increase)/decrease in receivables related to consolidated EC entities	- 33,321.28	2,715.41
Increase/(decrease) in provisions for risks and liabilities	459,914.13	662,720.93
Increase/(decrease) in provision for doubtful debts	620,005.74	536,999.15
Increase/(decrease) in deferred revenue	- 986,589.36	274,164.85
Increase/(decrease) in accounts payable	4,049,928.56	- 3,656,971.70
Increase/(decrease) in liabilities related to consolidated EC entities	- 2,638,665.08	10,561,534.20
(Gains)/losses on sale/disposal/derecognition of property, plant and equipment	174,505.58	154,256.65
Other non-cash movements	5,578.22	- 78,310.84
<b>Net cash flow from operating activities (a)</b>	<b>1,680,411.94</b>	<b>8,789,440.99</b>
<b>INVESTING ACTIVITIES</b>		
(Increase) of tangible and intangible fixed assets	- 19,124,082.43	- 14,979,350.48
<b>Net cash flow from investing activities (b)</b>	<b>- 19,124,082.43</b>	<b>-14,979,350.48</b>
<b>NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS (a+b)</b>	<b>- 17,443,670.49</b>	<b>- 6,189,909.49</b>
<b>CASH AND CASH EQUIVALENTS AT THE BEGINNING OF THE PERIOD</b>	<b>80,197,286.80</b>	<b>86,387,196.29</b>
<b>CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD</b>	<b>62,753,616.31</b>	<b>80,197,286.80</b>

## 9. Statement of changes in net assets

Amounts in Euro

	Accumulated surplus	Economic outturn for the year	Net assets
<b>Balance as of 31 December 2015</b>	<b>101,881,400.70</b>	<b>&lt;9,469,426.78&gt;</b>	<b>92,411,973.92</b>
Allocation of economic result 2015	<9,469,426.78>	9,469,426.78	<b>0</b>
Economic result 2016	0	<17,605,871.40>	<17,605,871.40>
<b>Balance as of 31 December 2016</b>	<b>92,411,973.92</b>	<b>&lt;17,605,871.40&gt;</b>	<b>74,806,102.52</b>

## 10. Notes to the financial statements

### 10.1. Intangible fixed assets

Intangible fixed assets are identifiable non-monetary assets without physical substance and it is probable that the asset will produce future economic benefit for the Agency.

In the case of the Agency this comprises computer software licences, consulting and internal staff costs related to the development of software to support the Agency's core activities.

In 2016 the Agency capitalised internally generated computer software in value of € 4.33 Million due to five projects being finished.

The table below summarises the accounting movements for the year.

EUR thousands

Intangible fixed assets	Internally generated computer software	Other computer software	Intangible asset under construction	Total
<b>Cost</b>				
<b>Balance 01.01.2016</b>	<b>67,849</b>	<b>9,399</b>	<b>9,269</b>	<b>86,517</b>
Additions	0	395	16,823	17,218
Transfers	4,293	39	<4,332>	0
Reclassification	0	<5>	<3>	<8>
De-recognition	0	0	0	0
<b>Balance 31.12.2016</b>	<b>72,142</b>	<b>9,828</b>	<b>21,757</b>	<b>103,727</b>
<b>Amortisation</b>				
<b>Balance 01.01.2016</b>	<b>&lt;63,966&gt;</b>	<b>&lt;8,243&gt;</b>	<b>0</b>	<b>&lt;72,209&gt;</b>
Amortisation	<3,488>	<598>	0	<4,086>
Transfers	0	0	0	0
De-recognition	0	0	0	0
<b>Balance 31.12.2016</b>	<b>&lt;67,454&gt;</b>	<b>&lt;8,841&gt;</b>	<b>0</b>	<b>&lt;76,295&gt;</b>
<b>Net book value</b>				
<b>Balance 31.12.2016</b>	<b>4,688</b>	<b>987</b>	<b>21,757</b>	<b>27,432</b>



## 10.2. Tangible fixed assets

The last remaining € 1.33 Million of tangible assets under construction related to the acquisition of the 10<sup>th</sup> floor has been transferred to the relevant asset category.

In 2016 the Agency has acquired new computer hardware for € 1.55 Million and disposed of the same for a net book value of € 106,000.

The table below summarises the accounting movements for the year.

EUR Thousands

Tangible fixed assets	Building and fitting out cost	Computer hardware	Furniture and equipment	Tangible assets under construction	Total
<b><u>Cost</u></b>					
<b>Balance 01.01.2016</b>	<b>59,946</b>	<b>7,120</b>	<b>11,062</b>	<b>1,049</b>	<b>79,177</b>
Additions	0	1,553	66	285	1,904
Transfers	1,334	0	0	<1,334>	0
Disposals	<71>	<788>	0	0	<859>
Reclassification	<109>	3	109	0	3
<b>Balance 31.12.2016</b>	<b>61,100</b>	<b>7,888</b>	<b>11,237</b>	<b>0</b>	<b>80,225</b>
<b><u>Depreciation</u></b>					
<b>Balance 01.01.2016</b>	<b>&lt;17,238&gt;</b>	<b>&lt;5,020&gt;</b>	<b>&lt;3,115&gt;</b>	<b>0</b>	<b>&lt;25,373&gt;</b>
Depreciation	<12,677>	<1,418>	<1,749>	0	<15,844>
Disposals	4	682	0	0	686
Reclassification	3	0	<3>	0	0
<b>Balance 31.12.2016</b>	<b>&lt;29,908&gt;</b>	<b>&lt;5,756&gt;</b>	<b>&lt;4,867&gt;</b>	<b>0</b>	<b>&lt;40,531&gt;</b>
<b><u>Net book value</u></b>					
<b>Balance 31.12.2016</b>	<b>31,192</b>	<b>2,132</b>	<b>6,370</b>	<b>0</b>	<b>39,694</b>

### **10.3. Current receivable**

This item includes € 44.42 Million of fees invoiced to marketing authorisation holders and applicants remaining open at 31.12.2016. Included in the amount is € 5.73 Million of fees with deferred payment relating to applications by Micro, Small and Medium enterprises (SMEs) and for medicinal products to be used in a human pandemic situation.

The provision for doubtful debts is a specific provision i.e. the amounts concerned are unlikely to be collected for specific customers and it amounts to € 1,772,944.89 (2015: € 1,152,939.15).

The risk analysis for this financial instrument is disclosed in section 11 of this report.

### **10.4. VAT recoverable from member states**

The protocol agreement between the Agency and the United Kingdom (UK) authorities provides that the Agency pays value added tax (VAT) and air passenger duty (APD) on goods and services invoiced by UK registered entities and by entities registered with the VAT MOSS scheme and subsequently reclaims the amounts. The VAT claim for September to December 2016, corresponding to a Pounds Sterling revaluated amount at year-end of € 3,300,116.75, together with the claim of other Euro denominated VAT amounts, is expected to be recovered in early 2017.

The risk analysis for this financial instrument is disclosed in section 11 of this report.

### **10.5. Sundry receivables and prepaid expenses**

This item includes:

EUR thousands

<b>Sundry receivables and prepaid expenses</b>	<b>31.12.2016</b>	<b>31.12.2015</b>
Rental payment of office premises	4,544	5,270
Prepaid expenditure for evaluation services	3,076	3,340
Other prepaid expenditure	1,893	1,155
Sundry receivables	0	7
<b>Total sundry receivables and prepaid expenses</b>	<b>9,513</b>	<b>9,772</b>

## 10.6. Cash and cash equivalents

Cash and cash equivalents balances comprises the following:

EUR thousands

Cash and cash equivalents	31.12.2016	31.12.2015
Short term deposits < 3 months including accrued interest GBP deposit Lloyds Bank Plc (EUR equivalent)	0	0
Bank accounts GBP account Lloyds Bank (EUR equivalent)	223	118
Bank accounts GBP account HSBC Bank Plc (EUR equivalent)	4	4
Bank accounts EUR account Lloyds Bank	52,395	69,943
Bank accounts EUR account HSBC Bank Plc	10,132	10,132
<b>Total cash and cash equivalent</b>	<b>62,754</b>	<b>80,197</b>

The cash balances at the year-end, together with VAT recoverable and other sundry receivables, are earmarked to account for the budget carry forwards as disclosed in Part II, Aggregated reports on the implementation of the budget and explanatory notes.

The risk analysis for this financial instrument is disclosed in section 11 of this report.

## 10.7. Non-current liabilities

Non-current liabilities include a discounted provision for risk and charges against assets of € 13.60 Million to reflect the estimated maximum cost the Agency might incur for restoring the premises at 30 Churchill Place, London to their original state at the end of the existing lease contract in 2039. The yearly 'unwinding' of the discount (3.5%) is recognised as a cost in the statement of financial performance.

This item also includes € 49.01 Million as non-current deferred revenue relating to the inducement received by the landlord as part of the lease of the new office premises at 30 Churchill Place, London. Such inducement corresponds to 37 months of rent free period, released against annual rents over the life of the lease (25 years); and for fit-out 'Category A' inducements released in line with the depreciation of the fit out costs (4 years).

In respect of property-related obligations, please refer also to note 10.9 below, dealing with non-budgetary commitments and contingent liabilities.

## 10.8. Current payables

Current payables represent amounts accrued for goods and services due at 31 December 2016 for a total of € 42.07 Million. The amount includes Pounds Sterling denominated accrued charges for a revaluated amount at year end of € 3.55 Million.

It also includes accrued charges of € 3.47 Million for untaken leave, calculated on the basis of the staff average cost based on the Agency's population and the specific country correction coefficient and no longer based on the methodology in use at the Commission (2015: € 1.55 Million).

The risk analysis for this financial instrument with regard to the foreign currencies (FX) to which the Agency is exposed for its financial liabilities as at 31 December 2016, is disclosed in section 11 of this report.

EUR thousands

Current payables	31.12.2016	31.12.2015
Accounts payable and accrued charges	9,515	9,731
Accrued expenditure for evaluation services	28,807	26,518
Accrued charges for untaken leave and other staff costs	3,748	1,765
<b>Total current payables</b>	<b>42,070</b>	<b>38,014</b>

## 10.9. Non-budgetary commitments and contingent liabilities

On 29 March 2017, the United Kingdom notified the European Council of its decision to withdraw from the European Union. An agreement setting out the arrangements for its withdrawal will be negotiated.

The seat of the Agency was decided by common agreement between the representatives of the governments of the member states, meeting at the head of state and government level (Official Journal C323-1 30.11.1993). Its expected relocation can only occur as a result of a legislative process involving the Commission, the European Parliament and the Council.

At the date on which these accounts are authorised, no decision has been made with regard to the future location of the Agency.

Potential costs related to a possible removal of the Agency's seat encompass:

- the obligations from the existing office lease contract
- the cost of the removal of the offices and of the staff of the Agency with their families.

Other than the obligations deriving from the lease, it is not practicable at this stage to give an estimate of those costs as there are uncertainties as to the future location of the seat, to the part of the staff which would follow the Agency and to the timing of a future removal.

The major future commitment entered into by the Agency is the rental contract of the building at 30 Churchill Place, London E14 5EU. At present it is estimated that rent payable for the period 2017 to 2039 amounts to approximately € 448 Million inclusive of landlord and estate service charges, insurance and business rates.

The Agency's future contractual obligations, excluding the rental contract described above, are estimated to be up to a maximum of € 2 Million.

The Agency is co-defendant together with the European Commission in a number of administrative appeals filed in the Courts by applicants. These legal cases or administrative appeals can be considered to be part of the normal course of business for a pharmaceutical regulatory authority. At this moment there is no reason to believe that any significant financial obligation would arise as a result of these cases. However this cannot be guaranteed until judgement is received from the Court.

### **10.10. Fees and charges relating to marketing authorisations**

The Agency charges fees for applications for marketing authorisation, for variations and other changes to marketing authorisations, and annual fees for authorised medicines as well as procedural fees to marketing authorisation holders for the assessment of pharmacovigilance procedures, i.e. periodic safety update reports (PSURs), post-authorisation safety studies (PASS), referrals initiated as a result of the evaluation of pharmacovigilance data in respect of medicinal products for human use. In addition the Agency charges annual fees to support its activities with regard to the provision of pharmacovigilance-related services in the areas of information technology systems and literature monitoring. The Agency levies these annual fees on the basis of the data on medicinal products provided to the Agency by the marketing authorisation holders in each EU member state, and is therefore dependant on the accuracy and completeness of that data to establish the correct amount receivable from each marketing authorisation holder in accordance with the requirement of Article 60 of the Agency's Financial Regulation.

EUR thousands

<b>Fees and administrative revenue</b>	<b>2016</b>	<b>2015</b>
Fees for initial applications	26,515	25,943
Annual fees	75,980	70,350
Other fees mainly post authorization variations	128,836	119,115
Fees for Pharmacovigilance activities	25,400	25,280
<b>Fees revenue</b>	<b>256,731</b>	<b>240,688</b>
Processing Parallel Distribution notifications	9,785	9,777
Processing Export Certificates	2,372	2,665
Other administrative fees	1,480	1,824
<b>Administrative revenue</b>	<b>13,637</b>	<b>14,266</b>
<b>Total fees and administrative revenue</b>	<b>270,368</b>	<b>254,954</b>

The Agency also charges an administrative fee for the notification of parallel distribution. A Community marketing authorization is valid throughout the EU and a centrally authorized medicinal product is by definition identical in all Member States. Products placed on the market in one Member State can be marketed in any other part of the Community by a "parallel distributor" independent of the marketing authorization holder. Typically, this is done to benefit from price differentials. The Agency checks compliance of such products distributed in parallel with the appropriate terms of the Community marketing authorization. In addition, the Agency issues certificates of a medicinal product in conformity with the arrangements laid down by the World Health Organization. These certify the marketing authorization and good manufacturing status of medicinal products in the EU and are intended for use in support of marketing authorization applications in and export to non-EU countries.

### **10.11. Contribution from EU entities and budgetary outturn balance**

This item comprises:

EUR thousands		
Contribution from EU entities	2016	2015
EC general subsidy	2,038	18,669
Balance of budget outturn from previous years	1,949	1,500
EU orphan medicinal products contribution	11,520	13,508
EEA contribution	56	554
<i>less surplus of budget current year</i>	<i>-10,231</i>	<i>-12,767</i>
<b>Contribution from EU entities</b>	<b>5,332</b>	<b>21,464</b>

In compliance with Article 20 of the framework Financial Regulation, if the budgetary result is positive, it shall be repaid to the Commission up to the amount of the contribution paid during the year. The Commission treats this amount as earmarked revenue, which can at the discretion of the Commission be included in the contribution to the Agency budgets of the following years. If the budgetary result is negative, it shall be offset against positive budget result of the Agency in the following years.

Each year the European Parliament and Council allocate a special contribution from the EU budget to allow the Agency to offer financial incentives to sponsors of orphan medicinal products. In 2016 the Agency has recognised € 11.52 Million of revenue for orphan medicinal products, for a corresponding cash contribution of € 12.76 Million received by the Commission. More details on the implementation of the budgetary revenue is provided in Part II, Aggregated reports on the implementation of the budget and explanatory notes.

### 10.11.1. Other consolidated entities

The Agency's receivable and payable balances with the consolidated EU entities, corresponding to 33k and 437k respectively, shall be disclosed separately in the balance sheet.

### 10.12. External assigned revenue for projects

This item comprises € 5.32 Million of recognized revenue related to the landlord inducement received as part of the contractual arrangements concerning the move to the new building at 30 Churchill Place, London, as outlined more in details in note 10.7, and € 0.01 Million for other assigned revenue for projects.

### 10.13. Sundry revenue

This item includes:

Sundry revenue	EUR thousands	
	2016	2015
Refund of service charges and translation expenditure	82	890
Other miscellaneous recoveries	267	134
<b>Total sundry revenue</b>	<b>349</b>	<b>1,024</b>

### 10.14. Staff expenses

As at 31 December 2016, the Agency's headcount included a total of 587 temporary agents, 143 contract agents and 38 national experts on secondment (2015: 587, 153 and 35). Compared to 2015, the total headcount had decreased by 1%, from 775 to 768.

Overall, staff expenses have increased by 12%, from € 101.27 Million at 31.12.2015 to € 113.06 Million at 31.12.2016. This is due primarily to the Agency's contribution to the cost of the EU pension scheme, obligatory as from 1<sup>st</sup> January 2016 and to the change in methodology for calculating the accrued charges for untaken leave, as outlined in note 10.8, Current payables.

The annual update of the basic salary and allowances was 3.3%. The London salary weighting coefficient is adjusted each year to compensate for equal but opposite movements in the Euro/Pound Sterling exchange rate (2016/2017: 0.8255; 2015/2016: 0.7085) and for comparative changes in the European cost of living index (2016: 141.8; 2015: 166.9). The differences of exchange for salaries related transactions are charged to the statement of financial performance under non-operating activities, see note 10.17 and 10.17.1.

### **10.15. Administrative expenditure**

This item comprises:

EUR thousands

<b>Administrative expenditure</b>	<b>2016</b>	<b>2015</b>
Rent and service charges	19,083	20,005
Other building occupancy costs	2,457	1,360
Communication and networking expenditure on annual IT costs	14,256	15,724
Others, i.e. telecommunication, library, etc.	1,227	1,583
<b>Total administrative expenditure</b>	<b>37,023</b>	<b>38,672</b>

The rental expenditure, paid by the Agency in Pound Sterling due to its location in London, has decreased in comparison to the previous year due to the Euro appreciation against the Pound Sterling.

### **10.16. Operating expenditure**

The principal items included are:

EUR thousands

<b>Operating expenditure</b>	<b>2016</b>	<b>2015</b>
Share of evaluation and annual fees to NCAs	102,031	97,119
Share of evaluation of pharmacovigilance procedures fees to NCAs	11,007	10,802
Reimbursement of Committee Members traveling costs and accommodation	7,812	7,906
Translations	3,684	3,866
IT operational expenditures	887	4,328
Studies and consultants	4,370	5,372
Other operating expenditures	537	589
<b>Total operating expenditure</b>	<b>130,328</b>	<b>129,982</b>

The IT operational expenditures include software development costs which are below the Agency's threshold of € 1,000,000 for capitalisation of internally generated intangible asset.



## 10.17. Non-operating activities

This item relates to income from financial sources as follows:

EUR thousands

Non-operating activities	2016	2015
Bank interest income	10	34
Revenue for ancillary services	56	87
Bank charges	<45>	<47>
Differences on exchange	2,586	<208>
<b>Total non-operating activities</b>	<b>2,607</b>	<b>&lt;134&gt;</b>

### 10.17.1. Differences on exchange

These are made up as follows:

EUR thousands

Differences on exchange	2016	2015
Exchange gain (loss) on hedged amounts and other non-Euro currency purchases	<502>	1,443
Exchange gain (loss) on salary related transactions	3,090	<1,655>
Other differences	<2>	4
<b>Total differences on exchange</b>	<b>2,586</b>	<b>&lt;208&gt;</b>

The exchange gain on salary related transactions, paid by the Agency in Pound Sterling due to its location in London, is due to the Euro appreciation against the Pound Sterling (2016/2017: 0.8255; 2015/2016: 0.7085).

## 11. Financial assets and financial liabilities risk analysis

EU Accounting rule 11 requires the Agency to disclose information that enables users of its financial statements to evaluate the nature and the extent of risks arising from financial instruments to which the Agency is exposed at the end of the reporting period and how the Agency manages them.

Cash and cash equivalents are carried in the balance sheet at cost. They include cash in hand, deposits held at call and short term deposits with banks.

In line with its treasury policy, the Agency implements rigorous cash management, taking account of assigned revenue, in order to ensure that its cash balances are limited to duly justified requirements.

Treasury and payment operations are highly automated and rely on modern information systems. Specific procedures are applied to guarantee system security and to ensure segregation of duties in line with the Financial Regulation, the Agency's internal control standards, and audit principles.

Deposits are held only with banks who comply with the ratings issued by the European Commission's Accounting Officer and are spread between two banks.

The Agency's budget is drawn up and implemented in Euro and the accounts are presented in Euro with all the revenue being received in Euro but around 33% of the expenditure being paid in pounds sterling due to the location of the Agency in London.

Receivables are carried at original invoice amount less write-down for impairment. A write-down for impairment of receivables is established when there is objective evidence that the Agency will not be able to collect all amounts due. The amount of the write-down is the difference between the asset's carrying amount and the recoverable amount.

### 11.1. Credit quality of financial assets

EUR thousands

Counterparties <u>with</u> external credit rating	Note	31.12.2016	Credit rating	Agency
Bank accounts			F1	Fitch
GBP account Lloyds Bank (EUR equivalent)	10.6	223	A1	Moody's
			A-1	S&P
Bank accounts			F1+	Fitch
GBP account HSBC Bank Plc (EUR equivalent)	10.6	4	Baa1	Moody's
			A-1+	S&P
Bank accounts			F1	Fitch
EUR account Lloyds Bank	10.6	52,395	A1	Moody's
			A-1	S&P
Bank accounts			F1+	Fitch
EUR account HSBC Bank Plc	10.6	10,132	Baa1	Moody's
			A-1+	S&P
Receivables from Member States			AA	Fitch
VAT (Foreign and Commonwealth Office – UK)	10.4	3,630	Aa1	Moody's
			AA	S&P

EUR thousands

Counterparties <u>without</u> external credit rating	Note	31.12.2016
Debtors who never defaulted	10.3	44,422
Debtors who defaulted in the past	n/a	0

### 11.2. Analysis of the age and impairment of financial assets

Of the € 2.54 Million past due but not impaired debtors, € 2.30 Million are overdue by less than 30 days. The new provision for doubtful debtors for the year was € 621,096.78 corresponding to less than 0.5% of the fee revenue 2016.

EUR thousands

	Note	Past due but not impaired			Impaired
		31.12.2016	<1 year	1-5 years	
Receivables from Member States	10.4	3,630	0	0	0
Debtors who never defaulted	10.3	44,422	2,547	0	1,773
Debtors who defaulted in the past	n/a	0	0	0	0

### 11.3. Liquidity risk

The Agency does not hold any derivative financial liabilities. The table below present the maturity analysis for non-derivative financial liabilities in relation to the remaining contractual maturities. These are the budgetary outturn 2016, payable to the European Commission and other consolidated EU entities, and the current payables with third parties, i.e. suppliers, staff and related accrued charges.

The Agency carries out regular cash-flow monitoring and forecasting of Euro and Pound Sterling cash requirements, and prepares annual budgetary accounts following the modified cash accounting basis to determine the level of EU budgetary contribution required to fund the Agencies activities not supported by fee income.

EUR thousands

	Note	31.12.2016	<1 year	1-5 years	> 5 years
Payables with consolidated entities	10.11 and 10.11.1	10,668	10,668	0	0
Other payables with third parties	10.8	42,070	42,070	0	0

## 11.4. Market risk disclosures

A sensitivity analysis is required in compliance with paragraph 28 of Accounting Rule 11 for each type of market risk that an entity is exposed to at the reporting date, showing how surplus or deficit and net assets would have been affected by changes in the relevant risk variable that were reasonably possible at that date.

The table below provides with an overview of the foreign currencies (FX) to which the Agency is exposed for its financial assets and financial liabilities as at 31 December 2016.

Asset and liabilities in pounds sterling at the end of the reporting period are converted into Euro on the basis of the exchange rate ruling at December 31, 2016. These are the amounts that will be exposed to changes in foreign currency rates which would impact the surplus or deficit in the statement of financial performance.

EUR thousands

Currency exposure at 31.12.2016	Note	GBP (EUR equivalent)
Cash and cash equivalent	10.6	227
Receivables from Member States VAT (Foreign and Commonwealth - UK)	10.4	3,300
<b>Total financial assets</b>		<b>3,527</b>
Payables with third parties	10.8	3,546
<b>Total financial liabilities</b>		<b>3,546</b>
<b>Net position</b>		<b>&lt;19&gt;</b>

Financial assets include € 3.53 Million of Pound Sterling denominated cash and cash equivalent and receivables from Member States. A 10% appreciation of the Euro against the Pound Sterling from the year end rate would lead to a negative difference on exchange impact of € 352,713. A 10% depreciation of the Euro against the Pound Sterling from the year end rate would lead to a positive difference on exchange impact of the same amount.

Financial liabilities include € 3.55 Million of the Pound Sterling denominated payables with third parties. A 10% appreciation of the Euro against the Pound Sterling from the year end rate would lead to a positive difference on exchange impact of € 354,598. A 10% depreciation of the Euro against the Pound Sterling from the year end rate would lead to a negative difference on exchange impact of the same amount.

EUR thousands

Sensitivity analysis	10% EUR appreciation	10% EUR depreciation
Impact on surplus/deficit	1.9	<1.9>

## **Part II: Aggregated reports on the implementation of the budget and explanatory notes**

### **12. Establishment of the budget and budget principles**

In accordance with Article 37 of Regulation (EU, Euratom) No 966/2012, each year the Agency shall send to the Commission, the European Parliament and the Council an estimate of its revenue and expenditure as specified in the constituent act.

As part of the procedure for adoption of the budget, the Commission shall send the Agency's statement of estimates to the European Parliament and the Council and propose the amount of the contribution for the Agency and the number of staff it considers that the body needs.

The budget of the Agency shall be adopted by the management board. Any amendment to the budget of the Agency shall be the subject of an amending budget adopted by the same procedure as the initial budget of the Agency, in accordance with the provisions of the constituent act and Article 33 of the Agency's Financial Regulation.

The budget of the Agency consists of:

- own revenue consisting of all fees and charges which the Agency is authorised to collect by virtue of the tasks entrusted to it, and any other revenue;
- revenue made up of any financial contributions of the host Member States;
- a contribution granted by the Union;
- revenue assigned to specific items of expenditure in accordance with Article 23(1) of the Agency's financial regulation;
- the expenditure of the Agency, including administrative expenditure.

The budget of the Agency shall be established and implemented in accordance with the following budget principles:

- **Unity and budget accuracy**

All revenue and expenditure should be incorporated in a single budget document.

Only the revenue and expenditure included in the budget are authorised. The principle of accuracy means that the Agency will not spend more than is necessary.

- **Annuality**

The principle of annuality requires budget operations to relate to a specific financial year, from 1 January to 31 December.

The budget of the Agency contains non-differentiated commitment and payments appropriations. Commitment appropriations cover the total cost of the legal commitments entered into during the financial year. Payment appropriations cover payments made to honour the legal commitments entered into in the financial year or the preceding financial year.

The appropriations authorised for a financial year shall be used solely to cover expenditure committed and paid in that financial year, and to cover amounts due against commitments from the preceding financial year.

Commitments shall be entered in the accounts on the basis of the legal commitments entered into up to 31 December. Payments shall be entered in the accounts for a financial year on the basis of the payments effected by the accounting officer by 31 December of that year.

- **Equilibrium**

The principle of equilibrium means that budget revenue must equal budget expenditure.

- **Unit of account**

The budget is drawn up and implemented in euros and the accounts shall be presented in euros.

- **Universality**

In line with this principle, budget revenue may not be assigned to specific items of expenditure (non-assignment rule) and revenue and expenditure may not be set off against each other (gross budget rule). Consequently, revenue is pooled and used without distinction to finance all expenditure. External assigned revenue and internal assigned revenue shall only be used to finance specific items of expenditure.

- **Specification**

The principle of specification means that each appropriation must have a given purpose and be assigned to a specific objective in order to prevent any confusion between appropriations, at both the authorisation and implementation stages. The principle of specification also applies to revenue and requires the various sources of revenue paid into the budget to be clearly identified.

- **Sound financial management**

The principle of sound financial management stipulates that the budget appropriations must be used according to the principles of economy, efficiency and effectiveness.

- **The principle of transparency**

The budget is established in compliance with the principle of transparency, ensuring sound information on implementation of the budget and the accounts.

## **13. Implementation of the 2016 budget**

The commitment appropriations and payment appropriations authorised for the financial year ended December 31, 2016 consist of:

- appropriations provided in the budget, including amending budgets;
- appropriations carried over by decision and automatic carry over; and
- appropriations provided following the receipt of revenue assigned during the financial year or during previous financial years and not used.

The revenue of the Agency is entered in the accounts for the financial year on the basis of the amounts collected during that financial year. The revenue of the Agency shall give rise to an equivalent amount of payment appropriations.

Following the referendum of 23<sup>rd</sup> June 2016 on the United Kingdom's membership of the European Union, the Pound Sterling depreciated considerably against the Euro. As a result, the Agency had significant gains on exchange rate differences in particular on salary and rent and building maintenance payments, which are made in Pound Sterling. Through an amending budget adopted by the Management Board at its October 2016 meeting, the budget was reduced by € 16.29 Million.

Amounts in EUR

Budget title	Initial adopted budget	Amending budgets and transfers	Final adopted budget	Carry over by decision from 2015	Automatic carry over from 2015
<b>Revenue</b>					
EU subsidy	12,366,000.00	-9,918,000.00	2,448,000.00		
Other EU contribution	14,735,000.00	0	14,735,000.00		
Fees	276,961,000.00	-6,371,000.00	270,590,000.00	not applicable	not applicable
Other revenue	20,649,000.00	0	20,649,000.00		
<b>Total</b>	<b>324,711,000.00</b>	<b>-16,289,000.00</b>	<b>308,422,000.00</b>		
<b>Expenditure</b>					
I - Staff	122,674,000.00	-10,057,000.00	112,617,000.00	0	889,175.05
II - Administrative	49,577,000.00	-2,685,000.00	46,892,000.00	0	3,755,066.12
III - Operating	152,460,000.00	-3,547,000.00	148,913,000.00	5,398,000.00	32,776,728.97
<b>Total</b>	<b>324,711,000.00</b>	<b>-16,289,000.00</b>	<b>308,422,000.00</b>	<b>5,398,000.00</b>	<b>37,420,970.14</b>

The Agency's adopted budget included also assigned revenue for €15.23 Million as inducement received by the landlord as part of the lease of the new office premises at 30 Churchill Place, London.

### **13.1. Budgetary result account for the year ended December 31, 2016**

The budget result consists of the difference between all the revenue collected in respect of that financial year and the amount of payments made against appropriations for that financial year increased by the amount of the appropriations for the same financial year carried over to the following year.

Such difference shall be increased on the one hand, by the net amount of appropriations carried over from previous financial years which have been cancelled<sup>2</sup> and, on the other hand, increased or decreased by the balance resulting from exchange gains and losses during the financial year, both realised and non-realised.

The positive outturn for the financial year 2016 is the result of the continued depreciation of the Pound Sterling against the Euro throughout the year, as well as a higher collection rate for fee income during the final weeks of the financial year.

<sup>2</sup> € 1,096,294.90 elapsing from carry over by decision and € 1,667,272.25 elapsing from automatic carry over, for a total of € 2,763,567.15

## Budgetary result account for the financial year ended December 31, 2016

	2016 Final	2015 Final
<b>REVENUE</b>		
Balancing Commission subsidy	16,812,924.18	18,668,607.31
Other subsidy from Commission	-	15,266,065.12
Fees and charges related to marketing authorisations	272,588,211.46	251,490,172.82
Other income	15,697,561.91	18,693,943.35
<b>TOTAL REVENUE (a)</b>	<b>305,098,697.55</b>	<b>304,118,788.60</b>
<b>EXPENDITURE</b>		
<b>Title 1 - Staff expenditure</b>		
Payments	109,772,025.73	102,761,496.48
Carry over	957,021.58	889,175.05
<b>Sub-total</b>	<b>110,729,047.31</b>	<b>103,650,671.53</b>
<b>Title 2 - Administrative expenditure</b>		
Payments	37,202,217.29	45,666,819.63
Carry over	3,204,776.79	3,755,066.12
<b>Sub-total</b>	<b>40,406,994.08</b>	<b>49,421,885.75</b>
<b>Title 3 - Operating Expenditure</b>		
Payments	107,122,132.61	103,906,891.25
Carry over	38,870,506.46	38,174,728.97
<b>Sub-total</b>	<b>145,992,639.07</b>	<b>142,081,620.22</b>
<b>Total Payments</b>	<b>254,096,375.63</b>	<b>252,335,207.36</b>
<b>Total Carry Over</b>	<b>43,032,304.83</b>	<b>42,818,970.14</b>
<b>TOTAL EXPENDITURE (b)</b>	<b>297,128,680.46</b>	<b>295,154,177.50</b>
<b>OUTTURN FOR THE FINANCIAL YEAR (a-b)</b>	<b>7,970,017.09</b>	<b>8,964,611.10</b>
Appropriation from previous year which lapse	2,763,567.15	2,359,093.58
Exchange differences for the year (gain +/loss -)	- 502,149.59	1,442,975.01
<b>BALANCE OF THE OUTTURN ACCOUNT FOR THE FINANCIAL YEAR</b>	<b>10,231,434.65</b>	<b>12,766,679.69</b>
Balance year N-1	12,766,679.69	1,949,934.18
Positive balance from year N-1 reimbursed in year N to the Commission	- 12,766,679.69 -	1,949,934.18
<b>Balance remaining open to be reimbursed to the Commission in year n+1</b>	<b>10,231,434.65</b>	<b>12,766,679.69</b>



## 13.2. Reconciliation of economic result with budget result

Amounts in EUR	<b>2016</b>	<b>2015</b>
	<b>Final</b>	<b>Final</b>
<b>Economic result (a) -</b>	<b>17,605,871.40</b>	<b>- 9,469,426.78</b>
<b>Adjustments for accrual items (not in budget result)</b>		
Reversal accrued expenditure at 31.12.2015	- 35,724,038.69	- 41,510,353.17
Expenditure accruals at 31.12.2016	38,968,970.14	38,014,086.75
Expenditure accruals at 31.12.2016 (EU entities)	- 42,243.60	229,156.55
Reversal prepayment/deferred expenditure at 31.12.2015	4,459,242.30	3,124,061.40
Prepayment/deferred expenditure at 31.12.2016	- 4,965,046.07	- 4,484,117.54
Payments made from automatic carry over (C82016)	35,753,697.89	36,626,193.68
Payments made from carry over by decision (C22016)	4,301,705.10	2,407,588.86
Other expenditure accrual movements not included in the budget result	5,020.11	- 258,856.20
Depreciation of intangible and tangible assets year year 2016	19,930,833.63	21,138,745.88
Disposal and de-recognition of assets year 2016	174,505.58	154,256.65
Provisions year 2016	620,005.74	1,199,720.08
Reversal accrued revenue at 31.12.2015	38,023,938.91	34,276,919.27
Accrued revenue at 31.12.2016	- 39,800,540.40	- 38,023,938.91
Reversal deferred revenue at 31.12.2015	- 24,961,407.81	- 19,003,013.81
Deferred revenue at 31.12.2016	29,659,047.60	24,961,407.81
Invoices issued in 2016 not cashed at 31.12.2016	- 42,412,344.38	- 44,213,171.33
Deferred revenue (non fees) year at 31.12.2016	9,908,542.45	11,982,014.81
Budget result (pre-financing) deducted from revenue (EU contribution)	10,231,434.65	12,766,679.69
Other revenue accrual movements not included in the budget result	97,747.91	470,048.90
<b>Total accrual items adjustment (b)</b>	<b>44,229,071.06</b>	<b>39,857,429.37</b>
<b>Adjustments for budgetary items (not in economic result)</b>		
Fixed asset acquisitions (less unpaid amounts)	- 19,124,082.43	- 14,979,350.48
Invoices issued before year 2016 and cashed in year 2016	43,001,055.10	37,817,904.14
Cancellation of unused carry overs from previous year (C8 and C22016)	2,763,567.15	2,359,093.58
Budgetary carry over to 2017 (C82017)	- 43,032,304.83	- 42,818,970.14
<b>Total budgetary items adjustment (c) -</b>	<b>16,391,765.01</b>	<b>- 17,621,322.90</b>
<b>Budgetary result (a+b+c)</b>	<b>10,231,434.65</b>	<b>12,766,679.69</b>

Adjustments for accrual items which are included in the economic result and not in the budgetary result mainly consist of: accruals made at year-end for eligible expenses incurred by Agency's for which an invoice has not yet been received; the budgetary payments made in the current year from carry-overs from previous years and the reversal of previous year accrued expenses; different elements such as asset depreciation and movement in provisions; the invoices issued to customers in the current year but not yet collected; accruals made at year end for earned revenue for which an invoice has not yet been issued, or, deferrals for invoices issued in relation to revenue to be earned in future; and the budget result which is deducted from the EU contribution in the economic result.

Adjustments for budgetary items which are included in the budget result and not in the economic result mainly consist of budgetary payments made for acquisition of fixed assets; amounts collected from invoices issued in previous years; appropriations that are carried forward to the next year; and the cancellation of unused appropriations carried over from the previous year.

### **13.3. Summary of the implementation of income appropriations**

The Agency has collected revenue for € 305.10 Million corresponding to 98.92% of the total income appropriations. Fees paid by the pharmaceutical industry for services provide amounted to € 272.60 Million corresponding to 89.34% of the total revenue for the year.

Amounts in EUR

Budget title	Total income appropriations	Entitlements established	Revenue collected	Revenue as a % of the budget
EU basic contribution	2,448,000.00	2,094,115.00	2,094,115.00	85.54%
Other EU contribution	14,735,000.00	14,718,809.18	14,718,809.18	99.89%
Fees	270,590,000.00	317,451,752.18	272,588,211.46	100.74%
Other revenue	20,649,000.00	15,743,587.98	15,697,561.91	76.02%
<b>Total</b>	<b>308,422,000.00</b>	<b>350,008,264.34</b>	<b>305,098,697.55</b>	<b>98.92%</b>

### **13.4. Summary of the implementation of commitment appropriations**

The Agency has issued commitments for € 297.13 Million corresponding to 96.34% of the total commitment appropriations.

Amounts in EUR

Budget title	Total commitment appropriations	Commitments made	%	Appropriations lapsing	%
I - Staff	112,617,000.00	110,729,047.31	98.32%	1,887,952.69	1.68%
II - Administrative	46,892,000.00	40,406,994.08	86.17%	6,485,005.92	13.83%
III - Operating	148,913,000.00	145,992,639.07	98.04%	2,920,360.93	1.96%
<b>Total</b>	<b>308,422,000.00</b>	<b>297,128,680.46</b>	<b>96.34%</b>	<b>11,293,319.54</b>	<b>3.66%</b>

### 13.5. Summary of the implementation of payment appropriations

The Agency has made payments for € 254.10 Million corresponding to 82.39% of the total payment appropriations. A total of € 43.03 Million appropriations, corresponding to 13.71% of the total payment appropriations, are carried over to the following year.

Amounts in EUR

Budget title	Total payment appropriations	Payments made	%	Appropriations carried over to next year	%
I - Staff	112,617,000.00	109,772,025.73	97.47%	957,021.58	0.85%
II - Administrative	46,892,000.00	37,202,217.29	79.34%	3,204,776.79	6.83%
III - Operating	148,913,000.00	107,122,132.61	71.94%	38,870,506.46	25.19%
<b>Total</b>	<b>308,422,000.00</b>	<b>254,096,375.63</b>	<b>82.39%</b>	<b>43,032,304.83</b>	<b>13.71%</b>

### 13.6. Summary of the implementation of appropriations carried over by decision

The Agency has implemented 79.69% of the appropriations carried over by decision from the previous year.

Amounts in EUR

Budget title	Total appropriations carried over by decision	Payments made	%	Appropriations lapsing	%
III - Operating - carry over by decision	5,398,000.00	4,301,705.10	79.69%	1,096,294.90	20.31%
<b>Total</b>	<b>5,398,000.00</b>	<b>4,301,705.10</b>	<b>79.69%</b>	<b>1,096,294.90</b>	<b>20.31%</b>

### 13.7. Summary of the implementation of appropriations carried over automatically

The Agency has implemented 95.54% of the appropriations carried over automatically from the previous year.

Amounts in EUR

Budget title	Total appropriations carried over automatically from previous year	Payments made	%	Appropriations lapsing	%
I - Staff	889,175.05	756,835.98	85.12%	132,339.07	14.88%
II - Administrative	3,755,066.12	3,113,104.90	82.90%	641,961.22	17.10%
III - Operating	32,776,728.97	31,883,757.01	97.28%	892,971.96	2.72%
<b>Total</b>	<b>37,420,970.14</b>	<b>35,753,697.89</b>	<b>95.54%</b>	<b>1,667,272.25</b>	<b>4.46%</b>

Details of the implementation of the Agency revenue and expenditure budget for 2016, by budget item, are provided in Annex I and Annex II.

# Annex I – Details of the implementation of budget revenue 2016

## Income appropriations and entitlements established

amounts in EUR

Budget line	Title	Income appropriations			Entitlements established		Total
		Initial adopted budget	Amending budgets	Final adopted budget	Current Year	Carried over	
1000	FEES COLLECTED	248,716,000.00	-	243,841,000.00	246,640,725.04	40,883,298.00	287,524,023.04
1001	FEES COLLECTED PHARMACOVIGILANCE	28,245,000.00	-	26,749,000.00	25,399,455.27	4,528,273.87	29,927,729.14
2000	EU BASIC CONTRIBUTION	11,690,000.00	-	2,038,000.00	2,037,869.78	-	2,037,869.78
2010	ORPHAN CONTRIBUTION	12,785,000.00	-	12,785,000.00	12,768,875.00	-	12,768,875.00
3000	EEA	676,000.00	-	410,000.00	56,245.22	-	56,245.22
5200	REVENUE FOR ADMINISTRATIVE ACTIVITIES AND ANCILLARY SERVICES	90,000.00	-	90,000.00	65,791.06	21,505.00	87,296.06
6000	EXTERNAL ASSIGNED REVENUE FOR PROJECTS AND PROGRAMME	249,000.00	-	249,000.00	12,801.00	64,642.53	77,443.53
6000R	EXTERNAL ASSIGNED REVENUE (RENT)	19,310,000.00	-	19,310,000.00	15,230,149.24	-	15,230,149.24
7000	BALANCE OF OUTTURN ACCOUNT OF PREVIOUS YEARS	1,950,000.00	-	1,950,000.00	1,949,934.18	-	1,949,934.18
9000	MISCELLANEOUS REVENUE	1,000,000.00	-	1,000,000.00	348,699.15	-	348,699.15
	<b>Total</b>	<b>324,711,000.00</b>	<b>-</b>	<b>308,422,000.00</b>	<b>304,510,544.94</b>	<b>45,497,719.40</b>	<b>350,008,264.34</b>

## Revenue collected on entitlements established

amounts in EUR

Budget line	Title	Entitlements established		Revenue		Receipts as % of budget	
		Total	On entitlements of current year	On entitlements carried over	Total	Receipts as % of budget	Outstanding
1000	FEES COLLECTED	287,524,023.04	206,237,214.04	38,511,718.00	244,748,932.04	10=9/3	11=6-9
1001	FEES COLLECTED PHARMACOVIGILANCE	29,927,729.14	23,405,376.89	4,433,902.53	27,839,279.42	100.37%	42,775,091.00
2000	EU BASIC CONTRIBUTION	2,037,869.78	2,037,869.78	-	2,037,869.78	104.08%	2,088,449.72
2010	ORPHAN CONTRIBUTION	12,768,875.00	12,768,875.00	-	12,768,875.00	99.99%	-
3000	EEA	56,245.22	56,245.22	-	56,245.22	99.87%	-
5200	REVENUE FOR ADMINISTRATIVE ACTIVITIES AND ANCILLARY SERVICES	87,296.06	51,036.06	21,505.00	72,541.06	13.72%	-
6000	EXTERNAL ASSIGNED REVENUE FOR PROJECTS AND PROGRAMME	77,443.53	12,801.00	33,371.46	46,172.46	80.60%	14,755.00
6000R	EXTERNAL ASSIGNED REVENUE (RENT)	15,230,149.24	15,230,149.24	-	15,230,149.24	18.54%	31,271.07
7000	BALANCE OF OUTTURN ACCOUNT OF PREVIOUS YEARS	1,949,934.18	1,949,934.18	-	1,949,934.18	78.87%	-
9000	MISCELLANEOUS REVENUE	348,699.15	348,699.15	-	348,699.15	100.00%	-
	<b>Total</b>	<b>350,008,264.34</b>	<b>262,096,200.56</b>	<b>43,000,496.99</b>	<b>305,098,697.55</b>	<b>98.92%</b>	<b>44,909,566.79</b>

# Annex II – Details of the implementation of budget expenditure 2016

## Commitment and payment appropriations (undifferentiated)

Budget line	Heading	amounts in EUR					Total commitment and payments (undifferentiated)
		Initial adopted budget	Budget appropriation	Final adopted budget	Carry-overs by decision	Additional appropriations	
		1	2	3=1+2	4	5	6=3+4+5
1100	BASIC SALARIES	41,517,000.00	659,000.00	40,858,000.00			40,858,000.00
1101	FAMILY ALLOWANCES	8,873,000.00	699,000.00	8,174,000.00			8,174,000.00
1102	EXPIRATION AND FOREIGN RESIDENCE ALLOWANCES	5,917,000.00	20,000.00	5,897,000.00			5,897,000.00
1103	TRAVEL EXPENSES	63,000.00		63,000.00			63,000.00
1114	BASIC SALARIES & ALLOWANCES FOR CONTRACT AGENTS	5,932,000.00	250,000.00	6,202,000.00			6,202,000.00
1120	FURTHER TRAINING, LANGUAGE COURSES AND RETRAINING	857,000.00	120,000.00	1,087,000.00			1,087,000.00
1140	MISCELLANEOUS ALLOWANCES & GRANTS	85,000.00		85,000.00			85,000.00
1141	TRAVEL EXPENSES FROM PLACE OF EMPLOYMENT TO PLACE OF ORIGIN	1,300,000.00		1,300,000.00			1,300,000.00
1143	FIXED SPECIFIC ALLOWANCES	6,000.00		6,000.00			6,000.00
1171	PROFESSIONAL SERVICES RELATING TO STAFF MANAGEMENT	45,000.00		45,000.00			45,000.00
1172	MISCELLANEOUS INSURANCES RELATING TO STAFF ACTIVITIES	200,000.00	20,000.00	220,000.00			220,000.00
1174	PAYMENT FOR ADMINISTRATIVE ASSISTANCE FROM THE EU INSTITUTIONS	450,000.00		450,000.00			450,000.00
1175	INTERIM SERVICES	3,212,000.00	520,000.00	3,732,000.00			3,732,000.00
1180	MISCELLANEOUS EXPENDITURE ON RECRUITMENT	220,000.00		220,000.00			220,000.00
1181	ALLOWANCES ON ENTERING & LEAVING THE SERVICE & ON TRANSFER	595,000.00		595,000.00			595,000.00
1300	RELIGIOUS	33,063,000.00	8,878,000.00	24,185,000.00			24,185,000.00
1300	DUTY	640,000.00	70,000.00	710,000.00			710,000.00
1300	RESTAURANT AND CANTEENS	570,000.00	60,000.00	630,000.00			630,000.00
1410	MEDICAL SERVICE	71,000.00		71,000.00			71,000.00
1520	STAFF EXCHANGES BETWEEN EU INSTITUTIONS	5,660,000.00	71,000.00	5,731,000.00			5,731,000.00
1530	COST OF ORGANISING GRADUATE TRAINEESHIPS	1,302,000.00	810,000.00	4,950,000.00			4,950,000.00
1600	MISCELLANEOUS WELFARE EXPENDITURE	453,000.00		453,000.00			453,000.00
1620	SOCIAL CONTACTS BETWEEN STAFF	30,000.00		30,000.00			30,000.00
1700	REPRESENTATION EXPENSES	40,000.00	20,000.00	100,000.00			100,000.00
1830	SOCIAL SECURITY FOR STAFF	11,314,000.00	62,000.00	11,252,000.00			11,252,000.00
2010	INSURANCE	17,060,000.00	995,000.00	16,065,000.00			16,065,000.00
2020	WATER, GAS, ELECTRICITY & HEATING	518,000.00	100,000.00	418,000.00			418,000.00
2030	MAINTENANCE AND CLEANING	777,000.00	120,000.00	657,000.00			657,000.00
2050	SECURITY & SURVEILLANCE OF BUILDINGS	1,646,000.00	130,000.00	1,516,000.00			1,516,000.00
2080	OTHER EXPENDITURE PRELIMINARY TO CONSTRUCTION OR FITTING-OUT	21,000.00		21,000.00			21,000.00
2090	OTHER EXPENDITURE ON BUILDINGS	78,000.00		78,000.00			78,000.00
2110	MAINTENANCE & SUPPORT OF CORP. PROCESSES	2,335,000.00	1,315,000.00	3,650,000.00			3,650,000.00
2114	MAINTENANCE & SUPPORT OF CORP. APPLICATIONS	5,148,000.00	632,000.00	4,516,000.00			4,516,000.00
2200	TECHNICAL EQUIPMENT & INSTALLATIONS	683,000.00	520,000.00	1,203,000.00			1,203,000.00
2203	LEASE, MAINTENANCE & REPAIR OF TECHN. EQUIPMENT & INSTALLATIONS	17,340,000.00	2,319,000.00	15,021,000.00			15,021,000.00
2210	FURNITURE	70,000.00		70,000.00			70,000.00
2232	VEHICLES	1,220,000.00	266,000.00	954,000.00			954,000.00
2250	INFORMATION CENTRE SERVICES	10,000.00	290,000.00	300,000.00			300,000.00
2300	STATIONERY & OFFICE SUPPLIES	480,000.00		480,000.00			480,000.00
2320	BANK CHARGES	211,000.00	60,000.00	151,000.00			151,000.00
2330	LEGAL EXPENSES	55,000.00		55,000.00			55,000.00
2353	DEPARTMENTAL REMOVALS & ASSOCIATED HANDLING	250,000.00	90,000.00	160,000.00			160,000.00
2354	ARCHIVING OF DOCUMENTS	20,000.00	90,000.00	110,000.00			110,000.00
2358	BUSINESS CONTINUITY	18,000.00		18,000.00			18,000.00
2359	OTHER OPERATING EXPENDITURE	83,000.00		83,000.00			83,000.00
2390	PUBLICATIONS	484,000.00	100,000.00	384,000.00			384,000.00
2400	POSTAL & DELIVERY CHARGES	2,000.00		2,000.00			2,000.00
2500	MEETINGS IN GENERAL	183,000.00		183,000.00			183,000.00
2501	MEMBERSHIP TO FORA	4,000.00		4,000.00			4,000.00
3002	CATERING	50,000.00	117,000.00	167,000.00			167,000.00
3003	OTHER EXPENDITURE IN RELATION TO MEETINGS	8,780,000.00	1,338,300.00	7,441,700.00			7,441,700.00
3013	EVALUATION OF PROCEDURES	155,000.00	39,900.00	115,100.00			115,100.00
3021	TRANSLATION CENTRE, LUXEMBOURG	500,000.00	120,000.00	380,000.00			380,000.00
3021	OTHER TRANSLATIONS	107,327,000.00	1,070,000.00	106,257,000.00			106,257,000.00
3031	STUDIES AND CONSULTANTS	11,815,000.00	570,000.00	12,405,000.00			12,405,000.00
3031	SUBSCRIPTION TO SPECIALISED RESEARCHED	3,660,000.00	1,500.00	2,438,200.00			2,438,200.00
3040	INFORMATION AND PUBLICATIONS	7,388,000.00	1,087,700.00	6,300,300.00			6,300,300.00
3105	BUSINESS IT DEVELOPMENT	474,000.00	186,200.00	287,800.00			287,800.00
		274,000.00	120,000.00	154,000.00			154,000.00
		10,477,000.00	2,485,000.00	12,962,000.00			12,962,000.00
	<b>Total</b>	<b>324,711,000.00</b>	<b>16,289,000.00</b>	<b>308,422,000.00</b>	<b>5,398,000.00</b>		<b>313,820,000.00</b>





# Implementation of automatic carry over from previous year

Budget line	Heading	1	2	3=2/1	4	5
		Commitments carried over from previous year (BAI)	Payments made	% Implementation	Cancellation of commitments which cannot be carried over	% cancellation
		amounts in EUR				
1100	BASIC SALARIES	-	-	0.00%	-	0.00%
1101	FAMILY ALLOWANCES	-	-	0.00%	-	0.00%
1102	EXPATRIATION AND FOREIGN RESIDENCE ALLOWANCES	-	-	0.00%	-	0.00%
1103	FIXED ALLOWANCES	-	-	0.00%	-	0.00%
1114	BASIC SALARIES & ALLOWANCES FOR CONTRACT AGENTS	-	-	0.00%	-	0.00%
1120	FURTHER TRAINING, LANGUAGE COURSES AND RETRAINING	-	-	0.00%	-	0.00%
1140	MISCELLANEOUS ALLOWANCES & GRANTS	31,373.83	25,037.89	79.81%	6,335.94	20.19%
1141	TRAVEL EXPENSES FROM PLACE OF EMPLOYMENT TO PLACE OF ORIGIN	-	-	0.00%	-	0.00%
1143	FIXED SPECIFIC ALLOWANCES	-	-	0.00%	-	0.00%
1171	PROFESSIONAL SERVICES RELATING TO STAFF MANAGEMENT	46,480.96	42,452.67	91.33%	4,028.29	8.67%
1172	MISCELLANEOUS INSURANCES RELATING TO STAFF ACTIVITIES	2,692.29	1,872.30	69.54%	819.99	30.46%
1174	PAYMENT FOR ADMINISTRATIVE ASSISTANCE FROM THE EU INSTITUTIONS	2,325.00	1,652.38	71.07%	672.62	28.93%
1175	INTERIM SERVICES	250,402.82	210,989.97	84.26%	39,412.85	15.74%
1180	MISCELLANEOUS EXPENDITURE ON RECRUITMENT	18,598.20	12,907.94	69.40%	5,690.26	30.60%
1181	ALLOWANCES ON ENTERING & LEAVING THE SERVICE & ON TRANSFER	4,780.00	1,691.45	35.39%	3,088.55	64.61%
1190	WEIGHTINGS	-	-	0.00%	-	0.00%
1300	DUTY TRAVEL	62,859.81	42,085.18	66.95%	20,774.63	33.05%
1400	RESTAURANT AND CANTEENS	40,663.75	37,536.69	92.31%	3,127.06	7.69%
1410	MEDICAL SERVICE	10,723.66	3,321.53	30.97%	7,402.13	69.03%
1520	STAFF EXCHANGES BETWEEN EU INSTITUTIONS	375,505.50	337,345.82	89.84%	38,159.68	10.16%
1530	COST OF ORGANISING GRADUATE TRAINEESHIPS	-	-	0.00%	-	0.00%
1531	MISCELLANEOUS HELPER EXPENDITURE	-	-	0.00%	-	0.00%
1620	SOCIAL CONTRIBUTION EXPENSES	19,049.60	18,131.00	95.18%	918.60	4.82%
1621	REPRESENTATION EXPENSES	23,719.65	21,811.16	91.95%	1,908.47	8.05%
1830	SOCIAL SECURITY FOR STAFF	-	-	0.00%	-	0.00%
2000	RENT	-	-	0.00%	-	0.00%
2010	INSURANCE	2,793.26	2,417.92	86.56%	375.34	13.44%
2020	WATER, GAS, ELECTRICITY & HEATING	133,443.12	114,281.06	85.64%	19,162.06	14.36%
2030	MAINTENANCE AND CLEANING	276,477.66	251,322.25	90.90%	25,155.41	9.10%
2040	FITTING-OUT OF PREMISES	440,231.32	240,099.32	54.54%	200,132.00	45.46%
2050	SECURITY & SURVEILLANCE OF BUILDINGS	117,841.75	109,018.59	92.51%	8,823.16	7.49%
2080	OTHER EXPENDITURE PRELIMINARY TO CONSTRUCTION OR FITTING-OUT	269,125.24	58,808.25	21.85%	210,316.99	78.15%
2090	OTHER EXPENDITURE ON BUILDINGS	34,583.92	1,875.95	5.42%	32,707.97	94.58%
2110	HARDWARE & SOFTWARE FOR CORP. PROCESSES	969,282.71	966,558.59	99.72%	2,724.12	0.28%
2114	MAINTENANCE & SUPPORT OF CORP. APPLICATIONS	1,405,118.33	1,287,535.74	91.63%	117,582.59	8.37%
2200	TECHNICAL EQUIPMENT & INSTALLATIONS	-	-	0.00%	-	0.00%
2203	LEASE, MAINTENANCE & REPAIR OF TECHN. EQUIPMENT & INSTALLATIONS	28,487.25	24,989.53	87.72%	3,497.72	12.28%
2210	FURNITURE	-	-	0.00%	-	0.00%
2232	VEHICLES	-	-	0.00%	-	0.00%
2250	INFORMATION CENTRE SERVICES	5,550.19	5,262.29	94.81%	287.90	5.19%
2300	STATIONERY & OFFICE SUPPLIES	741.85	294.26	39.67%	447.59	60.33%
2320	BANK CHARGES	5,000.00	4,398.43	87.97%	601.57	12.03%
2330	LEGAL EXPENSES	15,000.00	12,000.00	80.00%	3,000.00	20.00%
2340	DAMAGES	-	-	0.00%	-	0.00%
2353	DEPARTMENTAL REMOVALS & ASSOCIATED HANDLING	1,844.33	1,699.97	92.17%	144.36	7.83%
2354	ARCHIVING OF DOCUMENTS	449.39	406.51	90.46%	42.88	9.54%
2359	OTHER OPERATING EXPENDITURE	28,028.47	13,820.13	49.31%	14,208.34	50.69%
2380	PUBLICATIONS	1,348.46	830.53	61.66%	518.93	38.32%
2400	POSTAL & DELIVERY CHARGES	200.00	200.00	100.00%	-	0.00%
2500	MEETINGS IN GENERAL	19,320.87	17,285.56	88.55%	2,235.29	11.45%
2501	MEMBERSHIP TO FORA	-	-	0.00%	-	0.00%
3000	MEETINGS	234,199.18	207,665.26	89.07%	26,533.92	11.33%
3002	CATERING	13,176.78	11,241.97	85.32%	1,934.81	14.68%
3003	OTHER EXPENDITURE IN RELATION TO MEETINGS	21,354.43	21,354.43	100.00%	-	0.00%
3010	EVALUATION OF MEDICAL PRODUCTS	22,560,535.00	22,232,703.34	98.55%	327,831.66	1.45%
3013	EVALUATION OF PRIV PROCEDURES	3,539,832.55	3,380,761.49	95.51%	159,071.06	4.49%
3020	TRANSLATION CENTRE, LUXEMBOURG	259,124.95	259,084.45	99.98%	40.50	0.02%
3021	OTHER TRANSLATIONS	-	-	0.00%	-	0.00%
3030	STUDIES AND CONSULTANTS	2,614,331.25	2,338,937.05	89.47%	275,394.20	10.53%
3031	SUBSCRIPTION TO SPECIALISED RESEARCHED	222,427.06	222,427.06	100.00%	1.00	0.00%
3040	INFORMATION AND PUBLICATIONS	12,929.17	12,324.08	95.32%	605.09	4.68%
3105	BUSINESS IT DEVELOPMENT	3,317,008.03	3,216,477.88	96.97%	100,530.15	3.03%
	<b>Total</b>	<b>37,420,970.14</b>	<b>35,753,697.89</b>	<b>95.54%</b>	<b>1,667,272.25</b>	<b>4.46%</b>





EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/MB/44499/2017

## Opinion on the Final Accounts for the Financial Year 2016

Adopted by written procedure

### The Management Board,

**Having regard** to the European Parliament and Council Regulation (EC) No 726/2004 as amended, and in particular Article 68(4) thereof,

**Having regard** to the Agency's Financial Regulation as adopted by its Management Board on 15 January 2014 and in particular Article 99 thereof,

**Having regard** to the European Court of Auditors' observations on the provisional accounts of the European Medicines Agency for the aforesaid period dated 18 May 2017

### Sole Article

Is of the opinion that the annual accounts for the financial year ended 31 December 2016 are legal and regular in all aspects.

London, 28 June 2017

Christa Wirthumer-Hoche  
Chairman of the Management Board

