



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/269015/2019  
Administration and Corporate Management Division

## Annual accounts

Financial year 2018

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## **Accounting Officer's certificate on the annual accounts for the financial year 2018**

The annual accounts of the European Medicines Agency for the year 2018 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, 2018.

*[signature on file]*

Paola Samassa

Accounting Officer  
Amsterdam, 03 June 2019

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# 1. Introduction

## ***1.1. Legal foundation and principal activities of the Agency***

The European Medicines Agency ("the Agency" or "EMA") is a decentralised Agency of the European Union (EU) based in Amsterdam, the Netherlands.

In the context of the United Kingdom's notification on 29 March 2017 of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union ('TEU'), the other 27 Member States, meeting on 20 November 2017 in the margins of the Council, selected Amsterdam, the Netherlands, as the new seat of the European Medicines Agency<sup>1</sup>.

During the financial year 2018 the Agency was based in London and it has physically relocated to the Netherlands in early March 2019. EMA's new permanent headquarters, a tailor-made building in the Zuidas business district of Amsterdam, are planned for completion in November 2019. The Dutch government has offered temporary premises to EMA, the Spark building in the Sloterdijk area of Amsterdam, from 1 January 2019 until its permanent building is completed.

The EMA began operating on 26 January 1995<sup>2</sup>. The centralised authorisation procedure for human and veterinary medicines is based on Regulation (EC) No 726/2004, which established the European Medicines Agency (EMA).

EMA's mission is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. The Agency:

- supports medicines development by giving scientific advice and providing guidance to developers of medicines;
- carries out robust scientific evaluations of medicines for human and veterinary use that are the basis of the European Commission's decision on whether a medicine can be authorised for marketing throughout the EU;
- monitors the safety of medicines in the EU throughout their lifespan; and
- provides information on medicines to healthcare professionals and patients.

EMA is responsible for the centralised procedure for the authorisation of medicines resulting in a single evaluation and a single authorisation for the whole of the EU. The centralised procedure is compulsory for certain medicines, including human medicines intended for the treatment of HIV/AIDS, cancer, diabetes or neurodegenerative diseases, designated orphan medicines intended for the treatment of rare diseases, and medicines derived from genes, cells, tissue-engineering and biotechnology processes.

EMA coordinates the work of around 4,500 experts made available by the EU Member States. These experts evaluate the medicines and are members of the Agency's scientific committees, its working parties and groups.

The Agency's recommendations on medicines are based on rigorous scientific standards and the available evidence. Pharmaceutical companies applying for a marketing authorisation for a medicine have to submit comprehensive data on the safety, efficacy and quality of their medicine. These data

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<sup>1</sup> Regulation (EU) 2018/1718 of the European Parliament and of the Council of 14 November 2018 amending Regulation (EC) No 726/2004 as regards the location of the seat of the European Medicines Agency

<sup>2</sup> The Community codes for veterinary and human medicines are set out in Directive 2001/82/EC and Directive 2001/83/EC respectively. They provide the legal framework for the authorisation, manufacture and distribution of medicines in the EU.

are scrutinised by the Agency's experts, who will recommend the marketing authorisation of a medicine if the data convincingly show that its benefits outweigh its risks.

EMA is a scientific body. Decisions on whether to grant, suspend or revoke a marketing authorisation for centrally authorised medicines are issued by the European Commission, based on the Agency's scientific opinions. Once granted by the European Commission, the centralised marketing authorisation is valid in all EU and EEA-EFTA states (Iceland, Liechtenstein and Norway). This allows the marketing authorisation holder to market the medicine and make it available to patients and healthcare professionals throughout the EEA.

Additional information can be found on the EMA's website [www.ema.europa.eu](http://www.ema.europa.eu).

## **1.2. Legal basis and presentation of the annual accounts**

The accounts of the European Medicines Agency are kept in accordance with the provisions of Title IX of the Commission Delegated Regulation (EU) No 2019/715 of 18 December 2018 on the framework financial regulation for the Union bodies referred to in Article 70 of Regulation (EU, Euratom) No 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the Financial Regulation applicable to the general budget of the European Communities.

The accounting system of the Agency, in common with all European institutions, consists of general accounts and budgetary accounts. The general accounts record, on the accrual basis in chronological order using the double entry method, all events and operations which affect the economic and financial situation and the assets and liabilities of the Agency. The budgetary accounts, based on the modified cash accounting principle<sup>3</sup>, provide a detailed record of the implementation of the budget of the Agency. The accounts are kept in euro on the basis of the calendar year.

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:

<b>Item</b>	<b>Accrual</b>	<b>Budget</b>
Fee revenue	Revenue recognized when services are provided	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	Expenditure recognized when goods/services are received/provided	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

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<sup>3</sup> This differs from cash-based accounting because of elements such as carryovers

the economic outturn is presented in Section 5, Reports on the implementation of the budget and explanatory notes.

The annual accounts of the Agency comprise:

- the financial statements of the Agency, produced from the general accounts and comprising the balance sheet, the statement of financial performance, the cash flow statement, the statement of changes in net assets and the relevant explanatory notes which supplement the information contained in the financial statements;
- the reports on the implementation of the budget of the Agency produced from the budgetary accounts.

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 European Medicines 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 fair view, financial statements must not only supply relevant information to describe the nature and range of the 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 officer of the Agency shall send the provisional accounts to the accounting officer of the Commission and to the Court of Auditors by 1 March of the following year.

The Court of Auditors shall, by 1 June of the following year at the latest, make its observations on the provisional accounts of the Agency. On receiving the Court of Auditors' observations on the provisional accounts of the Agency, the accounting officer shall draw up the final accounts of the Agency. The director shall send them to the management board, which shall give an opinion on these accounts.

The director shall send the final accounts, together with the opinion of the management board, to the accounting officer of the Commission, the Court of Auditors, the European Parliament and the Council, by 1 July of the following financial year.

The final accounts shall be accompanied by a note drawn up by the accounting officer, in which the latter declares that the final accounts were prepared in accordance with Title IX and with the applicable accounting principles, rules and methods.

A link to the pages of the website where the final accounts of the Union body are disclosed shall be published in the Official Journal of the European Union by 15 November of the following year.



## 2. Financial statements

### 2.1. Balance sheet

	Note	31.12.2018 Final	31.12.2017 Final
<i>Amounts in EUR</i>			
<b>NON-CURRENT ASSETS</b>			
Intangible fixed assets	4.1.1	39,915,457.95	35,389,120.30
Tangible fixed assets	4.1.2	18,273,004.57	24,458,004.27
<b>TOTAL NON CURRENT ASSETS</b>		<b>58,188,462.52</b>	<b>59,847,124.57</b>
<b>CURRENT ASSETS</b>			
Current receivable	4.2.1	31,327,409.10	40,114,678.74
Provision for doubtful debts	4.2.1	(452,025.05)	(1,935,147.22)
Receivables from consolidated EU entities	4.2.2	6,278.21	3,832.91
VAT recoverable from member states	4.2.3	2,835,377.33	1,875,965.50
Sundry Receivables			
Accrued marketing authorisation fees	4.2.4	44,804,049.26	42,211,292.40
Prepaid expenses	4.2.5	9,029,564.95	8,317,864.57
Cash and cash equivalents	4.2.6	70,340,427.12	70,865,028.21
<b>TOTAL CURRENT ASSETS</b>		<b>157,891,080.92</b>	<b>161,453,515.11</b>
<b>TOTAL ASSETS</b>		<b>216,079,543.44</b>	<b>221,300,639.68</b>
<b>NON-CURRENT LIABILITIES</b>			
Provision for staff relocation			
Provision for risk and charges	4.3.1	14,569,000.48	29,618,228.97
Deferred revenue	4.3.2	43,000,549.99	45,197,209.70
<b>TOTAL NON CURRENT LIABILITIES</b>		<b>57,569,550.47</b>	<b>74,815,438.67</b>
<b>CURRENT LIABILITIES</b>			
Provision for risk and charges due within 1 year	4.3.1	17,846,390.34	3,086,040.00
Deferred revenue due within 1 year	4.3.2	2,204,875.62	4,237,467.54
Deferred marketing authorisation fees	4.4.1	21,568,573.56	20,861,746.70
Current payables	4.4.2	50,145,140.84	44,869,225.18
Sundry payables			
Payables to consolidated EU entities	4.4.3	284,768.87	420,232.44
Budgetary result payable to European Commission	4.4.4	13,802,754.48	14,468,303.00
<b>TOTAL CURRENT LIABILITIES</b>		<b>105,852,503.71</b>	<b>87,943,014.86</b>
<b>TOTAL LIABILITIES</b>		<b>163,422,054.18</b>	<b>162,758,453.53</b>
<b>NET ASSETS</b>		<b>52,657,489.26</b>	<b>58,542,186.15</b>
<b>NET ASSETS</b>			
Accumulated surplus/deficit		58,542,186.15	74,806,102.52
Economic result of the year		(5,884,696.89)	(16,263,916.37)
<b>NET ASSETS</b>		<b>52,657,489.26</b>	<b>58,542,186.15</b>

## 2.2. Statement of financial performance

	Note	2018	2017
<i>Amounts in EUR</i>		<b>Final</b>	<b>Final</b>
<b>OPERATING REVENUE</b>			
Fees and charges related to marketing authorisations	4.5.1	277,026,681.54	284,752,714.64
Contribution from EU entities	4.5.2	20,327,176.15	13,951,626.41
External assigned revenue for projects	4.5.3	3,958,623.63	5,451,504.27
Sundry revenue	4.5.4	201,353.43	130,462.36
Reversal of previous years provision	4.5.5	1,504,534.28	-
<b>TOTAL OPERATING REVENUE</b>		<b>303,018,369.03</b>	<b>304,286,307.68</b>
<b>OPERATING EXPENDITURE</b>			
Staff expenses	4.6.1	109,380,128.93	123,813,409.21
Administrative expenditure	4.6.2	46,788,138.90	42,265,607.74
Operating expenditure	4.6.3	137,062,723.49	136,995,704.37
Depreciation		15,045,969.79	18,645,906.98
Disposal and derecognition of assets		3,336.27	8,317.26
Other expenditure	4.6.4	740,702.99	905,613.45
<b>TOTAL OPERATING EXPENDITURE</b>		<b>309,021,000.37</b>	<b>322,634,559.01</b>
<b>Surplus (deficit) from operating activities</b>		<b>(6,002,631.34)</b>	<b>(18,348,251.33)</b>
Surplus (deficit) from non-operating activities	4.7	117,934.45	2,084,334.96
<b>Surplus (deficit) from ordinary activities</b>		<b>(5,884,696.89)</b>	<b>(16,263,916.37)</b>
Surplus (deficit) from extraordinary items		-	-
<b>ECONOMIC RESULT OF THE YEAR</b>		<b>(5,884,696.89)</b>	<b>(16,263,916.37)</b>

## 2.3. Cash flow statement

<i>Amounts in EUR</i>	<b>2018 Final</b>	<b>2017 Final</b>
<b>Economic result of the year</b>	<b>(5,884,696.89)</b>	<b>(16,263,916.37)</b>
<b>OPERATING ACTIVITIES</b>		
Amortization (intangible fixed assets)	5,394,495.13	3,193,283.01
Depreciation (tangible fixed assets)	9,651,474.66	15,452,623.97
(Increase)/decrease in current receivable and accrued fees	6,194,512.78	1,896,175.92
(Increase)/decrease in other receivables	(1,671,112.21)	2,949,453.60
(Increase)/decrease in receivables related to consolidated EC entities	(2,445.30)	29,488.37
Increase/(decrease) in provisions for risks and liabilities	(288,878.15)	19,103,951.12
Increase/(decrease) in provision for doubtful debts	(1,483,122.17)	162,202.33
Increase/(decrease) in deferred revenue	(3,522,424.77)	(14,059,872.39)
Increase/(decrease) in accounts payable	5,275,915.66	2,795,148.30
Increase/(decrease) in liabilities related to consolidated EC entities	(801,012.09)	4,220,457.85
(Gains)/losses on sale/disposal/derecognition of property, plant and equipment	3,336.27	8,317.26
<b>Net cash flow from operating activities (a)</b>	<b>12,866,042.92</b>	<b>19,487,312.97</b>
<b>INVESTING ACTIVITIES</b>		
(Purchase) of tangible and intangible fixed assets	(13,390,644.01)	(11,375,901.07)
<b>Net cash flow from investing activities (b)</b>	<b>(13,390,644.01)</b>	<b>(11,375,901.07)</b>
<b>Net increase/(decrease) in cash and cash equivalents (a+b)</b>	<b>(524,601.09)</b>	<b>8,111,411.90</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>70,865,028.21</b>	<b>62,753,616.31</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>70,340,427.12</b>	<b>70,865,028.21</b>

## 2.4. Statement of changes in net assets

<i>Amounts in EUR</i>	<b>Accumulated surplus</b>	<b>Economic outturn for the year</b>	<b>Net assets</b>
<b>Balance as of 31 December 2017</b>	<b>74,806,102.52</b>	<b>(16,263,916.37)</b>	<b>58,542,186.15</b>
Allocation of economic result 2017	(16,263,916.37)	16,263,916.37	-
Economic result 2018	-	(5,884,696.89)	(5,884,696.89)
<b>Balance as of 31 December 2018</b>	<b>58,542,186.15</b>	<b>(5,884,696.89)</b>	<b>52,657,489.26</b>

### 3. Significant accounting policies

The financial statements of the Agency shall present information, including information on accounting policies, in a manner that ensures it is relevant, reliable, comparable and understandable. These financial statements have been prepared following, in all material respects, the accounting rules adopted by the accounting officer of the European Commission based on internationally accepted accounting standards for the public sector (IPSAS) and the generally accepted accounting principles, 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 reality over appearance**

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.

### **3.1. Basis of preparation**

The financial statements are presented annually. The accounting year begins on 1 January and ends on 31 December.

#### **3.1.1. Functional and reporting currency**

The financial statements are presented in Euro (EUR), the Euro being the Agency's functional and reporting currency.

#### **3.1.2. Transactions and balances**

Foreign currency transactions are translated into euros using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of foreign currency transactions and from the re-translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in the statement of financial performance.

Different conversion methods apply to property, plant and equipment and intangible assets, which retain their value in euros at the rate that applied at the date when they were purchased.

Year-end balances of monetary assets and liabilities denominated in foreign currencies, mainly Pounds Sterling (GBP), are converted into euros on the basis of the European Central Bank (ECB) exchange rates applying on 31 December: 1 EUR = GBP 0.89453 (31.12.2018)

#### **3.1.3. Key sources of estimation uncertainty and significant judgements**

In accordance with IPSAS and generally accepted accounting principles, the financial statements necessarily include amounts based on estimates and assumptions made by management on the basis of the most reliable information available. Significant estimates include, but are not limited to: amounts for employee benefit liabilities, provisions, financial risk on accounts receivable, accrued income and charges, contingent assets and liabilities, degree of impairment of intangible assets and property, plant and equipment and amounts disclosed in the notes concerning financial instruments. Actual results could differ from those estimates. Changes in estimates are reflected in the period in which they become known.

IPSAS also require disclosing judgements that management has made in the process of applying accounting policies and that have the most significant effect on the amounts recognised in the financial statements. In that respect, a significant judgement relates to the relocation of the Agency from London to Amsterdam as a result of Regulation (EU) 2018/1718 of the European Parliament and of the Council of 14 November 2018 amending Regulation (EC) No 726/2004 as regards the location of the seat of the European Medicines Agency.

As disclosed in note 4.8.1 on operating leases and note 4.8.2 on contingent assets and liabilities, the existing lease contract for the premises at 30 Churchill Place, London has a term that expires on 30 June 2039 and will thus need to be early terminated or subject to a reassignment or a subletting agreement with a third party. In this context, management had to make a significant judgement on the recognition of a provision for onerous lease contract at closing 2018.

At the date the final accounts are issued, management is of the opinion that such a provision shall not be recognised for the reasons developed below:

- EMA was not a party and had no say in the decision to relocate the Agency from London to Amsterdam. Although on 20 February 2019 the High Court of Justice of England and Wales ruled against EMA's request to cancel the lease, deciding that Brexit and its consequences were not a justification for "frustrating" the lease, management is of the view that EMA – as an agency with a legal personality distinct from the EU institutions – can ultimately not be financially impacted by this decision.

- As the lease contract does not contain an early termination clause but allows reassigning or subletting to third parties subject to the landlord's consent, estimating the net cost of exiting from the contract, if any, is at this stage highly subjective and unreliable. In case of subletting, the final terms and conditions of such a subletting agreement, including with respect to inducement and restoration, would largely affect the net cost for EMA, if any.

On that basis, management is of the view that the all IPSAS conditions to recognise a provision for onerous lease contract are not met at the date the final accounts are issued, in particular with respect to the reliable estimation of the net amount of EMA's obligation, if any. A contingent liability is however disclosed in note 4.8.2 on contingent assets and liabilities.

Consistent with this view and the uncertainties surrounding the case, management also decided not to modify at this stage the treatment of the deferred revenue relating to the inducement received by the landlord (see note 4.3.2 Deferred revenue) and the provision for restoring the premises (see note 4.3.1 Provisions for risks and charges).

The net carrying amount on 31 December 2018 of assets and liabilities associated with the premises at 30 Churchill Place, London, are the followings:

- Assets for an amount of € 11.25 Million for the capitalised building and fitting-out costs (see note 4.1.2 Tangible fixed assets); and
- Liabilities for an amount of € 59.78 Million composed of:
  - o Provision for dilapidation for an amount of € 14.57 Million (see note 4.3.1 Provision for risk and charges); and
  - o Deferred inducement received for an amount of € 45.21 Million (see note 4.3.2 Deferred revenue).

## **3.2. Balance sheet and statement of financial performance**

### **3.2.1. Intangible and tangible 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.

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 statement of financial performance 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:

<b><i>Asset class description</i></b>	<b><i>Depreciation rate</i></b>
Internally generated computer software	25%
Other computer software	25%
Building and fitting out costs	25%
Computer hardware	25%
Office furniture	10%
Technical equipment	12.5%-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 charged to the statement of financial performance.

### **3.2.2. 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 statement of financial performance on a straight-line basis over the period of the lease.

The Agency has not entered into financing leases, where the lessee has substantially all the risks and rewards of ownership.

### **3.2.3. 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. The amount of the write-down, if any, is recognised in the statement of financial performance.

### **3.2.4. Cash and cash equivalents**

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

### **3.2.5. Provisions**

Provisions are recognized when the Agency has a present legal or constructive obligation towards third parties as a result of past events, it is more likely than not that an outflow of resources will be required to settle the obligation, and the amount can be reliably estimated. Provisions are not recognized for future operating losses. The amount of the provision is the best estimate of the expenses expected to be required to settle the present obligation at the reporting date.



### **3.2.6. Current payables**

Current payables arising from the purchase of goods and services are recognised at invoice reception for the original amount and corresponding expenses arising from the purchase of goods and services are recognised when the supplies are delivered and accepted by the Agency. They are valued at the original invoice amount.

In accordance with EU accounting rule 12 a liability for employee accumulated compensated absences (untaken leave) at year-end is included on the balance sheet under current payables. 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 Agency's staff average cost and the specific country correction coefficient.

### **3.2.7. Accrued and deferred expenses and income**

Expenses are accounted for in the period to which they relate. At the balance sheet date expenses related to the supplies or services delivered during the period for which an invoice has not yet been received are estimated and recognised in the statement of financial performance.

At year-end if no invoice has been received but the service has been performed or the goods delivered, the amount to be recognised is estimated reliably by the authorising officer on the basis of the budgetary carry over and the stage of completion of the service. By analogy, if the payment has been made in advance for services or goods that have not yet been received, the expense will be deferred and recognised in the subsequent accounting period.

The accounting policy for the recognition of fees revenue and associated expenditure arising from the evaluation of applications by the national competent authorities (NCAs) of the Member States is outlined in section 3.2.8.

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

The Agency charges a fee to applicants for services rendered in accordance with Council Regulation EC No 1905/2005 of 14 December 2005 amending Council Regulation (EC) 297/95 of 10 February 1995 for the evaluation of medicinal products, as amended by Commission Regulation (EU) No 2018/471 of 21 March 2018 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 NCAs of the Member States who receive a fixed percentage of the fee, generally 50% except for annual fees, which is 30%.

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.

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 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 are accrued at the same time as the revenue is recognised.

The Agency also 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.

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 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.

### **3.3. 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 10%<sup>4</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.

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<sup>4</sup> updated rate as of July 2018, the weightings not being taken into account

Accordingly, no provisions for pension payments or any pension fund deficits are required to be included in these accounts.

### ***3.4. Contingent assets and liabilities***

A contingent asset is a possible asset that arises from past events and of which the existence will be confirmed only by the occurrence or non-occurrence of one or more uncertain future events not wholly within the control of the Agency. A contingent asset is disclosed when an inflow of economic benefits or service potential is probable.

A contingent liability is a possible obligation that arises from past events and of which the existence will be confirmed only by the occurrence or non-occurrence of one or more uncertain future events not wholly within the control of the Agency; or a present obligation that arises from past events but is not recognised because: it is not probable that an outflow of resources embodying economic benefits or service potential will be required to settle the obligation or in the rare circumstances where the amount of the obligation cannot be measured with sufficient reliability.

### ***3.5. 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 note 4.9.

## 4. Notes to the financial statements

### 4.1. Non-current assets

#### 4.1.1. 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 and other strategies, programmes and projects in specific areas of EMA business.

These include the EU Telematics strategy, which aims to establish and maintain common IT systems together with EMA's partners in the European medicines regulatory network; EMA's approach to implementing the ISO IDMP standards through the management of master data on medicinal products; and various EMA programmes and projects delivering new or enhanced IT systems in defined business areas, such as clinical trials, pharmacovigilance and veterinary medicines.

In 2018 the Agency has capitalised internally generated computer software in value of € 22.49 Million due to three projects being finished. The accounting policy for the capitalisation of internally generated computer software is outlined in note 3.2.1.

The table below summarises the accounting movements for the year.

<i>Amounts in EUR</i>	<b>Internally generated computer software</b>	<b>Other computer software</b>	<b>Intangible asset under construction</b>	<b>Total</b>
<b>Gross carrying amounts 01.01.2018</b>	<b>74,252,641.46</b>	<b>10,045,559.24</b>	<b>30,579,441.01</b>	<b>114,877,641.71</b>
Additions	-	650,251.67	9,270,581.11	9,920,832.78
Transfers	22,486,266.37	-	(22,486,266.37)	-
<b>Gross carrying amounts 31.12.2018</b>	<b>96,738,907.83</b>	<b>10,695,810.91</b>	<b>17,363,755.75</b>	<b>124,798,474.49</b>
<b>Accumulated amortisation and impairment 01.01.2018</b>	<b>(70,155,162.56)</b>	<b>(9,333,358.85)</b>	<b>-</b>	<b>(79,488,521.41)</b>
Amortisation	(5,010,713.52)	(383,781.61)	-	(5,394,495.13)
<b>Accumulated amortisation and impairment 31.12.2018</b>	<b>(75,165,876.08)</b>	<b>(9,717,140.46)</b>	<b>-</b>	<b>(84,883,016.54)</b>
<b>Net carrying amounts 31.12.2018</b>	<b>21,573,031.75</b>	<b>978,670.45</b>	<b>17,363,755.75</b>	<b>39,915,457.95</b>

### 4.1.2. Tangible fixed assets

Tangible fixed assets consist of property related items and equipment, for use in the production or supply of Agency's services and expected to be used during more than one reporting period.

In the case of the Agency this comprises building and fitting out costs of the Agency's premises at 30 Churchill Place, security and audio-visual equipment, kitchen equipment and furniture for offices and restaurant. Computer hardware includes the investment made in IT infrastructure in relation to the relocation of EMA data centre facilities.

The table below summarises the accounting movements for the year.

<i>Amounts in EUR</i>	<b>Building and fitting out cost</b>	<b>Computer hardware</b>	<b>Furniture and equipment</b>	<b>Total</b>
<b>Gross carrying amounts 01.01.2018</b>	<b>61,099,264.10</b>	<b>7,088,805.95</b>	<b>11,243,357.26</b>	<b>79,431,427.31</b>
Additions	-	3,464,245.21	5,566.02	3,469,811.23
Disposals	-	(17,057.16)	-	(17,057.16)
<b>Gross carrying amounts 31.12.2018</b>	<b>61,099,264.10</b>	<b>10,535,994.00</b>	<b>11,248,923.28</b>	<b>82,884,181.38</b>
<b>Accumulated depreciation and impairment 01.01.2018</b>	<b>(42,583,156.26)</b>	<b>(5,797,879.25)</b>	<b>(6,592,387.53)</b>	<b>(54,973,423.04)</b>
Depreciation	(7,262,141.79)	(1,148,041.81)	(1,241,291.06)	(9,651,474.66)
Disposals	-	13,720.89	-	13,720.89
<b>Accumulated depreciation and impairment 31.12.2018</b>	<b>(49,845,298.05)</b>	<b>(6,932,200.17)</b>	<b>(7,833,678.59)</b>	<b>(64,611,176.81)</b>
<b>Net carrying amounts 31.12.2018</b>	<b>11,253,966.05</b>	<b>3,603,793.83</b>	<b>3,415,244.69</b>	<b>18,273,004.57</b>

## 4.2. Current assets

### 4.2.1. Current receivable

This item includes € 31.32 Million of fees invoiced to marketing authorisation holders and applicants remaining open at 31.12.2018. Included in the amount is € 5.19 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 € 452,025.05 (2017: € 1,935,147.22).

The risk analysis for this financial instrument is disclosed in note 4.9.

### 4.2.2. Receivable from consolidated EU entities

This item consists of amounts receivable from consolidated EU entities for staff social security contributions.

### 4.2.3. 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 amount of VAT recoverable as at 31.12.2018 is expected to be received in early 2019.

The risk analysis for this financial instrument is disclosed in section 4.9 of this report.

### 4.2.4. Accrued marketing authorisation fees

This item includes fees that have been earned as at 31 December but that have not yet been invoiced to the applicants. It mainly relates to annual fees which 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 accounting policy for the recognition of fees revenue is outlined in note 3.2.8.

### 4.2.5. Prepaid expenses

This item includes:

<i>Amounts in EUR</i>	<b>31.12.2018</b>	<b>31.12.2017</b>
Rental payment of office premises for Q1 2019	3,669,717.54	3,329,804.46
Prepaid expenditure for evaluation services	2,702,030.72	2,972,899.59
Other prepaid expenditure	2,657,816.69	2,015,160.52
<b>Total</b>	<b>9,029,564.95</b>	<b>8,317,864.57</b>

### 4.2.6. Cash and cash equivalents

Cash and cash equivalents balances comprise the following:

<i>Amounts in EUR</i>	<b>31.12.2018</b>	<b>31.12.2017</b>
GBP account Lloyds Bank	1,229,404.38	1,455,848.30
GBP account HSBC Bank	2,743.45	3,192.29
EUR account Lloyds Bank	58,976,802.70	59,274,441.43
EUR account HSBC Bank	10,131,476.59	10,131,546.19
<b>Total</b>	<b>70,340,427.12</b>	<b>70,865,028.21</b>

The cash balances at the year-end are earmarked to account for the budget carry forwards as disclosed in section 5, reports on the implementation of the budget and explanatory notes.

The risk analysis for this financial instrument is disclosed in note 4.9.

### 4.3. Non-current liabilities

#### 4.3.1. Provision for risk and charges

This item include a discounted provision for risk and charges against assets of € 14.57 Million to reflect the estimated maximum cost the Agency might incur for restoring the premises at 30 Churchill Place, London to their original state. The yearly present value adjustment (unwinding 3.5%) is recognised as a cost in the statement of financial performance. In respect of property-related obligations, please refer also to note 3.1.3 on key sources of estimation uncertainty and significant judgments and note 4.8 on other significant disclosures, dealing with operating leases and contingent liabilities.

This item includes also a provision to reflect the best estimate of the cost the Agency might incur for relocating staff to Amsterdam, the Netherlands. Estimates have been made on the basis of the outcome of a staff retention survey carried out in September 2017 as part of business continuity planning, indicating that 80% of current staff is prepared to relocate to Amsterdam. The amounts are expected to be paid during 2019 as indicated in the table below. The effect of the time value of money is considered not material therefore no present value adjustment is made to the provision.

<i>Amounts in EUR</i>	<b>Carrying amount 01.01.2018</b>	<b>Additional provisions</b>	<b>Amounts used / reversals</b>	<b>Present value adjustments</b>	<b>Amounts 31.12.2018</b>
Long term provision for dilapidation	14,076,328.97	-	-	492,671.51	14,569,000.48
Short term provision for staff relocation	18,627,940.00	-	(781,549.66)	-	17,846,390.34
<b>Total</b>	<b>32,704,268.97</b>	<b>-</b>	<b>(781,549.66)</b>	<b>492,671.51</b>	<b>32,415,390.82</b>

#### 4.3.2. Deferred revenue

This item relates to the inducement received by the landlord as part of the lease of the office premises at 30 Churchill Place, London. Such inducement consists of a capital contribution of € 46.00 Million corresponding to 37 months of rent free period, released against annual rents over the life of the lease (25 years); a capital contribution of € 14.00 Million for fit-out 'Category A' inducements released in line with the depreciation of the fit out costs (4 years) and a rent free period, corresponding to € 9.00 Million.

In respect of property-related obligations, please refer also to note 3.1.3 on key sources of estimation uncertainty and significant judgments and note 4.8 on other significant disclosures, dealing with operating leases and contingent liabilities.

*Amounts in EUR*

<b>Gross carrying amount as at 01.01.2018</b>	<b>69,050,254.72</b>
Additions for the year	-
<b>Gross carrying amount as at 31.12.2018</b>	<b>69,050,254.72</b>
<b>Accumulated rent release as at 01.01.2018</b>	<b>(19,615,577.48)</b>
Rent release for the year	(4,229,251.64)
<b>Accumulated rent release as at 31.12.2018</b>	<b>(23,844,829.12)</b>
<b>Net carrying amount 31.12.2018</b>	<b>45,205,425.60</b>
<i>of which due within one year</i>	<i>2,204,875.62</i>

## **4.4. Current liabilities**

### **4.4.1. Deferred marketing authorisation fees**

Deferred revenue is listed as a liability on the balance sheet, because under accrual accounting the fees revenue recognition process has not been completed and the Agency's service is still due to the applicant. The accounting policy for the recognition of fees revenue is outlined in note 3.2.8.

### **4.4.2. Current payables**

Current payables represent amounts accrued for goods and services due at 31 December 2018 for a total of € 50.14 Million. The amount includes Pounds Sterling denominated accrued charges for a revalued amount at year end of € 1.18 Million. It also includes accrued charges of € 4.45 Million (2017: € 3.39 Million) for employees accumulated compensated absences (untaken leave).

<i>Amounts in EUR</i>	<b>31.12.2018</b>	<b>31.12.2017</b>
Accounts payable and accrued charges	12,173,123.25	8,119,927.63
Accrued expenditure for evaluation services	33,129,479.93	33,174,552.91
Accrued charges for untaken leave and other staff payables	4,842,537.66	3,574,744.64
<b>Total</b>	<b>50,145,140.84</b>	<b>44,869,225.18</b>

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 2018, is disclosed in note 4.9 of this report.

### **4.4.3. Payable to consolidated EU entities**

This item consists of pre-financing, accrued charges and other payables amounts with consolidated EU entities for staff social security contributions.

### **4.4.4. Budgetary result payable to the European Commission**

The budgetary result of the Agency for the financial year 2018 amounts to € 13.80 Million.

In compliance with Article 20 of the current 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.

The amount of contribution received from the Commission in 2018 is provided at note 4.5.2.



## 4.5. Operating revenue

### 4.5.1. 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.

<i>Amounts in EUR</i>	<b>2018</b>	<b>2017</b>
Fees for initial applications	21,025,354.51	25,439,228.74
Annual fees	88,115,332.82	81,974,317.80
Other fees mainly post authorization variations	128,207,797.63	135,315,362.85
Fees for Pharmacovigilance activities	26,865,856.58	28,235,515.25
Processing Parallel Distribution notifications	8,325,020.00	9,469,050.00
Processing Export Certificates	2,920,190.00	2,366,420.00
Other administrative fees	1,567,130.00	1,952,820.00
<b>Total</b>	<b>277,026,681.54</b>	<b>284,752,714.64</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.

### 4.5.2. Contribution from EU entities

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 2018 the Agency has recognised € 13.39 Million of revenue for orphan medicinal products.

More details on the implementation of the budgetary revenue are provided in section 5, reports on the implementation of the budget and explanatory notes.

This item comprises:

<i>Amounts in EUR</i>	<b>2018</b>	<b>2017</b>
EC general subsidy	10,503,205.00	2,438,000.00
EU orphan medicinal products contribution	13,395,290.98	13,155,030.72
EEA contribution	-	60,219.00
Balance of budget outturn from previous years	10,231,434.65	12,766,679.69
<i>less surplus of budget current year</i>	<i>(13,802,754.48)</i>	<i>(14,468,303.00)</i>
<b>Total</b>	<b>20,327,176.15</b>	<b>13,951,626.41</b>

#### **4.5.3. External assigned revenue for projects**

This item comprises € 3.87 Million of recognized revenue related to the landlord inducement received as part of the contractual arrangements for the premises at 30 Churchill Place, London, as outlined more in details in note 4.3.2, and € 91,994 for other assigned revenue for projects.

#### **4.5.4. Sundry revenue**

This item includes recoveries of amounts wrongly paid in previous years and recoveries of interest for payments of fees received beyond the established terms.

#### **4.5.5. Reversal of previous years provision**

This item relates to the reversal of the provision for doubtful debts made in previous years where the debt has been eventually recovered by the Agency.

### **4.6. Operating expenditure**

#### **4.6.1. Staff expenses**

As at 31 December 2018, the Agency's headcount included a total of 581 temporary agents, 170 contract agents and 30 national experts on secondment (2017: 583, 147 and 36). Compared to 2017, the total headcount had increased by 1.9% from 766 to 781.

Staff expenses amounts to € 109.38 Million at 31.12.2018, an overall increase by 4% compared to 31.12.2017 (i.e. € 105.18 net of the provision of €18.62 Million for the cost for installation and resettlement allowances, travel and removal costs and daily subsistence the Agency might incur for relocating staff to Amsterdam, the Netherlands, as outlined in note 4.3.1.).

The annual update of the basic salary was 1.7%. The London salary weighting coefficient is adjusted each year to compensate for equal but opposite movements in the Euro/Pound Sterling exchange rate (2018/2019: 0.8852; 2017/2018: 0.8799) and for comparative changes in the European cost of living index (2018: 134.7%; 2017: 133.5%) The differences of exchange for salaries related transactions are charged to the statement of financial performance under non-operating activities, see note 4.7.

#### 4.6.2. Administrative expenditure

This item comprises:

<i>Amounts in EUR</i>	<b>2018</b>	<b>2017</b>
Rent and service charges	18,230,619.73	17,655,514.94
Other building occupancy costs	3,929,300.73	2,785,027.61
Maintenance and support of IT applications	21,654,301.17	19,018,502.54
Business consultancy and audit services	361,966.75	855,441.09
Information and communication, memberships, library and subscriptions	2,611,950.52	1,951,121.56
<b>Total</b>	<b>46,788,138.90</b>	<b>42,265,607.74</b>

The rental expenditure, paid by the Agency in Pound Sterling due to its location in London, has increased in comparison to the previous year due to exchange rate fluctuations.

#### 4.6.3. Operating expenditure

The principal items included are:

<i>Amounts in EUR</i>	<b>2018</b>	<b>2017</b>
Share of evaluation and annual fees to NCAs	100,080,991.19	105,875,376.92
Share of evaluation of pharmacovigilance procedures fees to NCAs	11,665,804.67	12,816,703.86
Reimbursement of delegates attending meetings	7,118,113.09	8,381,396.99
Translations	4,318,521.90	4,716,096.25
Business IT development	10,744,312.89	1,686,894.71
Studies and consultants	3,134,979.75	3,519,235.64
<b>Total</b>	<b>137,062,723.49</b>	<b>136,995,704.37</b>

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

The decrease in share of evaluation and annual fees paid to the NCAs is consequent to the decrease in fees presented in section 4.5.1.

#### 4.6.4. Other expenditure

This item includes the charges related to the discount (unwinding) of the dilapidation for the year and provision for bad debtors for the year.

#### 4.7. Non-operating activities

This item relates to income and expenses from financial sources as follows:

<i>Amounts in EUR</i>	<b>2018</b>	<b>2017</b>
Bank interest income	-	3,154.18
Revenue for ancillary services	129,935.03	199,414.07
Bank charges	(44,403.63)	(40,924.71)
Differences on exchange	32,403.05	1,922,691.42
<b>Total</b>	<b>117,934.45</b>	<b>2,084,334.96</b>

### 4.7.1. Differences on exchange

These are made up as follows:

<i>Amounts in EUR</i>	<b>2018</b>	<b>2017</b>
Exchange gain (loss) on hedged amounts and other non-Euro currency purchases	(157,575.44)	581,555.58
Exchange gain (loss) on salary related transactions	189,855.05	1,340,586.94
Other differences	123.44	548.90
<b>Total</b>	<b>32,403.05</b>	<b>1,922,691.42</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 (2018/2019: 0.8852; 2017/2018: 0.8799).

## 4.8. Other significant disclosures

### 4.8.1. Operating leases

On 1<sup>st</sup> July 2014 the Agency entered into a 25 years rental contract with Canary Wharf landlords for the office premises at 30 Churchill Place, London E14 5EU. The term of the lease expires on 30<sup>th</sup> June 2039.

The schedule for the estimated future payments in relation to this operating lease is as follows:

<i>Amounts in EUR</i>	<b>Lease payments</b>			<b>Total</b>
	<b>&lt;1 year</b>	<b>1-5 years</b>	<b>&gt; 5 years</b>	
Rent	14,599,723.88	72,998,619.39	211,695,996.22	299,294,339.49
Building service charge	2,561,855.95	12,809,279.73	37,146,911.23	52,518,046.91
Estate service charge	1,110,303.73	5,551,518.67	16,099,404.16	22,761,226.57
Landlord insurance	354,376.04	1,771,880.21	5,138,452.60	7,264,708.84
Local authority rates	2,202,711.20	21,420,936.13	62,120,714.79	85,744,362.12
<b>Total</b>	<b>20,828,970.80</b>	<b>114,552,234.13</b>	<b>332,201,478.99</b>	<b>467,582,683.92</b>

As part of the lease of the office premises, the Agency has received a cash inducement by the landlord for € 60.00 Million. Additional information can be found in note 4.3.2.

Note 4.3.1 provides additional information in relation to the discounted provision of € 14.57 Million as the estimated maximum cost the Agency might incur for restoring the premises to their original state at the end of the existing lease contract.

Please also refer to note 3.1.3 on key sources of estimation uncertainty and significant judgments, and note 4.8.2, below, on contingent assets and liabilities.

#### **4.8.2. Contingent assets and 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 is being negotiated. On 20 November 2017, the other 27 Member States, meeting in the margins of the General Affairs Council ('Article 50'), selected Amsterdam, the Netherlands, as the new seat of the European Medicines Agency.

Having regard to Article 50(3) of the Treaty on European Union, the Agency should take its new seat as of 30 March 2019. Regulation (EC) No 726/2004, which established the European Medicines Agency (EMA), has been amended accordingly.

We refer to note 3.1.3 dealing with key sources of estimation uncertainty and significant judgments with respect to the management position not to recognise a provision for onerous lease contract but to disclose a contingent liability at closing 2018.

The total amounts due under the lease contract are disclosed in note 4.8.1 on operating leases. A maximum of EUR 465 million, corresponding to the portion covering the period after the 30 March 2019, date when the Agency takes its new seat in Amsterdam, is to be viewed as contingent liability. The net financial impact for the Agency, if any, depends on termination negotiations with the landlord or on the contractual terms of any subletting agreement entered into with a third party.

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.

#### **4.8.3. Outstanding budgetary commitments not yet expensed**

The amount of outstanding budgetary commitments not yet expensed as the reporting date is 3.4 Million, equivalent to the budgetary carry over or RAL i.e. "Reste à liquider", representing the open commitments as at 31.12.2018 for which payments and/or de-commitments have not yet been made, less related amounts that have been included as liabilities on the balance sheet and as expenses in the statement of financial performance.

#### **4.8.4. Other contractual commitments**

The Agency's future legal commitments not yet covered by a budgetary commitment at the reporting date are estimated to be up to a maximum of € 4.8 Million.

### **4.9. 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.

#### 4.9.1. Credit quality of financial assets

##### Counterparties with external credit rating

These are the cash and cash equivalents balances referred to in note 4.2.6 and the amount of VAT recoverable as at 31.12.2018 referred to in note 4.2.3.

<i>Amounts in EUR</i>	<b>31.12.2018</b>	<b>Credit rating</b>	<b>Agency</b>
GBP account Lloyds Bank	1,229,404.38	F1	Fitch
		P-1	Moody's
		A-1	S&P
GBP account HSBC Bank Plc	2,743.45	F1+	Fitch
		P-1	Moody's
		A-1+	S&P
EUR account Lloyds Bank	58,976,802.70	F1	Fitch
		P-1	Moody's
		A-1	S&P
EUR account HSBC Bank Plc	10,131,476.59	F1+	Fitch
		P-1	Moody's
		A-1+	S&P
Receivables from Member States VAT (Foreign and Commonwealth Office - UK)	2,835,377.33	AA	Fitch
		Aa2	Moody's
		AA	S&P

##### Counterparties without external credit rating

These are the current receivable balances referred to in note 4.2.1.

<i>Amounts in EUR</i>	<b>31.12.2018</b>
Debtors who never defaulted	32,095,350.86
Debtors who defaulted in the past	-

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

Of the € 2.87 Million past due but not impaired debtors, € 2.43 Million are overdue by less than 30 days. The new provision for doubtful debtors for the year was € 248K, corresponding to less than 0.09% of the fee revenue 2018.

Amounts in EUR	31.12.2018	Past due but not impaired			Impaired
		<1 year	1-5 years	> 5 years	
Receivables from Member States	2,835,377.33	-	-	-	-
Debtors who never defaulted	32,095,350.86	2,804,968.07	61,689.82	-	2,347,354.06
Debtors who defaulted in the past		-	-	-	-

#### 4.9.3. 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 2018, 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 referred to in note 4.4.4, 4.4.3 and 4.4.2 respectively.

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.

Amounts in EUR	31.12.2018	<1 year	1-5 years	> 5 years
Payables with consolidated entities	14,087,523.35	14,087,523.35	-	-
Other payables with third parties	50,145,140.84	50,145,140.84	-	-

#### 4.9.4. 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 2018.

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, 2018. 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.

**Currency exposure at 31.12.2018***Amounts in EUR*

	<b>31.12.2018</b>	<b>31.12.2017</b>
Cash and cash equivalent	1,232,147.83	1,459,040.59
Receivables from Member States VAT (Foreign and Commonwealth - UK)	1,621,400.28	1,779,125.38
<b>Total financial assets (a)</b>	<b>2,853,548.11</b>	<b>3,238,165.97</b>
Payables with third parties	1,175,095.06	885,297.10
<b>Total financial liabilities (b)</b>	<b>1,175,095.06</b>	<b>885,297.10</b>
<b>Net position (a-b)</b>	<b>1,678,453.05</b>	<b>2,352,868.87</b>

Financial assets include € 2.85 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 € 285,355. 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 € 1.18 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 € 117,510. 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.

The impact on the net position for a 10% appreciation of the Euro against the Pound Sterling from the year end rate would lead to a surplus of € 167,845.31. A 10% depreciation of the Euro against the Pound Sterling from the year end rate would lead to a deficit of the same amount.

**4.10. Related party disclosures**

The related parties of the Agency are its key management personnel.

<b>Highest grade description</b>	<b>Grade</b>	<b>Number of persons of this grade at at 31.12.2018</b>
Executive Director	AD15	1
Deputy Executive Director	AD14	1
Executive Board Member	AD14	1
Executive Board Member	AD13	5
Executive Board Member	AD12	5
Executive Board Member	AD11	1

Transactions between the Agency and the key management personnel take place as part of the normal operations of the Agency and in this case no specific disclosure requirements are necessary for these transactions in accordance with the EU accounting rule 15.

The remuneration, allowances and other entitlements are covered by the Conditions of Employment of Other Servants of the European Communities.



#### **4.11. Events after the balance sheet date**

On 20 February 2019, the High Court of Justice of England and Wales ruled against EMA's request to cancel the lease on its premises at 30 Churchill Place, deciding that Brexit and its consequences were not a justification for 'frustrating' the lease (i.e. terminating the contract due to unforeseeable circumstances).

On 15 April 2019 the Agency lodged an appeal against the ruling. It is estimated to have the appeal heard by December 2019, with a ruling likely by first quarter of 2020. The Agency keeps evaluating all available options, in close cooperation with the European Commission and in consultation with the management board members. In case of a negative outcome, legal costs are estimated to be in the range of Euro 1 million.

Please also refer to note 3.1.3 on key sources of estimation uncertainty and significant judgments, and note 4.8.2 on contingent assets and liabilities.

No additional material items came to the attention of the Accounting Officer of the Agency or were reported to him that would require separate disclosure under this section.

## 5. Reports on the implementation of the budget and explanatory notes

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

In accordance with Article 40 of Regulation (EU, Euratom) No 2018/1046, 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.

## 5.2. Budgetary result account for the year ended December 31, 2018

Amounts in EUR

	2018 Final	2017 Final
<b>REVENUE</b>		
Balancing Commission subsidy	32,591,579.65	28,533,368.69
Fees and charges related to marketing authorisations	284,157,353.53	278,813,329.23
Other income	332,191.89	10,013,727.38
<b>TOTAL REVENUE (a)</b>	<b>317,081,125.07</b>	<b>317,360,425.30</b>
<b>EXPENDITURE</b>		
<b>Title 1 - Staff expenditure</b>		
Payments	111,202,313.62	105,684,747.83
Carry over	1,381,902.98	1,108,008.19
<b>Sub-total</b>	<b>112,584,216.60</b>	<b>106,792,756.02</b>
<b>Title 2 - Administrative expenditure</b>		
Payments	42,930,257.60	43,541,113.72
Carry over	8,367,302.12	5,823,015.24
<b>Sub-total</b>	<b>51,297,559.72</b>	<b>49,364,128.96</b>
<b>Title 3 - Operating Expenditure</b>		
Payments	99,148,506.55	104,581,653.49
Carry over	45,072,597.17	47,086,047.27
<b>Sub-total</b>	<b>144,221,103.72</b>	<b>151,667,700.76</b>
<b>Total Payments</b>	<b>253,281,077.77</b>	<b>253,807,515.04</b>
<b>Total Carry Over</b>	<b>54,821,802.27</b>	<b>54,017,070.70</b>
<b>TOTAL EXPENDITURE (b)</b>	<b>308,102,880.04</b>	<b>307,824,585.74</b>
<b>OUTTURN FOR THE FINANCIAL YEAR (a-b)</b>	<b>8,978,245.03</b>	<b>9,535,839.56</b>
Appropriation from previous year which lapse	4,982,084.89	4,350,907.86
Exchange differences for the year (gain +/-loss -)	(157,575.44)	581,555.58
<b>BALANCE OF THE OUTTURN ACCOUNT FOR THE FINANCIAL YEAR</b>	<b>13,802,754.48</b>	<b>14,468,303.00</b>
Balance year N-1	14,468,303.00	10,231,434.65
Positive balance from year N-1 reimbursed in year N to the Commission	(14,468,303.00)	(10,231,434.65)
<b>Balance remaining open to be reimbursed to the Commission in year n+1</b>	<b>13,802,754.48</b>	<b>14,468,303.00</b>

### 5.2.1. Reconciliation of economic result with budget result

<i>Amounts in EUR</i>	<b>2018 Final</b>	<b>2017 Final</b>
<b>Economic result (a)</b>	<b>(5,884,696.89)</b>	<b>(16,263,916.37)</b>
<b>Adjustments for accrual items (not in budget result)</b>		
Reversal accrued expenditure at 31.12.2017	(43,911,801.20)	(41,499,941.35)
Expenditure accruals at 31.12.2018	49,442,109.56	43,811,129.20
Expenditure accruals at 31.12.2018 (EU entities)	128,260.00	100,672.00
Reversal prepayment/deferred expenditure at 31.12.2017	4,980,812.28	4,965,046.07
Prepayment/deferred expenditure at 31.12.2018	(5,329,147.11)	(4,980,812.28)
Payments made from automatic carry over (C82018)	43,322,944.21	38,681,396.97
Payments made from carry over by decision (C22018)	5,712,041.60	-
Other expenditure accrual movements not included in the budget result	486,666.26	476,099.09
Depreciation of intangible and tangible assets year 2018	15,045,969.79	18,645,906.98
Disposal and de-recognition of assets year 2018	3,336.27	8,317.26
Provisions year 2018	(2,038,111.83)	19,057,542.33
Reversal accrued revenue at 31.12.2017	42,211,292.40	39,800,540.40
Accrued revenue at 31.12.2018	(44,804,049.26)	(42,211,292.40)
Reversal deferred revenue at 31.12.2017	(20,861,746.70)	(29,659,047.60)
Deferred revenue at 31.12.2018	21,568,573.56	20,861,746.70
Invoices issued in 2017 not cashed at 31.12.2018	(29,291,887.72)	(35,197,897.03)
Deferred revenue (non fees) year at 31.12.2018	(3,866,629.27)	4,261,747.76
Budget result (pre-financing) deducted from revenue (EU contribution)	13,802,754.48	14,468,303.00
Other revenue accrual movements not included in the budget result	(362,622.36)	(362,622.36)
<b>Total accrual items adjustment (b)</b>	<b>46,238,764.96</b>	<b>51,226,834.74</b>
<b>Adjustments for budgetary items (not in economic result)</b>		
Fixed asset acquisitions (less unpaid amounts)	(13,390,644.01)	(11,375,901.07)
Invoices issued before year 2018 and cashed in year 2018	36,679,047.80	40,547,448.54
Cancellation of unused carry overs from previous year (C2C82018)	4,982,084.89	4,350,907.86
Budgetary carry over to 2019 (C2C82019)	(54,821,802.27)	(54,017,070.70)
<b>Total budgetary items adjustment (c)</b>	<b>(26,551,313.59)</b>	<b>(20,494,615.37)</b>
<b>Budgetary result (a+b+c)</b>	<b>13,802,754.48</b>	<b>14,468,303.00</b>

### **5.2.2. Notes to the budget result**

In 2018 the Agency had a budgetary surplus of € 13,802,754.48.

The budget result consists of the difference between all the revenue collected in respect of that financial year (€ 317.08 Million) and the amount of payments made against appropriations for that financial year (€ 253.28 Million) increased by the amount of the appropriations for the same financial year carried over to the following year (€ 54.82 Million). Appropriations carried over include automatic carry over (€ 53.32 Million) and carry over by decision (€ 1.5 Million).

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 (€ 4.98 Million) 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 (€ 157 thousand).

### **5.2.3. Notes to the reconciliation of the budget result with the economic result**

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.

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.

### 5.3. Implementation of the 2018 budget

In the initial adopted budget, adopted by the EMA management board on 14<sup>th</sup> December 2017, the amount of appropriations was € 337.76 Million. The revenue and expenditure estimates in the initial budget are typically adjusted during the budgetary year, such modification presented in Amending Budgets.

During 2018 there was neither amending budget nor transfer.

Of the final adopted budget, 90% were fees from pharmaceutical companies and 10% contribution from EU.

#### Revenue

<i>Amounts in EUR</i>	<b>Initial adopted budget</b>	<b>Amending budgets and transfers</b>	<b>Final adopted budget</b>
EU basic contribution	8,989,000.00	1,416,000.00	10,405,000.00
Other EU contribution	23,532,000.00	- 1,416,000.00	22,116,000.00
Fees	304,508,000.00	-	304,508,000.00
Other revenue	732,000.00	-	732,000.00
<b>Total</b>	<b>337,761,000.00</b>	<b>-</b>	<b>337,761,000.00</b>

Automatic carry overs from 2017 were € 47.83 Million and appropriations carried over by decision from 2017 to 2018 were € 6.18 Million.

During 2018 six transfers were adopted.

#### Expenditure

<i>Amounts in EUR</i>	<b>Initial adopted budget</b>	<b>Amending budgets and transfers</b>	<b>Final adopted budget</b>	<b>Carry over by decision from 2017</b>	<b>Automatic carry over from 2017</b>
I - Staff	125,550,000.00	36,000.00	125,586,000.00	-	1,108,008.19
II - Administrative	56,267,000.00	70,000.00	56,337,000.00	-	5,823,015.24
III - Operating	155,944,000.00	(106,000.00)	155,838,000.00	6,181,000.00	40,905,047.27
<b>Total</b>	<b>337,761,000.00</b>	<b>-</b>	<b>337,761,000.00</b>	<b>6,181,000.00</b>	<b>47,836,070.70</b>

### 5.3.1. Summary of the implementation of income appropriations

The Agency has collected revenue for € 317.08 Million corresponding to 93.88% of the total income appropriations.

Fees paid by the pharmaceutical industry for services provide amounted to € 284.15 Million corresponding to 89.61% of the total revenue collected in the year.

<i>Amounts in EUR</i>	<b>Total income appropriations</b>	<b>Entitlements established</b>	<b>Revenue collected</b>	<b>Revenue as a % of the budget</b>
EU basic contribution	10,405,000.00	10,503,205.00	10,503,205.00	100.94%
Other EU contribution	22,116,000.00	22,088,374.65	22,088,374.65	99.88%
Fees	304,508,000.00	315,933,976.47	284,157,353.53	93.32%
Other revenue	732,000.00	501,864.15	332,191.89	45.38%
<b>Total</b>	<b>337,761,000.00</b>	<b>349,027,420.27</b>	<b>317,081,125.07</b>	<b>93.88%</b>

### 5.3.2. Summary of the implementation of commitment appropriations

The Agency has issued commitments for € 312.31 Million corresponding to 90.80% of the total commitment appropriations, inclusive of the appropriations carried over by decision from the previous year.

In line with the provision of Article 14 of the current framework financial regulation, by decision of its management board the Agency carries over € 1.5 Million of appropriations which have not been used by the end of the financial year for which they were entered.

The implementation of the appropriations carried over by decision from the previous year is presented in section 5.3.4.

<i>Amounts in EUR</i>	<b>Total commitment appropriations</b>	<b>Commitments made</b>	<b>%</b>	<b>Carry over by decision to next year</b>	<b>Appropriations lapsing</b>	<b>%</b>
I - Staff	125,586,000.00	112,584,216.60	89.65%	-	13,001,783.40	10.35%
II - Administrative	56,337,000.00	51,297,559.72	91.05%	-	5,039,440.28	8.95%
III - Operating	162,019,000.00	148,433,145.32	91.61%	1,500,000.00	13,585,854.68	8.39%
<b>Total</b>	<b>343,942,000.00</b>	<b>312,314,921.64</b>	<b>90.80%</b>	<b>1,500,000.00</b>	<b>31,627,078.36</b>	<b>9.20%</b>

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

The Agency has made payments for € 258.99 Million corresponding to 75.30% of the total payment appropriations, inclusive of the appropriations carried over by decision from the previous year.



A total of € 53.32 Million appropriations, corresponding to 15.50% of the total payment appropriations, are carried over automatically to the following year.

<i>Amounts in EUR</i>	<b>Total payment appropriations</b>	<b>Payments made</b>	<b>%</b>	<b>Appropriations carried over to next year</b>	<b>%</b>
I - Staff	125,586,000.00	111,202,313.62	88.55%	1,381,902.98	1.10%
II - Administrative	56,337,000.00	42,930,257.60	76.20%	8,367,302.12	14.85%
III - Operating	162,019,000.00	104,860,548.15	64.72%	43,572,597.17	26.89%
<b>Total</b>	<b>343,942,000.00</b>	<b>258,993,119.37</b>	<b>75.30%</b>	<b>53,321,802.27</b>	<b>15.50%</b>

The implementation of the appropriations carried over by decision from the previous year is presented in section 5.3.5.

#### **5.3.4. Summary of the implementation of appropriations carried over automatically**

The Agency has implemented 90.57% of the appropriations carried over automatically from the previous year.

<i>Amounts in EUR</i>	<b>Total appropriations carried over automatically from previous year</b>	<b>Payments made</b>	<b>%</b>	<b>Appropriations lapsing</b>	<b>%</b>
I - Staff	1,108,008.19	838,493.14	75.68%	269,515.05	24.32%
II - Administrative	5,823,015.24	5,416,535.22	93.02%	406,480.02	6.98%
III - Operating	40,905,047.27	37,067,915.85	90.62%	3,837,131.42	9.38%
<b>Total</b>	<b>47,836,070.70</b>	<b>43,322,944.21</b>	<b>90.57%</b>	<b>4,513,126.49</b>	<b>9.43%</b>

#### **5.3.5. Summary of the implementation of appropriations carried over by decision from previous year**

The Agency has implemented 92.41% of the appropriations carried over by decision from the previous year.

<b>Budget title</b>	<b>Total appropriations carried over by decision</b>	<b>Payments made</b>	<b>%</b>	<b>Appropriations lapsing</b>	<b>%</b>
III – Operating – carry over by decision	6,181,000.00	5,712,041.60	92.41%	468,958.40	7.59%

Details of the implementation of the Agency revenue and expenditure budget for 2018, by budget item, are provided in sections 5.4 and 5.5 below.

## 5.4. Details of the implementation of budget revenue 2018

### Income appropriations and entitlements established

Amounts in EUR

Budget line	Title	Income appropriations			Entitlements established		
		Initial adopted budget	Amending budgets and transfers	Final adopted budget	Current Year	Carried over	Total
		1	2	3=1+2	4	5	6=4+5
1000	FEES COLLECTED	275,342,000.00	-	275,342,000.00	249,813,245.94	36,526,683.13	286,339,929.07
1001	FEES COLLECTED PHARMACOVIGILANCE	29,166,000.00	-	29,166,000.00	26,865,856.58	2,728,190.82	29,594,047.40
2000	EU BASIC CONTRIBUTION	8,989,000.00	1,416,000.00	10,405,000.00	10,503,205.00	-	10,503,205.00
2010	SPECIAL CONTRIBUTION FOR ORPHAN MEDICINAL PRODUCTS	13,416,000.00	1,416,000.00	12,000,000.00	11,856,940.00	-	11,856,940.00
5200	REVENUE FOR ADMINISTRATIVE ACTIVITIES AND ANCILLARY SERVICES	84,000.00	-	84,000.00	129,935.03	-	129,935.03
6000	EXTERNAL ASSIGNED REVENUE FOR PROJECTS AND PROGRAMME	148,000.00	-	148,000.00	91,994.36	78,581.33	170,575.69
7000	BALANCE OF OUTTURN ACCOUNT OF PREVIOUS YEARS	10,116,000.00	-	10,116,000.00	10,231,434.65	-	10,231,434.65
9000	MISCELLANEOUS REVENUE	500,000.00	-	500,000.00	201,353.43	-	201,353.43
	<b>Total</b>	<b>337,761,000.00</b>	<b>-</b>	<b>337,761,000.00</b>	<b>309,693,964.99</b>	<b>39,333,455.28</b>	<b>349,027,420.27</b>

### Revenue collected on entitlements established

Budget line	Title	Entitlements established	Revenue			Receipts as % of budget	Outstanding
		Total	On entitlements of current year	On entitlements carried over	Total		
		6=4+5	7	8	9=7+8	10=9/3	11=6-9
1000	FEES COLLECTED	286,339,929.07	222,623,776.94	34,052,592.00	256,676,368.94	93.22%	29,663,560.13
1001	FEES COLLECTED PHARMACOVIGILANCE	29,594,047.40	24,885,799.86	2,595,184.73	27,480,984.59	94.22%	2,113,062.81
2000	EU BASIC CONTRIBUTION	10,503,205.00	10,503,205.00	-	10,503,205.00	100.94%	-
2010	SPECIAL CONTRIBUTION FOR ORPHAN MEDICINAL PRODUCTS	11,856,940.00	11,856,940.00	-	11,856,940.00	98.81%	-
5200	REVENUE FOR ADMINISTRATIVE ACTIVITIES AND ANCILLARY SERVICES	129,935.03	40,050.00	-	40,050.00	47.68%	89,885.03
6000	EXTERNAL ASSIGNED REVENUE FOR PROJECTS AND PROGRAMME	170,575.69	60,723.29	31,271.07	91,994.36	62.16%	78,581.33
7000	BALANCE OF OUTTURN ACCOUNT OF PREVIOUS YEARS	10,231,434.65	10,231,434.65	-	10,231,434.65	101.14%	-
9000	MISCELLANEOUS REVENUE	201,353.43	200,147.53	-	200,147.53	40.03%	1,205.90
	<b>Total</b>	<b>349,027,420.27</b>	<b>280,402,077.27</b>	<b>36,679,047.80</b>	<b>317,081,125.07</b>	<b>93.88%</b>	<b>31,946,295.20</b>

## 5.5. Details of the implementation of budget expenditure 2018

### Commitment and payment appropriations (undifferentiated)

Amounts in EUR							
Budget line	Heading	Commitment/Payment appropriations (undifferentiated)					Total commitment and payments (undifferentiated) appropriations
		Budget appropriation			Additional appropriations		
		Initial adopted budget	Amending budgets and transfers	Final adopted budget	Carry-overs by decision	Assigned revenue	
		1	2	3=1+2	4	5	6=3+4+5
1100	BASIC SALARIES	44,711,000.00		44,711,000.00	-	-	44,711,000.00
1101	FAMILY ALLOWANCES	8,719,000.00	213,000.00	8,932,000.00	-	-	8,932,000.00
1102	EXPATRIATION AND FOREIGN RESIDENCE ALLOWANCES	6,279,000.00		6,279,000.00	-	-	6,279,000.00
1103	FIXED ALLOWANCES	57,000.00		57,000.00	-	-	57,000.00
1114	BASIC SALARIES AND ALLOWANCES FOR CONTRACT AGENTS	10,045,000.00		10,045,000.00	-	-	10,045,000.00
1115	SECONDED NATIONAL EXPERTS AND VISITING EXPERTS	5,545,000.00		5,545,000.00	-	-	5,545,000.00
1116	TRAINEES	2,157,000.00		2,157,000.00	-	-	2,157,000.00
1130	EMPLOYER'S SOCIAL SECURITY CONTRIBUTIONS	11,613,000.00	970,000.00	12,583,000.00	-	-	12,583,000.00
1140	MISCELLANEOUS ALLOWANCES AND GRANTS	67,000.00		67,000.00	-	-	67,000.00
1141	TRAVEL EXPENSES FROM PLACE OF EMPLOYMENT TO PLACE OF ORIGIN	1,280,000.00		1,280,000.00	-	-	1,280,000.00
1143	FIXED SPECIFIC ALLOWANCES	5,000.00	2,000.00	7,000.00	-	-	7,000.00
1181	ALLOWANCES AND EXPENSES ON ENTERING AND LEAVING THE SERVICE OR ON TRANSFER	3,576,000.00	(970,000.00)	2,606,000.00	-	-	2,606,000.00
1190	WEIGHTINGS AND EXCHANGE RATES	19,202,000.00		19,202,000.00	-	-	19,202,000.00
1200	EXPENDITURE RELATING TO STAFF RECRUITMENT	500,000.00	45,000.00	545,000.00	-	-	545,000.00
1300	DUTY TRAVEL EXPENSES AND INCIDENTAL EXPENDITURE	2,712,000.00		2,712,000.00	-	-	2,712,000.00
1410	MEDICAL SERVICE	475,000.00		475,000.00	-	-	475,000.00
1420	MISCELLANEOUS WELFARE EXPENDITURE	1,385,000.00	(260,000.00)	1,125,000.00	-	-	1,125,000.00
1430	SOCIAL CONTACTS BETWEEN STAFF	383,000.00		383,000.00	-	-	383,000.00
1500	STAFF TRAINING	900,000.00		900,000.00	-	-	900,000.00
1601	INTERIM SERVICES	5,329,000.00		5,329,000.00	-	-	5,329,000.00
1602	ADMINISTRATIVE ASSISTANCE FROM THE EU INSTITUTIONS	470,000.00		470,000.00	-	-	470,000.00
1603	PROFESSIONAL SERVICES RELATING TO STAFF MANAGEMENT	45,000.00		45,000.00	-	-	45,000.00
1700	RECEPTIONS AND EVENTS	95,000.00	36,000.00	131,000.00	-	-	131,000.00
2000	RENT	14,563,000.00	(660,460.00)	13,902,540.00	-	-	13,902,540.00
2010	INSURANCES	641,000.00		641,000.00	-	-	641,000.00
2030	MAINTENANCE AND CLEANING	1,239,000.00	180,000.00	1,419,000.00	-	-	1,419,000.00
2040	FITTING-OUT OF PREMISES	17,000.00	688,000.00	705,000.00	-	-	705,000.00
2050	SECURITY AND SURVEILLANCE OF BUILDINGS	628,000.00	(47,000.00)	581,000.00	-	-	581,000.00
2090	UTILITIES AND OTHER BUILDING CHARGES	4,709,000.00	21,000.00	4,730,000.00	-	-	4,730,000.00
2110	HARDWARE AND SOFTWARE	2,794,000.00		2,794,000.00	-	-	2,794,000.00
2114	MAINTENANCE AND SUPPORT OF APPLICATIONS	23,761,000.00	(38,000.00)	23,723,000.00	-	-	23,723,000.00
2115	IT DEVELOPMENT RELATED TO CORPORATE PROCESSES	-	38,000.00	38,000.00	-	-	38,000.00
2203	TECHNICAL EQUIPMENT AND INSTALLATIONS	763,000.00	(42,000.00)	721,000.00	-	-	721,000.00
2210	FURNITURE	11,000.00	(5,600.00)	5,400.00	-	-	5,400.00
2300	STATIONERY AND OFFICE SUPPLIES	71,000.00	22,000.00	93,000.00	-	-	93,000.00
2320	FINANCIAL CHARGES	56,000.00		56,000.00	-	-	56,000.00
2330	LEGAL EXPENSES AND ASSOCIATED COST	900,000.00		900,000.00	-	-	900,000.00
2358	BUSINESS CONTINUITY	89,000.00	(65,600.00)	23,400.00	-	-	23,400.00
2359	OTHER OPERATING EXPENDITURE	1,026,000.00	(100,340.00)	925,660.00	-	-	925,660.00
2400	POSTAL AND DELIVERY SERVICES	112,000.00	(5,000.00)	107,000.00	-	-	107,000.00
2500	OTHER MEETINGS	4,000.00	5,000.00	9,000.00	-	-	9,000.00
2501	MEMBERSHIPS WITH PROFESSIONAL BODIES	386,000.00	(20,000.00)	366,000.00	-	-	366,000.00
2600	RESTAURANT AND CATERING	777,000.00	100,000.00	877,000.00	-	-	877,000.00
2700	INFORMATION AND COMMUNICATION SERVICES	1,288,000.00		1,288,000.00	-	-	1,288,000.00
2800	BUSINESS CONSULTANCY AND AUDITS SERVICES	2,432,000.00		2,432,000.00	-	-	2,432,000.00
3000	REIMBURSEMENT OF PERSONS ATTENDING MEETINGS	7,925,000.00		7,925,000.00	-	-	7,925,000.00
3003	OTHER EXPENDITURE IN RELATION TO MEETINGS	392,000.00		392,000.00	-	-	392,000.00
3010	EVALUATION OF MEDICINAL PRODUCTS	114,382,000.00	(3,719,500.00)	110,662,500.00	-	-	110,662,500.00
3013	EVALUATION OF PHARMACOVIGILANCE PROCEDURES	13,238,000.00		13,238,000.00	-	-	13,238,000.00
3020	TRANSLATION CENTRE LUXEMBOURG	3,409,000.00		3,409,000.00	-	-	3,409,000.00
3021	OTHER TRANSLATIONS	1,585,000.00		1,585,000.00	-	-	1,585,000.00
3030	SCIENTIFIC STUDIES AND SERVICES	3,170,000.00		3,170,000.00	-	-	3,170,000.00
3105	BUSINESS IT DEVELOPMENT	11,843,000.00	3,613,500.00	15,456,500.00	6,181,000.00	-	21,637,500.00
Total		337,761,000.00	-	337,761,000.00	6,181,000.00	-	343,942,000.00

## Implementation of commitments appropriations

Amounts in EUR																
Budget line	Heading	Total commitment and payments (undifferentiated) appropriations	Commitments made					Appropriations carried over to next year				Appropriations lapsing				
			from final adopted budget	from carry-overs by decision	from assigned revenue	Total	%	carry-overs by decision	assigned revenue	Total	%	from final adopted budget	from carry-overs by decision	from assigned revenue	Total	%
1100 BASIC SALARIES		44,711,000.00	43,401,869.17	-	-	43,401,869.17	97.07%	-	-	-	0.00%	1,309,130.83	-	-	1,309,130.83	2.93%
1101 FAMILY ALLOWANCES		8,932,000.00	8,889,949.38	-	-	8,889,949.38	99.53%	-	-	-	0.00%	42,050.62	-	-	42,050.62	0.47%
1102 EXPATRIATION AND FOREIGN RESIDENCE ALLOWANCES		6,279,000.00	6,121,810.72	-	-	6,121,810.72	97.50%	-	-	-	0.00%	157,189.28	-	-	157,189.28	2.50%
1103 FIXED ALLOWANCES		57,000.00	47,673.05	-	-	47,673.05	83.64%	-	-	-	0.00%	9,326.95	-	-	9,326.95	16.36%
1114 BASIC SALARIES AND ALLOWANCES FOR CONTRACT AGENTS		10,045,000.00	7,597,455.59	-	-	7,597,455.59	75.63%	-	-	-	0.00%	2,447,544.41	-	-	2,447,544.41	24.37%
1115 SECONDED NATIONAL EXPERTS AND VISITING EXPERTS		5,545,000.00	3,944,519.36	-	-	3,944,519.36	71.14%	-	-	-	0.00%	1,600,480.64	-	-	1,600,480.64	28.86%
1116 TRAINEES		2,157,000.00	1,332,809.58	-	-	1,332,809.58	61.79%	-	-	-	0.00%	824,190.42	-	-	824,190.42	38.21%
1130 EMPLOYER'S SOCIAL SECURITY CONTRIBUTIONS		12,583,000.00	12,085,816.46	-	-	12,085,816.46	96.05%	-	-	-	0.00%	497,183.54	-	-	497,183.54	3.95%
1140 MISCELLANEOUS ALLOWANCES AND GRANTS		67,000.00	43,880.87	-	-	43,880.87	65.49%	-	-	-	0.00%	23,119.13	-	-	23,119.13	34.51%
1141 TRAVEL EXPENSES FROM PLACE OF EMPLOYMENT TO PLACE OF ORIGIN		1,280,000.00	1,201,132.31	-	-	1,201,132.31	93.84%	-	-	-	0.00%	78,867.69	-	-	78,867.69	6.16%
1143 FIXED SPECIFIC ALLOWANCES		7,000.00	6,292.44	-	-	6,292.44	89.89%	-	-	-	0.00%	707.56	-	-	707.56	10.11%
1181 ALLOWANCES AND EXPENSES ON ENTERING AND LEAVING THE SERVICE OR ON TRANSFER		2,606,000.00	1,135,410.59	-	-	1,135,410.59	43.57%	-	-	-	0.00%	1,470,589.41	-	-	1,470,589.41	56.43%
1190 WEIGHTINGS AND EXCHANGE RATES		19,202,000.00	18,387,711.50	-	-	18,387,711.50	95.76%	-	-	-	0.00%	814,288.50	-	-	814,288.50	4.24%
1200 EXPENDITURE RELATING TO STAFF RECRUITMENT		545,000.00	479,809.62	-	-	479,809.62	88.04%	-	-	-	0.00%	65,190.38	-	-	65,190.38	11.96%
1300 DUTY TRAVEL EXPENSES AND INCIDENTAL EXPENDITURE		2,712,233.06	1,761,233.06	-	-	1,761,233.06	64.94%	-	-	-	0.00%	950,766.94	-	-	950,766.94	35.06%
1410 MEDICAL SERVICE		475,000.00	305,298.18	-	-	305,298.18	64.27%	-	-	-	0.00%	169,701.82	-	-	169,701.82	35.73%
1420 MISCELLANEOUS WELFARE EXPENDITURE		1,125,000.00	503,407.60	-	-	503,407.60	44.75%	-	-	-	0.00%	621,592.40	-	-	621,592.40	55.25%
1430 SOCIAL CONTACTS BETWEEN STAFF		383,000.00	114,793.80	-	-	114,793.80	29.97%	-	-	-	0.00%	268,206.20	-	-	268,206.20	70.03%
1500 STAFF TRAINING		900,000.00	537,099.28	-	-	537,099.28	59.68%	-	-	-	0.00%	362,900.72	-	-	362,900.72	40.32%
1601 INTERIM SERVICES		5,329,000.00	4,112,753.52	-	-	4,112,753.52	77.18%	-	-	-	0.00%	1,216,246.48	-	-	1,216,246.48	22.82%
1602 ADMINISTRATIVE ASSISTANCE FROM THE EU INSTITUTIONS		470,000.00	467,893.17	-	-	467,893.17	99.55%	-	-	-	0.00%	2,106.83	-	-	2,106.83	0.45%
1603 PROFESSIONAL SERVICES RELATING TO STAFF MANAGEMENT		45,000.00	-	-	-	-	0.00%	-	-	-	0.00%	45,000.00	-	-	45,000.00	100.00%
1700 RECEPTIONS AND EVENTS		131,000.00	105,597.35	-	-	105,597.35	80.61%	-	-	-	0.00%	25,402.65	-	-	25,402.65	19.39%
2000 RENT		13,902,540.00	13,902,540.00	-	-	13,902,540.00	100.00%	-	-	-	0.00%	-	-	-	-	0.00%
2010 INSURANCES		641,000.00	570,210.87	-	-	570,210.87	88.96%	-	-	-	0.00%	70,789.13	-	-	70,789.13	11.04%
2030 MAINTENANCE AND CLEANING		1,419,000.00	1,306,587.96	-	-	1,306,587.96	92.08%	-	-	-	0.00%	112,412.04	-	-	112,412.04	7.92%
2040 FITTING-OUT OF PREMISES		705,000.00	704,517.08	-	-	704,517.08	99.93%	-	-	-	0.00%	482.92	-	-	482.92	0.07%
2050 SECURITY AND SURVEILLANCE OF BUILDINGS		581,000.00	543,409.18	-	-	543,409.18	93.53%	-	-	-	0.00%	37,590.82	-	-	37,590.82	6.47%
2090 UTILITIES AND OTHER BUILDING CHARGES		4,730,000.00	4,695,347.13	-	-	4,695,347.13	99.27%	-	-	-	0.00%	34,652.87	-	-	34,652.87	0.73%
2110 HARDWARE AND SOFTWARE		2,794,000.00	1,959,100.36	-	-	1,959,100.36	70.12%	-	-	-	0.00%	834,899.64	-	-	834,899.64	29.88%
2114 MAINTENANCE AND SUPPORT OF APPLICATIONS		23,723,000.00	21,737,608.02	-	-	21,737,608.02	91.63%	-	-	-	0.00%	1,985,391.98	-	-	1,985,391.98	8.37%
2115 IT DEVELOPMENT RELATED TO CORPORATE PROCESSES		38,000.00	34,521.82	-	-	34,521.82	90.85%	-	-	-	0.00%	3,478.18	-	-	3,478.18	9.15%
2203 TECHNICAL EQUIPMENT AND INSTALLATIONS		721,000.00	699,277.44	-	-	699,277.44	96.99%	-	-	-	0.00%	21,722.56	-	-	21,722.56	3.01%
2210 FURNITURE		5,400.00	5,343.32	-	-	5,343.32	98.95%	-	-	-	0.00%	56.68	-	-	56.68	1.05%
2300 STATIONERY AND OFFICE SUPPLIES		93,000.00	54,171.23	-	-	54,171.23	58.25%	-	-	-	0.00%	38,828.77	-	-	38,828.77	41.75%
2320 FINANCIAL CHARGES		56,000.00	44,403.63	-	-	44,403.63	79.29%	-	-	-	0.00%	11,596.37	-	-	11,596.37	20.71%
2330 LEGAL EXPENSES AND ASSOCIATED COST		900,000.00	570,375.94	-	-	570,375.94	63.38%	-	-	-	0.00%	329,624.06	-	-	329,624.06	36.62%
2358 BUSINESS CONTINUITY		23,400.00	23,310.21	-	-	23,310.21	99.62%	-	-	-	0.00%	89.79	-	-	89.79	0.38%
2359 OTHER OPERATING EXPENDITURE		925,660.00	632,560.23	-	-	632,560.23	68.34%	-	-	-	0.00%	293,099.77	-	-	293,099.77	31.66%
2400 POSTAL AND DELIVERY SERVICES		107,000.00	78,384.22	-	-	78,384.22	73.26%	-	-	-	0.00%	28,615.78	-	-	28,615.78	26.74%
2500 OTHER MEETINGS		9,000.00	5,708.69	-	-	5,708.69	63.43%	-	-	-	0.00%	3,291.31	-	-	3,291.31	36.57%
2501 MEMBERSHIPS WITH PROFESSIONAL BODIES		366,000.00	343,615.54	-	-	343,615.54	93.88%	-	-	-	0.00%	22,384.46	-	-	22,384.46	6.12%
2600 RESTAURANT AND CATERING		877,000.00	837,582.98	-	-	837,582.98	95.51%	-	-	-	0.00%	39,417.02	-	-	39,417.02	4.49%
2700 INFORMATION AND COMMUNICATION SERVICES		1,288,000.00	986,819.17	-	-	986,819.17	76.62%	-	-	-	0.00%	301,180.83	-	-	301,180.83	23.38%
2800 BUSINESS CONSULTANCY AND AUDITS SERVICES		2,432,000.00	1,562,164.70	-	-	1,562,164.70	64.23%	-	-	-	0.00%	869,835.30	-	-	869,835.30	35.77%
3000 REIMBURSEMENT OF PERSONS ATTENDING MEETINGS		7,925,000.00	7,445,133.13	-	-	7,445,133.13	93.94%	-	-	-	0.00%	479,866.87	-	-	479,866.87	6.06%
3003 OTHER EXPENDITURE IN RELATION TO MEETINGS		392,000.00	190,194.35	-	-	190,194.35	48.52%	-	-	-	0.00%	201,805.65	-	-	201,805.65	51.48%
3010 EVALUATION OF MEDICINAL PRODUCTS		110,662,500.00	102,363,635.06	-	-	102,363,635.06	92.50%	-	-	-	0.00%	8,298,864.94	-	-	8,298,864.94	7.50%
3013 EVALUATION OF PHARMACOVIGILANCE PROCEDURES		13,238,000.00	11,780,110.54	-	-	11,780,110.54	88.99%	-	-	-	0.00%	1,457,889.46	-	-	1,457,889.46	11.01%
3020 TRANSLATION CENTRE LUXEMBOURG		3,409,000.00	2,896,890.10	-	-	2,896,890.10	84.98%	-	-	-	0.00%	512,109.90	-	-	512,109.90	15.02%
3021 OTHER TRANSLATIONS		1,585,000.00	1,382,744.00	-	-	1,382,744.00	87.24%	-	-	-	0.00%	202,256.00	-	-	202,256.00	12.76%
3030 SCIENTIFIC STUDIES AND SERVICES		3,170,000.00	2,863,988.67	-	-	2,863,988.67	90.35%	-	-	-	0.00%	306,011.33	-	-	306,011.33	9.65%
3105 BUSINESS IT DEVELOPMENT		21,637,500.00	13,798,407.87	-	-	13,798,407.87	63.74%	-	-	-	0.00%	7,839,092.13	-	-	7,839,092.13	36.26%
<b>Total</b>		<b>343,942,000.00</b>	<b>306,602,880.04</b>	<b>5,712,041.60</b>	<b>-</b>	<b>312,314,921.64</b>	<b>90.80%</b>	<b>1,500,000.00</b>	<b>-</b>	<b>1,500,000.00</b>	<b>0.44%</b>	<b>31,158,119.96</b>	<b>468,958.40</b>	<b>-</b>	<b>31,627,078.36</b>	<b>9.20%</b>

## Implementation of payment appropriations

Amounts in EUR											
Budget line	Heading	Total commitment and payments (undifferentiated) appropriations	Payments made					Appropriations carried over to next year			
			from final adopted budget	from carry-overs by decision	from assigned revenue	Total	%	automatic carry-overs (commitments made MINUS payments made)	assigned revenue	Total	%
		1	2	3	4	5=2+3+4	6	7=column 5 CMT - 2	8	9=7+8	10=9/1
1100	BASIC SALARIES	44,711,000.00	43,401,869.17	-	-	43,401,869.17	97.07%	-	-	-	0.00%
1101	FAMILY ALLOWANCES	8,932,000.00	8,889,949.38	-	-	8,889,949.38	99.53%	-	-	-	0.00%
1102	EXPATRIATION AND FOREIGN RESIDENCE ALLOWANCES	6,279,000.00	6,121,810.72	-	-	6,121,810.72	97.50%	-	-	-	0.00%
1103	FIXED ALLOWANCES	57,000.00	47,673.05	-	-	47,673.05	83.64%	-	-	-	0.00%
1114	BASIC SALARIES AND ALLOWANCES FOR CONTRACT AGENTS	10,045,000.00	7,597,455.59	-	-	7,597,455.59	75.63%	-	-	-	0.00%
1115	SECONDED NATIONAL EXPERTS AND VISITING EXPERTS	5,545,000.00	3,588,519.36	-	-	3,588,519.36	64.72%	356,000.00	-	356,000.00	6.42%
1116	TRAINEES	2,157,000.00	1,330,817.80	-	-	1,330,817.80	61.70%	1,991.78	-	1,991.78	0.09%
1130	EMPLOYER'S SOCIAL SECURITY CONTRIBUTIONS	12,583,000.00	12,085,816.46	-	-	12,085,816.46	96.05%	-	-	-	0.00%
1140	MISCELLANEOUS ALLOWANCES AND GRANTS	67,000.00	43,880.87	-	-	43,880.87	65.49%	-	-	-	0.00%
1141	TRAVEL EXPENSES FROM PLACE OF EMPLOYMENT TO PLACE OF ORIGIN	1,280,000.00	1,201,132.31	-	-	1,201,132.31	93.84%	-	-	-	0.00%
1143	FIXED SPECIFIC ALLOWANCES	7,000.00	6,292.44	-	-	6,292.44	89.89%	-	-	-	0.00%
1181	ALLOWANCES AND EXPENSES ON ENTERING AND LEAVING THE SERVICE OR ON TRANFE	2,606,000.00	1,031,827.51	-	-	1,031,827.51	39.59%	103,583.08	-	103,583.08	3.97%
1190	WEIGHTINGS AND EXCHANGE RATES	19,202,000.00	18,387,711.50	-	-	18,387,711.50	95.76%	-	-	-	0.00%
1200	EXPENDITURE RELATING TO STAFF RECRUITMENT	545,000.00	450,251.78	-	-	450,251.78	82.62%	29,557.84	-	29,557.84	5.42%
1300	DUTY TRAVEL EXPENSES AND INCIDENTAL EXPENDITURE	2,712,000.00	1,441,971.41	-	-	1,441,971.41	53.17%	319,261.65	-	319,261.65	11.77%
1410	MEDICAL SERVICE	475,000.00	259,048.73	-	-	259,048.73	54.54%	46,249.45	-	46,249.45	9.74%
1420	MISCELLANEOUS WELFARE EXPENDITURE	1,125,000.00	501,201.98	-	-	501,201.98	44.55%	2,205.62	-	2,205.62	0.20%
1430	SOCIAL CONTACTS BETWEEN STAFF	383,000.00	84,097.95	-	-	84,097.95	21.96%	30,695.85	-	30,695.85	8.01%
1500	STAFF TRAINING	900,000.00	458,745.91	-	-	458,745.91	50.97%	78,353.37	-	78,353.37	8.71%
1601	INTERIM SERVICES	5,329,000.00	3,754,730.94	-	-	3,754,730.94	70.46%	358,022.58	-	358,022.58	6.72%
1602	ADMINISTRATIVE ASSISTANCE FROM THE EU INSTITUTIONS	470,000.00	437,893.17	-	-	437,893.17	93.17%	30,000.00	-	30,000.00	6.38%
1603	PROFESSIONAL SERVICES RELATING TO STAFF MANAGEMENT	45,000.00	-	-	-	-	0.00%	-	-	-	0.00%
1700	RECEPTIONS AND EVENTS	131,000.00	79,615.59	-	-	79,615.59	60.78%	25,981.76	-	25,981.76	19.83%
2000	RENT	13,902,540.00	13,902,540.00	-	-	13,902,540.00	100.00%	-	-	-	0.00%
2010	INSURANCES	641,000.00	566,828.75	-	-	566,828.75	88.43%	3,382.12	-	3,382.12	0.53%
2030	MAINTENANCE AND CLEANING	1,419,000.00	1,282,493.60	-	-	1,282,493.60	90.38%	24,094.36	-	24,094.36	1.70%
2040	FITTING-OUT OF PREMISES	705,000.00	13,440.00	-	-	13,440.00	1.91%	691,077.08	-	691,077.08	98.03%
2050	SECURITY AND SURVEILLANCE OF BUILDINGS	581,000.00	529,799.26	-	-	529,799.26	91.19%	13,609.92	-	13,609.92	2.34%
2090	UTILITIES AND OTHER BUILDING CHARGES	4,730,000.00	4,544,415.67	-	-	4,544,415.67	96.08%	150,931.46	-	150,931.46	3.19%
2110	HARDWARE AND SOFTWARE	2,794,000.00	1,417,434.73	-	-	1,417,434.73	50.73%	541,665.63	-	541,665.63	19.39%
2114	MAINTENANCE AND SUPPORT OF APPLICATIONS	23,723,000.00	16,191,922.11	-	-	16,191,922.11	68.25%	5,545,685.91	-	5,545,685.91	23.38%
2115	IT DEVELOPMENT RELATED TO CORPORATE PROCESSES	38,000.00	34,521.82	-	-	34,521.82	90.85%	-	-	-	0.00%
2203	TECHNICAL EQUIPMENT AND INSTALLATIONS	721,000.00	665,609.40	-	-	665,609.40	92.32%	33,668.04	-	33,668.04	4.67%
2210	FURNITURE	5,400.00	5,343.32	-	-	5,343.32	98.95%	-	-	-	0.00%
2300	STATIONERY AND OFFICE SUPPLIES	93,000.00	51,829.05	-	-	51,829.05	55.73%	2,342.18	-	2,342.18	2.52%
2320	FINANCIAL CHARGES	56,000.00	39,903.63	-	-	39,903.63	71.26%	4,500.00	-	4,500.00	8.04%
2330	LEGAL EXPENSES AND ASSOCIATED COST	900,000.00	36,101.39	-	-	36,101.39	4.01%	534,274.55	-	534,274.55	59.36%
2358	BUSINESS CONTINUITY	23,400.00	23,310.21	-	-	23,310.21	99.62%	-	-	-	0.00%
2359	OTHER OPERATING EXPENDITURE	925,660.00	537,467.02	-	-	537,467.02	58.06%	95,093.21	-	95,093.21	10.27%
2400	POSTAL AND DELIVERY SERVICES	107,000.00	75,040.98	-	-	75,040.98	70.13%	3,343.24	-	3,343.24	3.12%
2500	OTHER MEETINGS	9,000.00	5,549.69	-	-	5,549.69	61.66%	159.00	-	159.00	1.77%
2501	MEMBERSHIPS WITH PROFESSIONAL BODIES	366,000.00	331,615.54	-	-	331,615.54	90.61%	12,000.00	-	12,000.00	3.28%
2600	RESTAURANT AND CATERING	877,000.00	648,422.69	-	-	648,422.69	73.94%	189,160.29	-	189,160.29	21.57%
2700	INFORMATION AND COMMUNICATION SERVICES	1,288,000.00	857,201.77	-	-	857,201.77	66.55%	129,617.40	-	129,617.40	10.06%
2800	BUSINESS CONSULTANCY AND AUDITS SERVICES	2,432,000.00	1,169,466.97	-	-	1,169,466.97	48.09%	392,697.73	-	392,697.73	16.15%
3000	REIMBURSEMENT OF PERSONS ATTENDING MEETINGS	7,925,000.00	6,901,473.74	-	-	6,901,473.74	87.08%	543,659.39	-	543,659.39	6.86%
3003	OTHER EXPENDITURE IN RELATION TO MEETINGS	392,000.00	121,123.75	-	-	121,123.75	30.90%	69,070.60	-	69,070.60	17.62%
3010	EVALUATION OF MEDICINAL PRODUCTS	110,662,500.00	74,601,249.66	-	-	74,601,249.66	67.41%	27,762,385.40	-	27,762,385.40	25.09%
3013	EVALUATION OF PHARMACOVIGILANCE PROCEDURES	13,238,000.00	7,916,321.35	-	-	7,916,321.35	59.80%	3,863,789.19	-	3,863,789.19	29.19%
3020	TRANSLATION CENTRE LUXEMBOURG	3,409,000.00	2,605,442.30	-	-	2,605,442.30	76.43%	291,447.80	-	291,447.80	8.55%
3021	OTHER TRANSLATIONS	1,585,000.00	1,382,744.00	-	-	1,382,744.00	87.24%	-	-	-	0.00%
3030	SCIENTIFIC STUDIES AND SERVICES	3,170,000.00	2,001,285.65	-	-	2,001,285.65	63.13%	862,703.02	-	862,703.02	27.21%
3105	BUSINESS IT DEVELOPMENT	21,637,500.00	3,618,866.10	5,712,041.60	-	9,330,907.70	43.12%	10,179,541.77	-	10,179,541.77	47.05%
Total		343,942,000.00	253,281,077.77	5,712,041.60	-	258,993,119.37	75.30%	53,321,802.27	-	53,321,802.27	15.50%

## Implementation of automatic carry over from previous year

Amounts in EUR

Budget line	Heading	Commitments carried over from previous year (RAL)	Payments made	% implementation	Cancellation of commitments which cannot be carried over	% cancellation
		1	2	3=2/1	4	5
1115	SECONDED NATIONAL EXPERTS AND VISITING EXPERTS	493,000.00	365,183.38	74.07%	127,816.62	25.93%
1181	ALLOWANCES AND EXPENSES ON ENTERING AND LEAVING THE SERVICE OR ON TRANSFER	56,548.22	54,075.84	95.63%	2,472.38	4.37%
1200	EXPENDITURE RELATING TO STAFF RECRUITMENT	5,842.29	1,707.82	29.23%	4,134.47	70.77%
1300	DUTY TRAVEL EXPENSES AND INCIDENTAL EXPENDITURE	151,436.48	106,094.75	70.06%	45,341.73	29.94%
1410	MEDICAL SERVICE	26,753.09	16,778.56	62.72%	9,974.53	37.28%
1420	MISCELLANEOUS WELFARE EXPENDITURE	1,487.06	1,436.33	96.59%	50.73	3.41%
1430	SOCIAL CONTACTS BETWEEN STAFF	22,662.39	18,991.03	83.80%	3,671.36	16.20%
1500	STAFF TRAINING	73,326.04	57,664.57	78.64%	15,661.47	21.36%
1601	INTERIM SERVICES	234,028.93	181,630.78	77.61%	52,398.15	22.39%
1602	ADMINISTRATIVE ASSISTANCE FROM THE EU INSTITUTIONS	3,639.98	580.52	15.95%	3,059.46	84.05%
1700	RECEPTIONS AND EVENTS	39,283.71	34,349.56	87.44%	4,934.15	12.56%
2010	INSURANCES	9,678.16	7,346.42	75.91%	2,331.74	24.09%
2030	MAINTENANCE AND CLEANING	212,021.16	202,777.26	95.64%	9,243.90	4.36%
2040	FITTING-OUT OF PREMISES	5,832.96	4,524.89	77.57%	1,308.07	22.43%
2050	SECURITY AND SURVEILLANCE OF BUILDINGS	101,496.51	92,214.09	90.85%	9,282.42	9.15%
2090	UTILITIES AND OTHER BUILDING CHARGES	112,039.39	108,197.07	96.57%	3,842.32	3.43%
2110	HARDWARE AND SOFTWARE	2,479,126.55	2,479,097.14	100.00%	29.41	0.00%
2114	MAINTENANCE AND SUPPORT OF APPLICATIONS	2,371,600.48	2,142,730.31	90.35%	228,870.17	9.65%
2115	IT DEVELOPMENT RELATED TO CORPORATE PROCESSES	141,952.99	54,029.91	38.06%	87,923.08	61.94%
2203	TECHNICAL EQUIPMENT AND INSTALLATIONS	27,685.36	26,980.08	97.45%	705.28	2.55%
2300	STATIONERY AND OFFICE SUPPLIES	18,288.03	14,032.49	76.73%	4,255.54	23.27%
2330	LEGAL EXPENSES AND ASSOCIATED COST	4,916.87	2,253.06	45.82%	2,663.81	54.18%
2359	OTHER OPERATING EXPENDITURE	60,693.59	39,386.38	64.89%	21,307.21	35.11%
2400	POSTAL AND DELIVERY SERVICES	4,354.25	4,188.11	96.18%	166.14	3.82%
2600	RESTAURANT AND CATERING	70,380.51	48,414.71	68.79%	21,965.80	31.21%
2700	INFORMATION AND COMMUNICATION SERVICES	52,881.75	50,040.49	94.63%	2,841.26	5.37%
2800	BUSINESS CONSULTANCY AND AUDITS SERVICES	150,066.68	140,322.81	93.51%	9,743.87	6.49%
3000	REIMBURSEMENT OF PERSONS ATTENDING MEETINGS	1,123,065.60	800,722.87	71.30%	322,342.73	28.70%
3003	OTHER EXPENDITURE IN RELATION TO MEETINGS	83,248.00	47,146.23	56.63%	36,101.77	43.37%
3010	EVALUATION OF MEDICINAL PRODUCTS	25,264,820.64	24,660,120.00	97.61%	604,700.64	2.39%
3013	EVALUATION OF PHARMACOVIGILANCE PROCEDURES	4,384,017.19	4,370,896.96	99.70%	13,120.23	0.30%
3020	TRANSLATION CENTRE LUXEMBOURG	258,648.45	246,820.15	95.43%	11,828.30	4.57%
3030	SCIENTIFIC STUDIES AND SERVICES	1,823,901.61	1,470,499.98	80.62%	353,401.63	19.38%
3105	BUSINESS IT DEVELOPMENT	7,967,345.78	5,471,709.66	68.68%	2,495,636.12	31.32%
<b>Total</b>		<b>47,836,070.70</b>	<b>43,322,944.21</b>	<b>90.57%</b>	<b>4,513,126.49</b>	<b>9.43%</b>