



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/133175/2022 *Corr 1 (annotations at page 39)*  
Administration and Corporate Management Division

## Annual accounts

Financial year 2021

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## **Certification of the accounts**

I acknowledge my responsibility for the preparation and presentation of the annual accounts of the European Medicines Agency in accordance with Article 102 of the Framework Financial Regulation ('FFR') and I hereby certify that the annual accounts of the European Medicines Agency for the year 2021 have been prepared in accordance with Title IX of the FFR and the accounting rules adopted by the Commission's Accounting Officer, as are to be applied by all the institutions and union bodies.

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. 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 results of the operations and the cash-flow of the European Medicines Agency.

Paola Samassa

Accounting Officer of the European Medicines Agency

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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<sup>1</sup>.

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).

The mission of the European Medicines Agency is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union (EU).

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

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

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.

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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.

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 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

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

<b>Item</b>	<b>Accrual</b>	<b>Budget</b>
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 the economic outturn is presented in section 5, budget implementation reports.

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 budget implementation reports 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	31.12.2021 Final	31.12.2020 Final
<i>Amounts in EUR</i>			
<b>NON-CURRENT ASSETS</b>			
Intangible fixed assets	4.1.1	68,767,223.78	56,341,006.36
Tangible fixed assets	4.1.2	20,919,988.43	21,782,604.37
Financial assets	4.1.3	14,155,051.25	39,698,438.52
Deferred expenditure	4.1.4	44,368,299.77	19,940,813.44
Recoverable from member states and the UK	4.2.2	2,550,000.00	2,700,000.00
<b>TOTAL NON CURRENT ASSETS</b>		<b>150,760,563.23</b>	<b>140,462,862.69</b>
<b>CURRENT ASSETS</b>			
Financial assets due within 1 year	4.1.3	4,046,014.42	-
Deferred expenditure due within 1 year	4.1.4	2,579,155.30	1,116,640.85
Receivables from exchange transactions	4.2.1	48,552,856.54	54,141,197.63
Recoverable from member states and the UK	4.2.2	2,188,540.15	2,982,205.97
Provision for doubtful debts	4.2.2	(1,284,981.99)	(2,356,085.58)
Accrued marketing authorisation fees	4.2.3	54,741,416.85	50,930,470.14
Prepaid expenses	4.2.4	12,208,973.09	10,880,918.18
Cash and cash equivalents	4.2.5	119,695,454.78	77,142,605.45
<b>TOTAL CURRENT ASSETS</b>		<b>242,727,429.14</b>	<b>194,837,952.64</b>
<b>TOTAL ASSETS</b>		<b>393,487,992.37</b>	<b>335,300,815.33</b>
<b>NON-CURRENT LIABILITIES</b>			
Deferred revenue	4.3.1	52,849,905.53	56,596,575.54
<b>TOTAL NON CURRENT LIABILITIES</b>		<b>52,849,905.53</b>	<b>56,596,575.54</b>
<b>CURRENT LIABILITIES</b>			
Deferred revenue due within 1 year	4.3.1	3,746,670.01	3,746,670.01
Financial liabilities due within 1 year	4.1.3	4,046,014.42	-
Payables under exchange transactions	4.4.1	66,087,753.97	61,004,208.03
Budgetary result payable to European Commission	4.4.2	24,982,180.86	4,368,320.96
Other prefinancing from EU entities	4.4.3	254,919.00	254,919.00
Payables with EU entities		66,756.24	81,983.20
Payables with member states and the UK	4.4.4	229,785.03	-
Sundry payables		52,777.70	28,954.40
Deferred marketing authorisation fees	4.4.5	26,210,201.21	21,979,971.23
Other deferred income	4.4.6	5,041,542.20	4,704,426.35
<b>TOTAL CURRENT LIABILITIES</b>		<b>130,718,600.64</b>	<b>96,169,453.18</b>
<b>TOTAL LIABILITIES</b>		<b>183,568,506.17</b>	<b>152,766,028.72</b>
<b>NET ASSETS</b>		<b>209,919,486.20</b>	<b>182,534,786.61</b>
<b>NET ASSETS</b>			
Accumulated surplus/deficit		182,534,786.61	119,581,299.01
Economic result of the year		27,384,699.59	62,953,487.60
<b>NET ASSETS</b>		<b>209,919,486.20</b>	<b>182,534,786.61</b>

## 2.2. Statement of financial performance

	Note	2021 Final	2020 Final
<i>Amounts in EUR</i>			
<b>OPERATING REVENUE</b>			
Fees and charges related to marketing authorisations	4.5.1	344,805,272.60	328,371,327.48
Contribution from EU entities	4.5.2	12,654,549.14	46,229,319.24
Revenue from landlord incentives	4.5.3	3,552,059.82	3,547,234.03
Sundry revenue	4.5.4	718,348.88	453,950.98
Reversal of previous years provision	4.5.5	1,228,044.21	2,723,247.00
Revenue from subletting	4.5.6	17,910,117.66	18,929,138.97
Revenue from non-exchange transactions		-	98,411.38
<b>TOTAL OPERATING REVENUE</b>		<b>380,868,392.31</b>	<b>400,352,629.08</b>
<b>OPERATING EXPENDITURE</b>			
Staff expenses	4.6.1	121,314,024.64	110,812,907.00
Administrative expenditure	4.6.2	62,119,655.76	65,929,625.54
Operating expenditure	4.6.3	158,244,172.08	144,974,319.37
Depreciation		13,094,562.62	11,962,547.82
Disposals and derecognition of assets		998,069.89	632,536.06
Other adjustments	4.6.4	157,229.25	2,203,986.51
<b>TOTAL OPERATING EXPENDITURE</b>		<b>355,927,714.24</b>	<b>336,515,922.30</b>
<b>Surplus (deficit) from operating activities</b>		<b>24,940,678.07</b>	<b>63,836,706.78</b>
Surplus (deficit) from non-operating activities	4.7	2,444,021.52	(883,219.18)
<b>Surplus (deficit) from ordinary activities</b>		<b>27,384,699.59</b>	<b>62,953,487.60</b>
Surplus (deficit) from extraordinary items		-	-
<b>ECONOMIC RESULT OF THE YEAR</b>		<b>27,384,699.59</b>	<b>62,953,487.60</b>

## 2.3. Cash flow statement

<i>Amounts in EUR</i>	<b>2021 Final</b>	<b>2020 Final</b>
<b>Economic result of the year</b>	<b>27,384,699.59</b>	<b>62,953,487.60</b>
<b>OPERATING ACTIVITIES</b>		
Amortization (intangible fixed assets)	8,774,458.24	8,185,058.88
Depreciation (tangible fixed assets)	4,320,104.38	3,777,488.94
(Increase)/decrease in current receivable and accrued fees	1,777,394.38	(19,563,029.42)
(Increase)/decrease in other receivables	21,112,983.76	5,436,871.10
(Increase)/decrease in receivables related to EU entities	-	8,285,039.42
Increase/(decrease) in provisions for risks and liabilities	-	(2,723,247.00)
Increase/(decrease) in provision for doubtful debts	(1,071,103.59)	1,959,133.11
Increase/(decrease) in deferred revenue	483,559.97	(4,686,254.94)
(Increase)/decrease in deferred expenditure	(25,890,000.78)	1,265,474.16
Increase/(decrease) in accounts payable	5,337,154.27	(9,306,344.87)
Increase/(decrease) in liabilities related to EU entities	20,598,632.94	4,272,002.01
(Gains)/losses on sale/disposal/derecognition of property, plant and equipment	998,069.89	632,742.88
Increase/(decrease) in financial liabilities	4,046,014.42	(15,983,943.35)
Increase/(decrease) in prepaid income	337,115.85	(224,146.45)
<b>Net cash flow from operating activities (a)</b>	<b>68,209,083.32</b>	<b>44,280,332.07</b>
<b>INVESTING ACTIVITIES</b>		
(Purchase) of tangible and intangible fixed assets	(25,656,233.99)	(16,721,617.69)
<b>Net cash flow from investing activities (b)</b>	<b>(25,656,233.99)</b>	<b>(16,721,617.69)</b>
<b>Net increase/(decrease) in cash and cash equivalents (a+b)</b>	<b>42,552,849.33</b>	<b>27,558,714.38</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>77,142,605.45</b>	<b>49,583,891.07</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>119,695,454.78</b>	<b>77,142,605.45</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 2020</b>	<b>119,581,299.01</b>	<b>62,953,487.60</b>	<b>182,534,786.61</b>
Allocation of economic result 2020	62,953,487.60	(62,953,487.60)	-
Economic result 2021	-	27,384,699.59	27,384,699.59
<b>Balance as of 31 December 2021</b>	<b>182,534,786.61</b>	<b>27,384,699.59</b>	<b>209,919,486.20</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, 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 0.84028 (31.12.2021).

#### **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.

Since the beginning of the COVID-19 related crisis, the Agency has taken a number of measures to monitor and mitigate the effects of the current pandemic, such as managing health and safety risks by implementing social distancing and working from home for employees and monitoring closely with the National Competent Authorities (NCAs) in the member states the effect of the pandemic on the supply chain, in order to ensure the continuity of the evaluation services of the medicinal products.

At the date these accounts are issued, EMA operations and result have not been significantly impacted by the current pandemic. Similarly, the pandemic as such did not trigger significant estimations to be made in the preparation of the financial statements 2021.

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 lease on the Agency's former office premises at 30 Churchill Place, London, runs until 2039 and does not contain a break clause, but the premises can be sublet or assigned subject to the landlord's consent.

The Agency's premises in the United Kingdom were not included in the EU-UK political negotiations on the Withdrawal Agreement.

Further to the High Court of Justice of England and Wales ruling of February 2019, stating that Brexit is not a cause for frustrating the lease agreement, the Agency sought contractual possibilities to dispose of the premises and mitigate the financial burden on the EU budget.

On 2<sup>nd</sup> July 2019 the Agency has reached an agreement with its landlord over its premises at 30 Churchill Place, London, in accordance with the discussions held with the EU budgetary authorities and it has sublet its former office premises to a subtenant under conditions that are consistent with the ones of the headlease, including the sublease term that extends until the expiry of EMA's headlease in June 2039.

As a result of the subletting, the Agency must continuously divert some of its human resources away from its public health remit to the management of a commercial property in a third country for which neither the Agency nor the EU have business use, an activity not foreseen in the Agency's founding regulation.

The EMA Management Board has raised with the EU institutions on numerous occasions the need for a resolution of this issue at the highest political level, to allow the Agency to fully focus its resources on the implementation of its recently expanded mandate and the Union's fight against public health emergencies.

Since EMA remains a party to the headlease with its Canary Wharf landlords, should the subtenant not be able to meet its obligations, the Agency could be exposed for all the amounts remaining payable under the headlease contractual obligations, including the reinstatement of the Agency's obligation for restoring the premises at 30 Churchill Place, London to their original state, as disclosed in note 4.8.1 on operating leases and note 4.8.2 on contingent assets and liabilities.

At the date these accounts are issued, the subtenant has met its contractual obligations and management is of the opinion that the subtenant will continue to do so in foreseeable future.

### **3.1.4. Application of new and revised European Union Accounting Rules (EAR)**

#### **Revised EAR 11 Financial Instruments**

In 2020, the Accounting Officer of the European Commission adopted the revised EU Accounting Rule 11 Financial Instruments (EAR 11), which is applicable as from 1 January 2021 and replaces the previous EAR 11 adopted in 2011.

The revised EAR 11 aligns the EU Accounting Rules on financial instruments to the recent changes of the underlying International Public Sector Accounting Standards (IPSAS), mainly the replacement of IPSAS 29 Financial Instruments: Recognition and Measurement with IPSAS 41 Financial Instruments.

The revised EAR 11 is based on the new IPSAS 41 'Financial Instruments', the amended IPSAS 28 'Financial Instruments: Presentation' and the amended IPSAS 30 'Financial Instruments: Disclosures' which were issued in August 2018. It establishes the financial reporting principles for financial assets and financial liabilities.

In accordance with the transition provisions of the revised EAR 11, the entity accounts for any changes from the initial application, on 1 January 2021. The revised EAR 11 does not require the restatement of prior periods.

### **3.1.5. Changes in accounting policies**

In the current year, EMA has applied the revised EAR 11, which introduces new requirements for:

- the classification and measurement of financial assets and financial liabilities,
- impairment for financial assets, and
- general hedge accounting.

Regarding the classification and measurement of financial assets and financial liabilities, the Agency's management has reviewed and assessed the EMA's existing financial assets and liabilities as at 1 January 2021 based on the facts and circumstances that existed at that date and concluded that the initial application of the revised EAR 11 has the following impact on the EMA's financial instruments in regards to their classification and measurement:

- The financial assets such as receivables and cash and cash equivalents are classified and measured at amortised cost under the revised EAR 11.
- In relation to the impairment of financial assets, in particular cash and cash equivalents and exchange receivables, the revised EAR 11 requires an expected credit loss model as opposed to an incurred credit loss model under the old EAR 11.
- The revised EAR 11, unlike the old EAR 11, is not applicable to the impairment of non-exchange recoverables.
- Classification and measurement of financial liabilities i.e. payables of EMA has not been modified by the requirements of the revised EAR 11.

For the impairment of financial assets an expected credit loss model is applied. The expected credit loss model requires the Agency to account for expected credit losses and changes in those expected credit losses at each reporting date to reflect changes in credit risk since initial recognition of the financial assets.

The impairment model and the write-off policy are outlined in note 3.5.1 and note 3.5.2 respectively.

The impact of the new impairment model is disclosed in note 4.2.1 on receivables from exchange transactions and note 4.9 on financial assets and financial liabilities risk analysis.



## **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 capitalisation of tangible assets is € 1,500.

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 of the Agency Financial Regulation. 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:

- Internally generated computer software 25%
- Other computer software 25%
- Building, leasehold improvements and fitting out costs 4%-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 i.e. financial assets measured at amortised cost. 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. Please refer also to sections 3.5.1 on impairment of financial assets and 3.5.2 on write-off policy.

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

Cash and cash equivalents are financial instruments carried in the balance sheet at cost, i.e. financial assets measured at amortised 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, i.e. financial liabilities measured at amortised cost.

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 2020/422 of 19 March 2020 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 10.1%<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. 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**

Revised 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.

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<sup>4</sup> updated rate as of 1 July 2021, the weightings not being taken into account

### **3.5.1. Impairment of financial assets**

The revised EAR 11 includes new requirements for the impairment of exchange receivables. Such new requirements are not applicable to the impairment of non-exchange recoverables.

For the impairment of financial assets an expected credit loss model is applied. The expected credit loss model requires the Agency to account for expected credit losses and changes in those expected credit losses at each reporting date to reflect changes in credit risk since initial recognition of the financial assets.

Specifically, the following assets are included in the scope for impairment assessment:

- trade (exchange receivables)
- non-current exchange receivables and lease receivables
- cash and cash equivalents.

For trade receivables without a significant financing component (short-term trade receivables), the revised EAR 11 provides a simplified approach for measuring the loss allowance at an amount equal to lifetime expected credit losses.

EMA determines the expected credit losses on these items by using a provision matrix, based on historical credit loss experience and on the past due status of the debtors, adjusted as appropriate to reflect current conditions and estimates of future economic conditions. Accordingly, the credit risk profile of these assets is presented based on their past due status in terms of the provision matrix.

If the credit risk on a financial instrument has increased significantly since initial recognition, the revised EAR 11 requires the Agency to measure the loss allowance for that financial instrument at an amount equal to the lifetime expected credit losses. On the other hand, if the credit risk on a financial instrument has not increased significantly since initial recognition, the Agency is required to measure the loss allowance for that financial instrument at an amount equal to 12 month expected credit losses.

For non-current exchange receivables and lease receivables revised EAR 11 provides a choice to measure expected credit losses applying lifetime or 12 month expected credit losses model.

All cash and cash equivalent balances are assessed for expected credit losses as well. They may have low credit risk at the reporting date if they are held with reputable international financial institutions with prime and high-grade external credit rating.

### **3.5.2. Write-off policy**

The Agency writes off a financial asset when there is information indicating that the counterparty is in severe financial difficulty and there is no realistic prospect of recovery, e.g. when the counterparty has been placed under liquidation or has entered into bankruptcy proceedings, or in the case of trade receivables, when the amounts are over five years past due, whichever occurs sooner.

Financial assets written off may still be subject to enforcement activities under the Agency's recovery procedures, or by legal action where appropriate. Any recoveries made are recognised in profit or loss.

## 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.

The development of some projects at the Agency have been following an agile and iterative delivery model, with functionalities delivered in short development cycles, which resulted in the capitalisation of internally generated computer software in value of € 9.32 million.

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 01.01.2021</b>	<b>103,134,149.86</b>	<b>10,910,129.73</b>	<b>43,627,236.24</b>	<b>157,671,515.83</b>
Additions	-	374,376.32	21,824,369.23	<b>22,198,745.55</b>
Transfers	9,319,302.96	-	(9,319,302.96)	-
Derecognition	(1,067,498.52)	-	-	<b>(1,067,498.52)</b>
Reclassification	-	(2,333,268.08)	-	<b>(2,333,268.08)</b>
<b>Gross carrying amounts 31.12.2021</b>	<b>111,385,954.30</b>	<b>8,951,237.97</b>	<b>56,132,302.51</b>	<b>176,469,494.78</b>
<b>Accumulated amortisation and impairment 01.01.2021</b>	<b>(90,927,599.02)</b>	<b>(10,402,910.45)</b>	-	<b>(101,330,509.47)</b>
Amortisation	(8,440,097.51)	(334,360.73)	-	<b>(8,774,458.24)</b>
Derecognition	69,428.63	-	-	<b>69,428.63</b>
Reclassification	-	2,333,268.08	-	<b>2,333,268.08</b>
<b>Accumulated amortisation and impairment 31.12.2021</b>	<b>(99,298,267.90)</b>	<b>(8,404,003.10)</b>	-	<b>(107,702,271.00)</b>
<b>Net carrying amounts 31.12.2021</b>	<b>12,087,686.40</b>	<b>547,234.87</b>	<b>56,132,302.51</b>	<b>68,767,223.78</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.

Tangible assets include furniture, audio-visual and IT equipment acquired by means of donation from the Dutch Government as part of the lease agreement for the EMA's new permanent headquarters, as well as further investment in the Information Technology (IT) infrastructure and the capitalisation of leasehold improvements, i.e. enhancements to the leased space paid for by the Agency.

The table below summarises the accounting movements for the year.

<i>Amounts in EUR</i>	<b>Leasehold improvements and fittings</b>	<b>Equipment</b>	<b>Furniture</b>	<b>Computer hardware</b>	<b>Total</b>
<b>Gross carrying amounts 01.01.2021</b>	<b>11,129,567.43</b>	<b>4,252,858.01</b>	<b>5,788,023.62</b>	<b>8,579,975.65</b>	<b>29,750,424.71</b>
Additions	9,015.36	17,280.00	621,485.53	2,809,707.55	<b>3,457,488.44</b>
Disposals	-	-	-	(348,537.78)	<b>(348,537.78)</b>
<b>Gross carrying amounts 31.12.2021</b>	<b>11,138,582.79</b>	<b>4,270,138.01</b>	<b>6,409,509.15</b>	<b>11,041,145.42</b>	<b>32,859,375.37</b>
<b>Accumulated depreciation and impairment 01.01.2021</b>	<b>(632,391.86)</b>	<b>(1,072,192.54)</b>	<b>(690,728.58)</b>	<b>(5,572,507.36)</b>	<b>(7,967,820.34)</b>
Depreciation	(632,767.49)	(1,054,085.31)	(633,887.23)	(1,999,364.35)	<b>(4,320,104.38)</b>
Disposals	-	-	-	348,537.78	<b>348,537.78</b>
<b>Accumulated depreciation and impairment 31.12.2021</b>	<b>(1,265,159.35)</b>	<b>(2,126,277.85)</b>	<b>(1,324,615.81)</b>	<b>(7,223,333.93)</b>	<b>(11,939,386.94)</b>
<b>Net carrying amounts 31.12.2021</b>	<b>9,873,423.44</b>	<b>2,143,860.16</b>	<b>5,084,893.34</b>	<b>3,817,811.49</b>	<b>20,919,988.43</b>

### 4.1.3. Financial assets

This item relates to € 18.20 million of Agency's cash held in an escrow account and which use is restricted to the fulfilment of potential liabilities for subtenant incentives that might arise in respect to the sublease agreement for the former office premises at 30 Churchill Place, London, of which € 4.05 are due within one year. In respect of property-related obligations, please refer also to note 3.1.3 on key sources of estimation uncertainty and significant judgements and note 4.8 on other significant disclosures, dealing with operating leases and contingent liabilities.

### 4.1.4. Deferred expenditure

This item relates to the lease incentive offered by the Agency to the subtenant as part of the sublease of the former office premises at 30 Churchill Place, London, released against annual rents received from the subtenant over the life of the sublease (20 years). The net carrying amount of lease incentives not yet released as expenditure at 31 December 2021 amounts to € 46.94 million.

#### **30 Churchill Place, London**

<i>Amounts in EUR</i>	<b>Gross carrying amount 01.01.2021</b>	<b>Additions / Adjustments</b>	<b>Gross carrying amount 31.12.2021</b>	<b>Accumulated expense release 01.01.2021</b>	<b>Release for the year</b>	<b>Accumulated release 31.12.2021</b>	<b>Net carrying amount 31.12.2021</b>
Rent free period	6,348,873.63	-	6,348,873.63	476,165.52	317,443.68	793,609.20	5,555,264.43
Sub-tenant incentive	15,983,943.35	27,787,774.64	43,771,717.98	799,197.17	1,580,330.17	2,379,527.33	41,392,190.65
<b>Total</b>	<b>22,332,816.98</b>	<b>27,787,774.64</b>	<b>50,120,591.61</b>	<b>1,275,362.69</b>	<b>1,897,773.85</b>	<b>3,173,136.54</b>	<b>46,947,455.08</b>
					<i>of which due within one year</i>		<i>2,579,155.30</i>

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

## **4.2. Current assets**

### **4.2.1. Receivables from exchange transactions**

This item includes € 48.34 million of fees invoiced to marketing authorisation holders and applicants remaining open at 31 December 2021 and other miscellaneous exchange receivables for € 208 thousand. Included in the amount is € 2.64 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 Agency has applied the impairment requirements of the revised EAR 11 to its short-term exchange receivables, determining the expected credit losses by using a provision matrix, based on historical credit loss experience and on the past due status of the debtors, adjusted as appropriate to reflect current conditions and estimates of future economic conditions.

The provision for short-term receivables of doubtful collection at 31 December 2021 amounts to € 267 thousand, i.e. the balance at 01 January 2021 (€ 296 thousand) less debts recovered during 2021 (€ 186 thousand) increased by the new loss allowance for 2021 (€ 157 thousand) and it is presented in the balance sheet together with the provision referred to in note 4.2.2.

Other exchange receivable amounts at 31 December 2021 are immaterial and the Agency has not recognised any loss allowance, on the basis of undue effort.

Analysis of the age and impairment of exchange receivables is disclosed in note 4.9.1.

### **4.2.2. Recoverable from member states and the UK**

This header includes € 2.7 million of financial incentive granted by the Dutch Government remaining to be received as a reduction of the overall annual rent amount over the 20 years duration of the lease, as outlined in note 4.3.1 on deferred revenue.

The protocol agreement between the Agency and the Netherlands (NL) provides that the Agency pays value added tax (Belasting Toegevoegde Waarde or BTW) on goods and services invoiced by NL registered entities and by entities registered with the VAT MOSS scheme and subsequently reclaims the amounts. The amount of BTW recoverable from the Dutch authority as at 31 December 2021 amounts at € 3 thousand.

€ 2.035 million of VAT on goods and services invoiced by UK registered entities reclaimed from the UK Foreign Commonwealth and Development Office (FCDO), which was past due as at 31 December 2021 has been partly recovered in the first quarter of 2022. The provision at year end has been adjusted to reflect the € 1.02 million VAT remaining past due at the date these accounts are issued.

### **4.2.3. 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.

#### 4.2.4. Prepaid expenses

This item includes:

<i>Amounts in EUR</i>	<b>31.12.2021</b>	<b>31.12.2020</b>
Rent and service charges EMA head-lease, London	4,010,114.88	3,759,576.19
Prepaid expenditure for evaluation services	3,486,698.43	3,624,379.95
Other prepaid expenditure	4,712,159.78	3,496,962.04
<b>Total</b>	<b>12,208,973.09</b>	<b>10,880,918.18</b>

#### 4.2.5. Cash and cash equivalents

Cash and cash equivalents balances comprise the following:

<i>Amounts in EUR</i>	<b>31.12.2021</b>	<b>31.12.2020</b>
EUR account ABN AMRO NL	5,311,387.01	8,976,752.80
EUR account ING Bank	101,776,482.45	36,664,393.54
EUR account ING Bank	9,974,402.16	29,982,157.50
GBP account ABN AMRO NL	1,596,574.70	1,519,301.61
GBP account ABN AMRO UK	1,036,608.46	-
<b>Total</b>	<b>119,695,454.78</b>	<b>77,142,605.45</b>

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

The risk analysis for this financial instrument is disclosed in note 4.9.1.

### 4.3. Non-current liabilities

#### 4.3.1. Deferred revenue

This item comprises the following:

##### ***Lease incentives for office premises at Domenico Scarlattilaan 6, Amsterdam, The Netherlands***

<b><u>Domenico Scarlattilaan 6, Amsterdam</u></b>	<b>Gross carrying amount 01.01.2021</b>	<b>Additions / Adjustments</b>	<b>Gross carrying amount 31.12.2021</b>	<b>Accumulated release 01.01.2021</b>	<b>Release for the year</b>	<b>Accumulated release 31.12.2021</b>	<b>Net carrying amount 31.12.2021</b>
<i>Amounts in EUR</i>							
Rent free period	3,170,662.00	-	3,170,662.00	158,533.10	158,533.10	317,066.20	2,853,595.80
Landlord incentive (rent)	3,000,000.00	-	3,000,000.00	150,000.00	150,000.00	300,000.00	2,700,000.00
Landlord inducement (enhancements)	14,918,703.57		14,918,703.57	1,233,261.29	1,233,261.29	2,466,522.58	12,452,180.99
<b>Total</b>	<b>21,089,365.57</b>	<b>-</b>	<b>21,089,365.57</b>	<b>1,541,794.39</b>	<b>1,541,794.39</b>	<b>3,083,588.78</b>	<b>18,005,776.79</b>
					<i>of which due within one year</i>		<i>1,541,794.39</i>

In accordance with the Dutch offer bid of 28 July 2017, the Dutch Government has granted the Agency an amount of € 18,000,000 as a financial incentive. The Agency has decided to use € 3 million as a

reduction of the overall annual rent amount as from January 2020 released against annual rents over the life of the lease (20 years) and € 15 million as a cash contribution for the enhancements to the leased space. In addition, the Dutch government has offered temporary premises to EMA, the Spark building in the Sloterdijk area of Amsterdam, from 1 January 2019 until 31 December 2019, which is also treated as a lease incentive and amounts to € 3.17 million. The net carrying amount of lease incentives not yet released as revenue at 31 December 2021 amounts to € 18.00 million.

#### **Lease incentives for former office premises at 30 Churchill Place, Canary Wharf London, UK**

Lease incentives received by the Agency in 2014 consisted of a cash contribution of € 46.00 million corresponding to 37 months of rent free period, released against annual rents paid to the landlord over the life of the lease (25 years); a cash contribution of € 14.00 million for 'Category A' fit out which has been released in line with the depreciation of the fit out costs (4 years) and a rent free period, corresponding to € 9.00 million. The net carrying amount of lease incentives not yet released as revenue at 31 December 2021 amount to € 38.59 million.

##### **30 Churchill Place, London**

<i>Amounts in EUR</i>	Gross carrying amount 01.01.2021	Additions	Gross carrying amount 31.12.2021	Accumulated release 01.01.2021	Release for the year	Accumulated release 31.12.2021	Net carrying amount 31.12.2021
Rent free period	9,065,559.00	-	9,065,559.00	2,357,045.16	362,622.36	2,719,667.52	6,345,891.48
Landlord inducement	59,984,695.72	-	59,984,695.72	25,897,535.20	1,842,253.26	27,739,788.46	32,244,907.26
<b>Total</b>	<b>69,050,254.72</b>	-	<b>69,050,254.72</b>	<b>28,254,580.36</b>	<b>2,204,875.62</b>	<b>30,459,455.98</b>	<b>38,590,798.74</b>
					<i>of which due within one year</i>		<i>2,204,875.62</i>

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

## **4.4. Current liabilities**

### **4.4.1. Payables under exchange transactions**

Current payables represent amounts accrued for goods and services due at 31 December 2021 for a total of € 66.00 million. It also includes accrued charges of € 8.34 million for employees accumulated compensated absences (untaken leave).

<i>Amounts in EUR</i>	<b>31.12.2021</b>	<b>31.12.2020</b>
Accounts payable and accrued charges	18,064,412.87	15,450,021.76
Accrued expenditure for evaluation services	39,168,936.63	37,360,408.85
Accrued charges for untaken leave and other staff payables	8,854,404.47	8,193,777.42
<b>Total</b>	<b>66,087,753.97</b>	<b>61,004,208.03</b>

The risk analysis for this financial instrument is disclosed in note 4.9.2.

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

This item consists of the balance remaining open at the end of the financial year 2021 to be reimbursed to the European Commission.

In compliance with Article 17 of the Agency's Financial Regulation, if the budget result is positive, it shall be repaid to the Commission up to the amount of the contribution paid during the year.

If the budget result is negative, it shall be entered in the budget of the Agency for the following financial year as payment appropriations or, where appropriate, offset against positive budget result of the Agency in the following financial years.

The amount of contribution received from the Commission in 2021 is provided at note 4.5.2.

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

#### **4.4.3. Other prefinancing from EU entities**

Included under this header is the prefinancing received from the European Commission (DGNEAR) in relation to the IPA programme.

#### **4.4.4. Payables with member states and the UK**

Included under this header is the balance of value added tax (VAT) due to the UK tax authority as at 31.12.2021 and payable in 2022.

#### **4.4.5. 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.

#### **4.4.6. Other deferred income**

This item relates to the amount invoiced to the subtenant for the rental payment for the first quarter 2022 of the premises at 30 Churchill Place, London.

### **4.5. Operating revenue**

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

<i>Amounts in EUR</i>	<b>2021</b>	<b>2020</b>
Fees for initial applications	28,508,600.21	27,488,792.51
Annual fees	107,057,217.74	100,500,693.74
Other fees mainly post authorization variations	166,801,871.01	155,676,331.23
Fees for Pharmacovigilance activities	26,901,567.81	27,405,660.00
Processing Parallel Distribution notifications	10,067,685.83	11,322,720.00
Processing Export Certificates	4,219,050.00	4,072,650.00
Other administrative fees	1,249,280.00	1,904,480.00
<b>Total</b>	<b>344,805,272.60</b>	<b>328,371,327.48</b>

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 regards 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 63 of the Agency's Financial Regulation.

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

This item comprises:

<i>Amounts in EUR</i>	<b>2021</b>	<b>2020</b>
European Commission general subsidy	25,449,575.00	33,703,605.00
EU orphan medicinal products contribution	12,187,155.00	11,374,395.00
Balance of budget outturn from previous years	-	13,802,754.48
Balance of budget outturn 2021	(24,982,180.86)	(12,651,435.24)
<b>Total</b>	<b>12,654,549.14</b>	<b>46,229,319.24</b>

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 2021 the such contribution amounted to € 12.19 million of revenue for orphan medicinal products.

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

#### 4.5.3. Revenue from landlord incentives

This item comprises € 3.55 million of recognized revenue related to the incentives received from the Dutch government and the landlord incentive received as part of the contractual arrangements for the premises at 30 Churchill Place, London, as outlined more in details in note 4.3.1 on deferred revenue.

#### 4.5.4. Sundry revenue

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

#### 4.5.5. Reversal of previous years provision

This item relates to the reversal of the provision for doubtful debts of previous years following the recovery of debts during the 2021.

#### 4.5.6. Revenue from subletting

This item includes revenue earned in relation to the subletting of the Agency's former office premises at 30 Churchill Place, London.

### 4.6. Operating expenditure

#### 4.6.1. Staff expenses

As at 31 December 2021, the Agency's headcount included a total of 644 temporary agents, 206 contract agents, 28 national experts on secondment, 100 interims and 38 trainees (2020: 596, 197, 32, 25 and 31). Compared to 2020, the total headcount had increased by 15% from 881 to 1016.

Such increase is reflected in the staff expenses, amounting to € 121.31 million at 31 December 2021 (2020: € 110.8 million). The header includes also the estimated cost for employee accumulated compensated absences (untaken leave) at year-end, referred to in note 4.4.1.

The annual update of the basic salary was 1.9%, the Netherlands salary weighting coefficient decreased from 113.9% to 111.4%, resulting in a net decrease of 0.35%. The employee's pension contribution remains unchanged at 10.1% of the basic salary.

#### 4.6.2. Administrative expenditure

This item comprises:

<i>Amounts in EUR</i>	<b>2021</b>	<b>2020</b>
Rent for EMA head-lease, Amsterdam	10,657,286.00	10,448,320.00
Service charges and building occupancy costs EMA head-lease, Amsterdam	4,517,074.82	6,264,615.43
Rent for EMA head-lease, London	15,504,506.24	15,252,907.57
Service charges and other building occupancy costs EMA head-lease, London	4,034,990.93	4,685,501.06
Maintenance and support of applications, IT consultancy corporate processes	23,153,685.04	25,469,150.77
Business consultancy and audit services	2,430,885.91	1,854,983.70
Information and communication services and other administrative expenditure	1,821,226.82	1,954,147.01
<b>Total</b>	<b>62,119,655.76</b>	<b>65,929,625.54</b>

The decrease in building occupancy costs, e.g. restaurant and catering costs, is mainly due to Agency's staff working remotely during the pandemic.

### 4.6.3. Operating expenditure

This item comprises:

<i>Amounts in EUR</i>	<b>2021</b>	<b>2020</b>
Share of evaluation and annual fees to NCAs	128,408,958.36	122,181,919.63
Share of evaluation of pharmacovigilance procedures fees to NCAs	12,097,660.52	12,233,646.30
Reimbursement of delegates attending meetings	143,102.46	1,072,252.16
Translations	4,745,452.86	5,294,294.69
Business IT development	6,413,023.91	-
Scientific studies and services	5,183,062.00	4,192,206.59
Data management	1,252,911.97	-
<b>Total</b>	<b>158,244,172.08</b>	<b>144,974,319.37</b>

Since the start of the pandemic in March 2020, all Agency's meetings have been held virtually. As a result, there has been a significant decrease in reimbursement of delegates attending meetings compared to the previous years.

Business IT development expenditures relates to costs incurred during the research phase of the project, for example preparatory work linked to IT aspects of the Agency's extended mandate, or to software development costs which are expensed because falling below the Agency's threshold of € 1,000,000 for capitalisation of internally generated intangible asset. Refer to note 4.1.1. for the intangible asset movements of the year.

Additional budget was allocated by the Agency for the provision of scientific studies and services, more specifically studies of benefit/risk assessments, efficacy of innovative clinical trials and the COVID-19 pandemic response.

Data management is a newly created budget item in 2021. It relates to cost incurred for the data quality management of the four SPOR data management services (substances, products, organisations and referentials) provided by EMA to power EU regulatory activities. Previously these costs were budgeted under the header Scientific studies and services and related to Eudravigilance data only.

### 4.6.4. Other adjustments

This item includes the provision for debts of doubtful collection for the year referred to note 4.2.1.

## 4.7. Non-operating activities

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

<i>Amounts in EUR</i>	<b>2021</b>	<b>2020</b>
Bank interest income	3,038.78	5,048.02
Bank negative interest and transactional charges	(488,761.51)	(205,347.70)
Exchange gain (loss) on hedged amounts and other non-Euro currency transactions	2,929,744.25	(682,919.50)
<b>Total</b>	<b>2,444,021.52</b>	<b>(883,219.18)</b>

Cash balances deposited in banks incurred negative interest for € 479 thousand due to the unfavourable current market conditions.

The exchange gain differences relate to the realised exchange differences for currency purchases and payments made in pound sterling and the revaluation at the closing date 31 December 2021 of the financial assets and liabilities held by the Agency in pound sterling and other exchange differences on salaries paid in currencies other than euro.

## **4.8. Other significant disclosures**

### **4.8.1. Operating leases**

#### ***EMA operating lease for office premises at Domenico Scarlattilaan 6, Amsterdam, The Netherlands***

On 15 November 2019 the Agency entered into a 20 years rental contract with the Dutch Government for the office premises at Domenico Scarlattilaan 6, Amsterdam 1083 HN.

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

<i>Amounts in EUR</i>	<b>Domenico Scarlattilaan 6, Amsterdam - Lease payments</b>			<b>Total</b>
	<b>&lt;1 year</b>	<b>1-5 years</b>	<b>&gt; 5 years</b>	
Rent	9,511,628.11	50,488,872.58	143,665,451.68	203,665,952.37
Building service charge	1,358,804.02	7,212,696.08	20,523,635.95	29,095,136.05
<b>Total</b>	<b>10,870,432.13</b>	<b>57,701,568.66</b>	<b>164,189,087.63</b>	<b>232,761,088.42</b>

As part of the lease of the office premises, the Agency has received a cash incentive by the Dutch Government for € 18.00 million of which € 3.00 million will be offset against the yearly rental payments over the duration of the lease term. Additional information is provided in note 4.3.1. on deferred revenue.

#### ***EMA operating lease for former office premises at 30 Churchill Place, London, UK***

On 1<sup>st</sup> July 2014 the Agency entered into a 25 years rental contract with its Canary Wharf landlords for the office premises at 30 Churchill Place, London E14 5EU.

EMA relocated to Amsterdam in March 2019 as a consequence of the outcome of the United Kingdom referendum on its EU membership.

The lease on its Canary Wharf premises runs until 2039 and does not contain a break clause, but the premises can be sublet or assigned subject to the landlord's consent.

On 2<sup>nd</sup> July 2019 the Agency reached an agreement with its landlord over its premises at 30 Churchill Place, London, in accordance with the discussions held with the EU budgetary authorities and it has sublet its premises at 30 Churchill Place to a subtenant under conditions that are consistent with the ones of the headlease, including the sublease term that extends until the expiry of EMA's headlease in June 2039.

The schedule for the estimated future payments to the Canary Wharf landlords in relation to this non-cancellable operating lease is as follows:

<i>Amounts in EUR</i>	<b>30 Churchill Place, London - Lease payments</b>			<b>Total</b>
	<b>&lt;1 year</b>	<b>1-5 years</b>	<b>&gt; 5 years</b>	
Rent	16,184,056.50	85,974,047.94	202,721,879.02	304,879,983.46
Building service charge	2,859,542.06	14,297,710.29	32,884,733.66	50,041,986.00
Estate service charge	1,215,475.79	6,077,378.97	13,977,971.63	21,270,826.39
Landlord insurance	401,559.00	2,007,795.02	4,617,928.55	7,027,282.57
<b>Total</b>	<b>20,660,633.36</b>	<b>108,356,932.21</b>	<b>254,202,512.85</b>	<b>383,220,078.43</b>

An equal amount of payments is expected to be received by the subtenant under the non-cancellable sublease.

As outlined in note 4.3.1, in 2014 the Agency has received a lease incentive from its Canary Wharf landlords consisting of a rent-free period and a cash contribution. The net carrying amount of such incentives not yet released as revenue at 31 December 2021 is € 6.34 million for the rent-free period and € 32.24 million for the cash incentive.

Likewise, as outlined in notes 4.1.3 and 4.1.4, the Agency has offered a lease incentive to its subtenant consisting of five months rent-free period corresponding to € 6.34 million and a cash contribution for € 55.68 million, of which € 43.77 million have been paid up to end of January 2022 and €14.15 are held in an escrow account, to be released upon the satisfaction of certain payment conditions.

#### **4.8.2. Contingent assets and liabilities**

The total amounts payable and receivable under the headlease and sublease contracts for the EMA former office premises at 30 Churchill Place, London are disclosed in note 4.8.1 on operating leases.

Potential costs deriving from the sublease agreement relate to the remaining incentive amount to be released to the subtenant, upon the satisfaction of certain payment conditions and estimated at €14.15 million at closing 2021.

In addition, since EMA remains a party to the headlease with its Canary Wharf landlords, should the subtenant not be able to meet its obligations, the Agency could be exposed for all the amounts remaining payable under the headlease contractual obligations, as disclosed in note 4.8.1 on operating leases and including the reinstatement of the Agency's obligation for restoring the premises at 30 Churchill Place, London to their original state. Based on the information available at the date these accounts are issued the dilapidation amount cannot be reliably estimated.

At the date these accounts are issued, the subtenant has met its contractual obligations and management is of the opinion that the subtenant will continue to do so in foreseeable future.

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 at the reporting date is € 25.48 million, equivalent to the budgetary carry over or RAL i.e. "Reste a liquider", representing the open commitments as at 31 December 2021 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 € 1.22 million.

## **4.9. Financial assets and financial liabilities risk analysis**

The revised 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 i.e. financial assets measured at amortised 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 three banks.

The Agency's budget is drawn up and implemented in euro and the accounts are presented in euro. The fees and charges related to marketing authorisation are received in euro. The total amounts paid and received under the headlease and sublease contracts for the premises at 30 Churchill Place, London and the deposit held in the Escrow account are in pound sterling.

Receivables are carried at original invoice amount less write-down for impairment i.e. financial assets measured at amortised cost. The amount of the write-down is the difference between the asset's carrying amount and the recoverable amount.

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

### **4.9.1. Credit risk**

#### **Credit quality of financial assets (credit rating)**

Counterparties with external credit rating correspond to the cash and cash equivalents balances referred to in note 4.2.5 and the financial assets referred to in note 4.1.3.

Amounts in EUR

Cash and cash equivalent

Other financial assets

## 2021

Counterparties **with** external credit rating :

Prime and high grade	119,695,454.78	18,201,065.67
Upper medium grade		
Lower medium grade		
Non-investment grade		

### Analysis of the age and impairment of exchange receivables

Receivables (gross carrying amount) includes items referred to in note 4.2.1 (€ 48.55) and the accrued marketing authorisation fees at note 4.2.3 (€ 54.74).

Regarding the recoverability of receivables from pharmaceutical companies, there has been no significant reductions in collection due to customers experiencing financial or cash flow difficulties as a result of the current pandemic.

There are no lease receivables at 31 December 2021.

Amounts in EUR

31.12.2021	Receivables gross carrying amount	Impairment (-)	Net receivables
Not past due	100,257,990.59	-	100,257,990.59
Past due 0-30 days	2,007,396.37	-	2,007,396.37
Past due 31-90 days	572,460.77	-	572,460.77
Past due 91 days - 1 year	200,177.78	(24,854.96)	175,322.82
Past due > 1 year	256,247.88	(242,508.93)	13,738.95
<b>Total</b>	<b>103,294,273.39</b>	<b>(267,363.89)</b>	<b>103,026,909.50</b>

### Recoverables outside the scope of EAR 11

As a consequence of its relocation, the Agency had to register for UK VAT with Her Majesty Revenue & Customs (HMRC) and started managing its UK VAT affairs as an overseas 'ordinary' taxpayer, as opposed to reclaiming UK VAT from the UK Foreign Commonwealth and Development Office (FCDO).

As outlined in note 4.2.2, € 2.035 million of VAT on goods and services invoiced by UK registered entities reclaimed from the FCDO, which was past due as at 31 December 2021 has been partly recovered in the first quarter of 2022. The provision at year end has been adjusted to reflect the € 1.02 million VAT remaining past due at the date these accounts are issued. The Agency is proactively engaging with the UK FCDO to recuperate the outstanding amounts.

### 4.9.2. Liquidity risk

The Agency does not hold any derivative financial liabilities. The table below presents the maturity analysis for non-derivative financial liabilities in relation to the remaining contractual maturities.

These are the current payables with third parties, i.e. suppliers and related accrued charges and payables with EU entities.

<i>Amounts in EUR</i>	<b>31.12.2021</b>	<b>&lt;1 year</b>	<b>1-5 years</b>	<b>&gt; 5 years</b>
Payables with EU entities	25,303,856.10	-	-	-
Other payables with third parties	66,370,316.70	-	-	-

### **4.9.3. Market risk**

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 2021.

Asset and liabilities in pounds sterling at the end of the reporting period are converted into euro on the basis of the exchange rate applying on 31 December 2021. 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.

*Amounts in EUR*

<b>31.12.2021</b>	<b>GBP EUR equivalent</b>	<b>EUR</b>	<b>Total EUR</b>
<b>Financial assets</b>	<b>20,834,248.83</b>	<b>220,089,181.12</b>	<b>240,923,429.95</b>
Receivables excluding receivables with EU entities		103,026,909.50	103,026,909.50
Cash and cash equivalent	2,633,183.16	117,062,271.62	119,695,454.78
Other financial assets	18,201,065.67		18,201,065.67
<b>Financial liabilities</b>	<b>359,953.33</b>	<b>91,314,219.47</b>	<b>91,674,172.80</b>
Payables with third parties	359,953.33	66,010,363.37	66,370,316.70
Payables with EU entities		25,303,856.10	25,303,856.10
<b>Net position</b>	<b>20,474,295.50</b>	<b>128,774,961.65</b>	<b>149,249,257.15</b>

A sensitivity analysis is required in compliance with paragraph 269 of EAR 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.

Financial assets include € 20.83 million of pound sterling denominated cash and cash equivalent and the restricted cash held in the escrow account. 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 € 2 million. 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. 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.

Highest grade description	Grade	Number of persons of this grade as at 31.12.2021
Executive Director	AD14	1
Executive Board Member	AD13	3
Executive Board Member	AD12	5

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***

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

As outlined in note 4.2.2 and noted 4.9.1, the provision for past due claims of VAT on goods and services invoiced by UK registered entities has been adjusted to reflect the € 1.02 million VAT remaining past due at the date these accounts are issued, following the partial recovery made in the first quarter of 2022.

COVID-19 may affect the recognition and measurement of some assets and liabilities on the balance sheet and of some revenue and expenses recognised in the statement of financial performance. Based on the facts and circumstances at the time of preparation of these financial statements, the financial effect of the pandemic cannot be reliably estimated.

Following the legal assessment of the EU Court judgement of 11 November 2021, C-948/19 Manpower Lit (equal treatment of temporary agency workers) the Agency's management has concluded that there is no impact on EMA's existing framework contract for provision of interim workers.

In accordance with EU accounting rule 19 on events after reporting date, the war in Ukraine - that began in February 2022 - is a non-adjusting event, thus not requiring any adjustments to the figures reported in these financial statements as at 31 December 2021. For subsequent reporting periods, the war may affect the recognition and measurement of some assets and liabilities on the balance sheet and also of some revenue and expenses recognised in the statement of financial performance. Based on the facts and circumstances at the time of preparation of these financial statements, in particular the evolving situation, the financial effect of the war in Ukraine on the cannot be reliably estimated.

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

## 5. Budget implementation reports

### ***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 its draft single programming document, as endorsed by its Management Board, containing, amongst others, an estimate of its revenue and expenditure.

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 34 of the Agency's Financial Regulation.

The budget of the Agency shall contain the following:

- non-differentiated appropriations;
- where justified by operational needs, differentiated appropriations, which consist of commitment appropriations and payment appropriations.

The appropriations authorised for the financial year shall consist of:

- appropriations consisting of the annual contribution granted by the Union;
- appropriations arising from own revenue consisting of all fees and charges which the Union body is authorised to collect by virtue of the tasks entrusted to it, and any other revenue;
- appropriations consisting of any financial contributions from the host Member States;
- appropriations provided following the receipt of revenue assigned during the financial year to specific items of expenditure in accordance with Article 20(1);
- appropriations carried over from the preceding financial years.

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, 2021

Amounts in EUR

		2021 Final	2020 Final
<b>REVENUE</b>			
Balancing Commission subsidy		37,636,730.00	58,880,754.48
Fees and charges related to marketing authorisations		341,638,051.87	316,888,818.51
Other income	28,327,448.07	<del>28,327,445.07</del>	27,937,888.86
<b>TOTAL REVENUE (a)</b>	<b>407,602,229.94</b>	<b>407,602,226.94</b>	<b>403,707,461.85</b>
<b>EXPENDITURE</b>			
<b>Title 1 - Staff expenditure</b>			
Payments		118,266,220.79	109,341,590.49
Carry over		7,269,429.51	5,321,084.19
<b>Sub-total</b>		<b>125,535,650.30</b>	<b>114,662,674.68</b>
<b>Title 2 - Administrative expenditure</b>			
Payments		56,527,128.71	98,291,424.51
Carry over		16,651,746.95	17,174,947.27
<b>Sub-total</b>		<b>73,178,875.66</b>	<b>115,466,371.78</b>
<b>Title 3 - Operating Expenditure</b>			
Payments		119,985,581.58	115,038,769.34
Carry over		72,518,760.98	53,087,186.15
<b>Sub-total</b>		<b>192,504,342.56</b>	<b>168,125,955.49</b>
<b>Total Payments</b>		<b>294,778,931.08</b>	<b>322,671,784.34</b>
<b>Total Carry Over</b>		<b>96,439,937.44</b>	<b>75,583,217.61</b>
<b>TOTAL EXPENDITURE (b)</b>		<b>391,218,868.52</b>	<b>398,255,001.95</b>
<b>OUTTURN FOR THE FINANCIAL YEAR (a-b)</b>	<b>16,383,361.42</b>	<b>16,383,358.42</b>	<b>5,452,459.90</b>
Appropriation from previous year which lapses		5,372,131.21	2,423,908.71
Adjustment for carry-over from the previous year of appropriations available at 31.12 arising from assigned revenue		282,281.55	5,360,330.71
Exchange differences for the year (gain +/-loss -)		2,944,406.68	(585,264.08)
<b>BALANCE OF THE OUTTURN ACCOUNT FOR THE FINANCIAL YEAR</b>	<b>24,982,180.86</b>	<b>24,982,177.86</b>	<b>12,651,435.24</b>
Balance year N-1		4,368,320.96	(8,283,114.28)
Positive balance from year N-1 reimbursed in year N to the Commission		(4,368,320.96)	-
<b>Balance remaining open to be reimbursed to the Commission in year n+1</b>	<b>24,982,180.86</b>	<b>24,982,177.86</b>	<b>4,368,320.96</b>

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

<i>Amounts in EUR</i>	<b>2021 Final</b>
<b>Economic result (a)</b>	<b>27,384,699.59</b>
<b>Adjustments for accrual items (not in budget result)</b>	
Adjustments for expenditure accrual cut-off (reversal 31.12.2020)	(54,136,307.02)
Adjustments for expenditure accrual cut-off (31.12.2021)	57,787,244.86
Payments made from payment appropriations carried over from previous year	69,928,804.85
Depreciation of intangible and tangible assets	13,094,562.62
Value reductions	998,069.89
Provisions	(1,070,814.96)
New prefinancing received in year 2021 and remaining open as at 31.12.2021	24,982,180.86
Recovery orders issued in 2021 not cashed at 31.12.2021	(47,384,536.63)
Adjustments for revenue accrual cut-off (reversal 31.12.2020)	21,020,558.01
Adjustments for revenue accrual cut-off (31.12.2021)	(21,455,994.81)
Other revenue accrual movements not included in the budget result	(521,163.36)
<b>Total accrual items adjustment (b)</b>	<b>63,242,604.31</b>
<b>Adjustments for budgetary items (not in economic result)</b>	
Fixed asset acquisitions (less unpaid amounts)	(25,656,233.99)
Recovery orders issued before year 2021 and cashed in year 2021	50,796,635.63
Payment appropriations carried over to 2022	(96,439,937.44)
Cancellation of unused carry overs payment appropriations from previous year	5,372,131.21
Adjustment for carry-over from the previous year of appropriations available at 31.12 arising from assigned revenue	282,281.55
<b>Total budgetary items adjustment (c)</b>	<b>(65,645,123.04)</b>
<b>Budgetary result (a+b+c)</b>	<b>24,982,180.86</b>
<i>Amount of exchange rate differences included in the budgetary result</i>	<i>2,929,744.25</i>



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

In 2021 the Agency had a positive budgetary result for € 24.98 million, to be reimbursed to the Commission in 2022.

The budget result consists of the difference between all the revenue collected in respect of that financial year (€407.60 million) and the amount of payments made against appropriations for that financial year (€ 294.78 million) increased by the amount of the appropriations for the same financial year carried over to the following year (€ 96.44 million).

Such difference is increased on the one hand, by the net amount of appropriations carried over from previous financial years which have been cancelled (€ 5.37 million) and the adjustment for carry-over from the previous year of appropriations available at 31 December arising from assigned revenue (€ 282 thousand) 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 (€ 2.94 million).

### **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;
- 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;
- cancellation of unused appropriations carried over from the previous year.

### 5.3. Implementation of the 2021 budget

In the initial adopted budget, adopted by the EMA management board on 17 December 2020, the amount of appropriations was € 385.92 million.

The revenue and expenditure estimates in the initial budget are typically adjusted during the budgetary year, such modification presented in Amending Budgets.

During 2021 one amending budget and eleven transfers were adopted, resulting in a final adopted budget of € 379.23.

#### Revenue

<i>Amounts in EUR</i>	<b>Initial adopted budget</b>	<b>Amending budgets and transfers</b>	<b>Final adopted budget</b>	<b>% over total final adopted budget</b>
EC subsidy	55,448,000.00	(17,811,000.00)	37,637,000.00	9.92%
Fees	330,409,000.00	8,522,000.00	338,931,000.00	89.37%
Other revenue	62,000.00	2,598,000.00	2,660,000.00	0.70%
<b>Total</b>	<b>385,919,000.00</b>	<b>(6,691,000.00)</b>	<b>379,228,000.00</b>	

#### Expenditure

<i>Amounts in EUR</i>	<b>Initial adopted budget</b>	<b>Amending budgets and transfers</b>	<b>Final adopted budget</b>	<b>Automatic carry over from 2020</b>
I - Staff	128,126,000.00	1,489,000.00	129,615,000.00	5,292,521.64
II - Administrative	56,175,000.00	(1,958,000.00)	54,217,000.00	17,174,947.27
III - Operating	176,226,000.00	19,170,000.00	195,396,000.00	52,833,467.15
IX - Provisional	25,392,000.00	(25,392,000.00)	-	-
<b>Total</b>	<b>385,919,000.00</b>	<b>(6,691,000.00)</b>	<b>379,228,000.00</b>	<b>75,300,936.06</b>

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

The Agency has collected revenue for € 407.60 million.

Fees paid by the pharmaceutical industry for services provided were € 341.64 million corresponding to 88% of the entitlements established.

<i>Amounts in EUR</i>	<b>Total income appropriations</b>	<b>Entitlements established</b>	<b>Revenue collected</b>	<b>%</b>	<b>Outstanding</b>
EC subsidy	37,637,000.00	37,636,730.00	37,636,730.00	100%	-
Fees	338,931,000.00	390,300,619.53	341,638,051.87	88%	48,662,567.66
Other revenue	2,660,000.00	2,889,358.10	2,881,561.83	100%	7,796.27
<b>Total</b>	<b>379,228,000.00</b>	<b>430,826,707.63</b>	<b>382,156,343.70</b>		<b>48,670,363.93</b>

In addition, the Agency has collected € 25.44 million as assigned revenue, corresponding to 90% of the entitlements established.

<i>Amounts in EUR</i>	<b>Total income appropriations</b>	<b>Entitlements established</b>	<b>Revenue collected</b>	<b>%</b>	<b>Outstanding</b>
Assigned revenue	-	28,162,207.28	25,445,886.24	90%	2,716,321.04
<b>Sub-total</b>	<b>-</b>	<b>28,162,207.28</b>	<b>25,445,886.24</b>		<b>2,716,321.04</b>

Details of the implementation of the Agency income for 2021, by budget item, are provided in section 5.4.1 below.

### 5.3.2. Summary of the implementation of the current year expenditure appropriations (C1)

The Agency has issued commitments for € 365.49 million corresponding to 96.38% of the total appropriations for the current year budget. Appropriations lapsing amount at € 13.7 million.

<i>Amounts in EUR</i>	<b>Total commitment appropriations</b>	<b>Commitments made</b>	<b>%</b>	<b>Appropriations lapsing</b>	<b>%</b>
I - Staff	129,615,000.00	125,481,672.60	96.81%	4,133,327.40	3.19%
II - Administrative	54,217,000.00	47,758,404.57	88.09%	6,458,595.43	11.91%
III - Operating	195,396,000.00	192,250,623.56	98.39%	3,145,376.44	1.61%
<b>Total</b>	<b>379,228,000.00</b>	<b>365,490,700.73</b>	<b>96.38%</b>	<b>13,737,299.27</b>	<b>3.62%</b>

Payments made were € 274.40 million corresponding to 75.08% of the total commitments.

A total of € 91.09 million, corresponding to 24.92% of the total commitments made, are carried over automatically to the following year.

<i>Amounts in EUR</i>	<b>Commitments made</b>	<b>Payments made</b>	<b>%</b>	<b>Commitments carried over to next year</b>	<b>%</b>
I - Staff	125,481,672.60	118,266,220.79	94.25%	7,215,451.81	5.75%
II - Administrative	47,758,404.57	36,148,199.82	75.69%	11,610,204.75	24.31%
III - Operating	192,250,623.56	119,985,581.58	62.41%	72,265,041.98	37.59%
<b>Total</b>	<b>365,490,700.73</b>	<b>274,400,002.19</b>	<b>75.08%</b>	<b>91,090,698.54</b>	<b>24.92%</b>

Details of the implementation of the Agency current year budget for 2021, by budget item, are provided in section 5.4.2 below.

### 5.3.3. Summary of the implementation of appropriations carried over automatically (C8)

The Agency has implemented 92.87% of the appropriations carried over automatically from the previous year.

	<b>Total appropriations carried over automatically from previous year</b>	<b>Payments made</b>	<b>%</b>	<b>Appropriations lapsing</b>	<b>%</b>
<i>Amounts in EUR</i>					
I - Staff	5,292,521.64	4,223,366.31	79.80%	1,069,155.33	20.20%
II - Administrative	17,174,947.27	16,446,980.24	95.76%	727,967.03	4.24%
III - Operating	52,833,467.15	49,258,458.30	93.23%	3,575,008.85	6.77%
<b>Total</b>	<b>75,300,936.06</b>	<b>69,928,804.85</b>	<b>92.87%</b>	<b>5,372,131.21</b>	<b>7.13%</b>

Details of the implementation of the Agency carry overs for 2021, by budget item, are provided in section 5.4.3 below.

### 5.3.4. Summary of the implementation of external assigned revenue (R0) and internal assigned revenue (CL)

External assigned revenue relates to amounts received for special projects and programmes as well as to the € 3 million incentive received by the Dutch government as a reduction of the overall annual rent amount as from January 2020 released against annual rents over the life of the lease (20 years).

	<b>Total appropriations</b>	<b>Commitments made</b>	<b>%</b>	<b>Payments made</b>	<b>%</b>	<b>Appropriations carried over to next year</b>
<i>Amounts in EUR</i>						
I - Staff	53,977.70	-	0.00%	-	0.00%	53,977.70
II - Administrative	3,176,545.27	476,545.27	15.00%	476,545.27	100.00%	2,700,000.00
III - Operating	253,719.00	-	0.00%	-	0.00%	253,719.00
<b>Total</b>	<b>3,484,241.97</b>	<b>476,545.27</b>	<b>13.68%</b>	<b>476,545.27</b>		<b>3,007,696.70</b>

Internal assigned revenue relates to the payments received in relation to the subletting of the Agency's former office premises at 30 Churchill Place, London and the corresponding equal payments made to the Agency's Canary Wharf landlords.

	<b>Total appropriations</b>	<b>Commitments made</b>	<b>%</b>	<b>Payments made</b>	<b>%</b>	<b>Appropriations carried over to next year</b>
<i>Amounts in EUR</i>						
I - Staff	-	-	-	-	-	-
II - Administrative	24,943,925.82	19,902,383.62	79.79%	19,902,383.62	100.00%	5,041,542.20
III - Operating	-	-	-	-	-	-
<b>Total</b>	<b>24,943,925.82</b>	<b>19,902,383.62</b>	<b>79.79%</b>	<b>19,902,383.62</b>		<b>5,041,542.20</b>

Details of the implementation of the Agency assigned revenue for 2021 are provided in sections 5.4.4 and 5.4.5 below.

## 5.4. Details of the implementation of budget revenue 2021 and budget expenditure 2021

### 5.4.1. Income appropriations, entitlements established, and revenue collected on entitlements established

Amounts in EUR

Budget line	Title	Income appropriations		
		Initial adopted budget	Amending budgets and transfers	Final adopted budget
		1	2	3=1+2
1000	FEES COLLECTED	302,127,000.00	8,735,000.00	310,862,000.00
1001	FEES COLLECTED PHARMACOVIGILANCE	28,282,000.00	(213,000.00)	28,069,000.00
2000	EU BASIC CONTRIBUTION	41,070,000.00	(15,620,155.00)	25,449,845.00
2010	SPECIAL CONTRIBUTION FOR ORPHAN MEDICINAL PRODUCTS	14,378,000.00	(2,190,845.00)	12,187,155.00
5200	REVENUE FOR ADMINISTRATIVE ACTIVITIES AND ANCILLARY SERVICES	62,000.00	(62,000.00)	-
7000	BALANCE OF OUTTURN ACCOUNT OF PREVIOUS YEARS	-	-	-
9000	MISCELLANEOUS REVENUE	-	2,660,000.00	2,660,000.00
<b>Total CURRENT YEAR budget</b>		<b>385,919,000.00</b>	<b>(6,691,000.00)</b>	<b>379,228,000.00</b>
6000	EXTERNAL ASSIGNED REVENUE FOR PROJECTS AND PROGRAMME	-	-	-
6010	INTERNAL ASSIGNED REVENUE	-	-	-
<b>Total ASSIGNED REVENUE budget</b>		<b>-</b>	<b>-</b>	<b>-</b>
<b>Total REVENUE budget</b>		<b>385,919,000.00</b>	<b>(6,691,000.00)</b>	<b>379,228,000.00</b>

Amounts in EUR

Budget line	Title	Entitlements established			Revenue			Receipts as % of budget	Outstanding
		Current Year	Carried over	Total	On entitlements of current year	On entitlements carried over	Total		
		4	5	6=4+5	7	8	9=7+8	10=9/3	11=6-9
1000	FEES COLLECTED	318,315,861.98	42,298,875.90	360,614,737.88	273,242,107.06	41,102,052.20	314,344,159.26	101.12%	46,270,578.62
1001	FEES COLLECTED PHARMACOVIGILANCE	26,908,693.89	2,777,187.76	29,685,881.65	24,621,073.22	2,672,819.39	27,293,892.61	97.24%	2,391,989.04
2000	EU BASIC CONTRIBUTION	25,449,575.00	-	25,449,575.00	25,449,575.00	-	25,449,575.00	100.00%	-
2010	SPECIAL CONTRIBUTION FOR ORPHAN MEDICINAL PRODUCTS	12,187,155.00	-	12,187,155.00	12,187,155.00	-	12,187,155.00	100.00%	-
5200	REVENUE FOR ADMINISTRATIVE ACTIVITIES AND ANCILLARY SERVICES	3,038.78	-	3,038.78	3,038.78	-	3,038.78	N/A	-
7000	BALANCE OF OUTTURN ACCOUNT OF PREVIOUS YEARS	-	-	-	-	-	-	N/A	-
9000	MISCELLANEOUS REVENUE	2,811,691.44	74,627.88	2,886,319.32	2,804,851.44	73,671.61	2,878,523.05	108.22%	7,796.27
<b>Total CURRENT YEAR budget</b>		<b>385,676,016.09</b>	<b>45,150,691.54</b>	<b>430,826,707.63</b>	<b>338,307,800.50</b>	<b>43,848,543.20</b>	<b>382,156,343.70</b>	<b>100.77%</b>	<b>48,670,363.93</b>
6000	EXTERNAL ASSIGNED REVENUE FOR PROJECTS AND PROGRAMME	351,960.42	2,850,000.00	3,201,960.42	351,960.42	150,000.00	501,960.42	N/A	2,700,000.00
6010	INTERNAL ASSIGNED REVENUE	18,162,154.43	6,798,092.43	24,960,246.86	20,239,499.47	4,704,426.35	24,943,925.82	N/A	16,321.04
<b>Total ASSIGNED REVENUE budget</b>		<b>18,514,114.85</b>	<b>9,648,092.43</b>	<b>28,162,207.28</b>	<b>20,591,459.89</b>	<b>4,854,426.35</b>	<b>25,445,886.24</b>	<b>-</b>	<b>2,716,321.04</b>
<b>Total REVENUE budget</b>		<b>404,190,130.94</b>	<b>54,798,783.97</b>	<b>458,988,914.91</b>	<b>358,899,260.39</b>	<b>48,702,969.55</b>	<b>407,602,229.94</b>		<b>51,386,684.97</b>

## 5.4.2. Implementation of current year budget (C1)

Amounts in EUR											
Budget line	Heading	CURRENT YEAR BUDGET - C1 2021									
		Budget appropriations			Budget implementation				Carry overs and cancellations		
		Initial adopted budget	Amending budgets and transfers	Final adopted budget	Commitments made	% Committed	Payments made	% Paid	Carry-overs automatic	% Carry-overs automatic	Appropriation lapsing
		1	2	3 (1+2)	4	(4/3)	5	(5/3)	6 (4-5)	(6/4)	8 (3-4)
1100	BASIC SALARIES	52,583,000.00	(1,188,000.00)	51,395,000.00	51,206,966.35	99.63%	51,206,966.35	99.63%	-	0.00%	188,033.65
1101	FAMILY ALLOWANCES	7,351,000.00	(398,000.00)	6,953,000.00	6,613,370.30	95.12%	6,613,370.30	95.12%	-	0.00%	339,629.70
1102	EXPATRIATION AND FOREIGN RESIDENCE ALLOWANCES	9,094,000.00	(269,000.00)	8,825,000.00	8,743,457.73	99.08%	8,743,457.73	99.08%	-	0.00%	81,542.27
1103	FIXED ALLOWANCES	44,000.00	-	44,000.00	34,239.95	77.82%	34,239.95	77.82%	-	0.00%	9,760.05
1114	BASIC SALARIES AND ALLOWANCES FOR CONTRACT AGENTS	12,440,000.00	(500,000.00)	11,940,000.00	11,835,435.61	99.12%	11,835,435.61	99.12%	-	0.00%	104,564.39
1115	SECONDED NATIONAL EXPERTS AND VISITING EXPERTS	3,868,000.00	(500,000.00)	3,368,000.00	2,428,473.14	72.10%	1,112,030.14	33.02%	1,316,443.00	54.21%	939,526.86
1116	TRAINEES	450,000.00	101,000.00	551,000.00	550,647.62	99.94%	171,842.71	31.19%	378,804.91	68.79%	352.38
1130	EMPLOYER'S SOCIAL SECURITY CONTRIBUTIONS	14,316,000.00	(627,000.00)	13,689,000.00	13,688,649.26	100.00%	13,688,649.26	100.00%	-	0.00%	350.74
1140	MISCELLANEOUS ALLOWANCES AND GRANTS	58,000.00	-	58,000.00	52,218.55	90.03%	52,218.55	90.03%	-	0.00%	5,781.45
1141	TRAVEL EXPENSES FROM PLACE OF EMPLOYMENT TO PLACE OF ORIGIN	1,321,000.00	80,000.00	1,401,000.00	1,389,033.67	99.15%	1,389,033.67	99.15%	-	0.00%	11,966.33
1143	FIXED SPECIFIC ALLOWANCES	8,000.00	-	8,000.00	2,100.00	26.25%	2,100.00	26.25%	-	0.00%	5,900.00
1181	ALLOWANCES AND EXPENSES ON ENTERING / LEAVING THE SERVICE / ON TRANSFER	1,996,000.00	(249,000.00)	1,747,000.00	1,372,814.03	78.58%	1,302,840.61	74.58%	69,973.42	5.10%	374,185.97
1190	WEIGHTINGS AND EXCHANGE RATES	8,480,000.00	1,600,000.00	10,080,000.00	8,895,007.50	88.24%	8,895,007.50	88.24%	-	0.00%	1,184,992.50
1200	EXPENDITURE RELATED TO STAFF RECRUITMENT	300,000.00	(16,000.00)	284,000.00	211,242.21	74.38%	154,365.52	54.35%	56,876.69	26.92%	72,757.79
1300	DUTY TRAVEL EXPENSES AND INCIDENTAL EXPENDITURE	750,000.00	(604,000.00)	146,000.00	24,508.37	16.79%	20,373.80	13.95%	4,134.57	12.87%	1,481.63
1410	MEDICAL SERVICE	695,000.00	0.00	695,000.00	623,312.13	89.69%	459,171.43	66.07%	164,140.70	26.33%	71,687.87
1420	MISCELLANEOUS WELFARE EXPENDITURE	1,974,000.00	(619,000.00)	1,355,000.00	1,020,397.34	75.31%	922,261.72	68.06%	98,135.62	9.62%	334,602.66
1430	SOCIAL CONTACTS BETWEEN STAFF	65,000.00	-	65,000.00	2,569.72	3.95%	2,569.72	3.95%	-	0.00%	62,430.28
1500	STAFF TRAINING	770,000.00	(90,000.00)	680,000.00	648,765.01	95.41%	484,261.33	71.21%	164,503.68	25.36%	31,234.99
1601	INTERIM SERVICES	6,703,000.00	3,477,000.00	10,180,000.00	10,068,636.31	98.91%	5,127,088.77	50.36%	4,941,547.54	49.08%	111,363.69
1602	ADMINISTRATIVE ASSISTANCE FROM THE EUROPEAN UNION INSTITUTIONS	820,000.00	899,000.00	1,711,000.00	1,701,230.40	99.43%	1,701,162.40	99.43%	68.00	0.00%	9,769.60
1603	PROFESSIONAL SERVICE RELATING TO STAFF MANAGEMENT	-	15,000.00	15,000.00	14,950.00	99.67%	14,950.00	99.67%	-	0.00%	50.00
1604	CONTRIBUTIONS TO EUROPEAN SCHOOLS	3,923,000.00	377,000.00	4,300,000.00	4,299,368.82	99.99%	4,299,368.82	99.99%	-	0.00%	631.18
1700	RECEPTIONS AND EVENTS	45,000.00	-	45,000.00	2,600.00	5.78%	1,776.32	3.95%	823.68	31.68%	42,400.00
1701	OPEN ACCESS PUBLICATIONS	80,000.00	-	80,000.00	51,678.58	64.60%	31,678.58	39.60%	20,000.00	38.70%	28,321.42
2000	RENT	10,507,000.00	1,000.00	10,508,000.00	10,507,286.00	99.99%	10,507,286.00	99.99%	-	0.00%	714.00
2010	INSURANCES	456,000.00	-	456,000.00	57,307.78	12.57%	42,654.34	9.35%	14,653.44	25.57%	398,692.22
2030	MAINTENANCE AND CLEANING	1,871,000.00	(235,000.00)	1,636,000.00	1,321,052.97	80.75%	1,208,769.52	73.89%	112,283.45	8.50%	314,947.03
2040	FITTING-OUT OF PREMISES	200,000.00	592,000.00	792,000.00	759,720.15	95.92%	62,910.48	7.94%	696,809.67	91.72%	32,279.85
2050	SECURITY AND SURVEILLANCE OF BUILDINGS	1,892,000.00	(36,000.00)	1,856,000.00	1,845,777.90	99.45%	1,487,549.36	80.15%	358,228.54	19.41%	10,222.10
2090	UTILITIES AND OTHER BUILDING CHARGES	471,000.00	(47,000.00)	424,000.00	322,045.26	75.95%	251,341.43	59.28%	70,703.83	21.95%	101,954.74
2110	HARDWARE AND SOFTWARE	602,000.00	1,214,000.00	1,816,000.00	1,809,924.20	99.67%	1,298,212.51	71.49%	511,711.69	28.27%	6,075.80
2114	MAINTENANCE AND SUPPORT OF APPLICATIONS	26,180,000.00	(2,774,000.00)	23,406,000.00	22,677,472.46	96.89%	17,680,388.08	75.54%	4,997,084.38	22.04%	728,527.54
2115	IT CONSULTANCY AND DEVELOPMENT RELATED TO CORPORATE PROCESSES	2,600,000.00	524,000.00	3,124,000.00	1,781,397.06	57.02%	94,972.70	3.04%	1,686,424.36	94.67%	1,342,602.94
2203	TECHNICAL EQUIPMENT AND INSTALLATIONS	638,000.00	(43,000.00)	595,000.00	585,658.00	98.43%	584,732.72	98.27%	925.28	0.16%	9,342.00
2210	FURNITURE	10,000.00	(1,000.00)	9,000.00	2,575.45	28.62%	1,458.78	16.21%	1,116.67	43.36%	6,424.55
2300	STATIONERY AND OFFICE SUPPLIES	45,000.00	(4,000.00)	41,000.00	26,030.10	63.49%	23,039.07	56.19%	2,991.03	11.49%	14,969.90
2320	FINANCIAL CHARGES	200,000.00	425,000.00	625,000.00	493,273.81	78.92%	332,510.81	53.20%	160,763.00	32.59%	131,726.19
2330	LEGAL EXPENSES AND ASSOCIATED COSTS	3,000,000.00	(913,000.00)	2,087,000.00	127,824.43	6.12%	35,961.03	1.72%	91,863.40	71.87%	1,959,175.57
2358	BUSINESS CONTINUITY	25,000.00	-	25,000.00	-	0.00%	-	0.00%	-	0.00%	25,000.00
2359	OTHER OPERATING EXPENDITURE	620,000.00	(38,000.00)	582,000.00	378,184.04	64.98%	376,558.08	64.70%	1,625.96	0.43%	203,815.96
2400	POSTAL AND DELIVERY SERVICES	60,000.00	(6,000.00)	54,000.00	31,097.72	57.59%	27,842.36	51.56%	3,255.36	10.47%	22,902.28
2500	OTHER MEETINGS	3,000.00	-	3,000.00	-	0.00%	-	0.00%	-	0.00%	3,000.00
2501	MEMBERSHIPS WITH PROFESSIONAL BODIES AND ORGANISATIONS	317,000.00	30,000.00	347,000.00	342,247.70	98.63%	341,911.25	98.53%	336.45	0.10%	4,752.30
2600	RESTAURANT AND CATERING	1,061,000.00	(106,000.00)	955,000.00	601,622.38	63.00%	437,239.77	45.78%	164,382.61	27.32%	353,377.62
2700	INFORMATION AND COMMUNICATION SERVICES	2,567,000.00	(256,000.00)	2,311,000.00	2,027,511.14	87.73%	1,081,953.76	46.82%	945,557.38	46.64%	283,488.86
2800	BUSINESS CONSULTANCY AND AUDIT SERVICES	2,850,000.00	(285,000.00)	2,565,000.00	2,060,396.02	80.33%	270,907.77	10.56%	1,789,488.25	86.85%	504,603.98
3000	REIMBURSEMENT OF PERSONS ATTENDING MEETINGS	6,700,000.00	(6,548,000.00)	152,000.00	138,144.46	90.88%	133,612.46	87.90%	4,532.00	3.28%	13,855.54
3003	OTHER EXPENDITURE IN RELATION TO MEETINGS	300,000.00	(294,000.00)	6,000.00	5,250.00	87.50%	-	0.00%	5,250.00	100.00%	750.00
3010	EVALUATION OF MEDICINAL PRODUCTS	120,663,000.00	11,789,000.00	132,452,000.00	131,039,552.93	98.93%	98,470,757.53	74.34%	32,568,795.40	24.85%	1,412,447.07
3013	EVALUATION OF PHARMACOVIGILANCE PROCEDURES	13,379,000.00	(500,000.00)	12,879,000.00	12,135,806.19	94.23%	7,972,725.40	61.90%	4,163,080.79	34.30%	743,193.81
3020	TRANSLATION CENTRE LUXEMBOURG	3,549,000.00	(244,000.00)	3,305,000.00	3,236,240.10	97.92%	2,773,220.50	83.91%	463,019.60	14.31%	68,759.90
3021	OTHER TRANSLATIONS	1,635,000.00	(98,000.00)	1,537,000.00	1,536,308.00	99.95%	1,536,308.00	99.95%	-	0.00%	692.00
3030	SCIENTIFIC STUDIES AND SERVICES	5,350,000.00	4,959,000.00	10,309,000.00	9,472,602.15	91.89%	1,569,766.04	15.23%	7,902,836.11	83.43%	836,397.85
3031	DATA MANAGEMENT	2,050,000.00	3,206,000.00	5,256,000.00	5,234,271.58	99.59%	718,760.96	13.68%	4,515,510.62	86.27%	21,728.42
3105	BUSINESS IT DEVELOPMENT	22,600,000.00	6,900,000.00	29,500,000.00	29,452,448.15	99.84%	6,810,430.69	23.09%	22,642,017.46	76.88%	47,551.85
9000	PROVISIONAL APPROPRIATION	25,392,000.00	(25,392,000.00)	-	-	-	-	-	-	0.00%	-
Total		385,919,000.00	(6,691,000.00)	379,228,000.00	365,490,700.73		274,400,002.19		91,090,698.54	24.92%	13,737,299.27

### 5.4.3. Implementation of automatic carry over from previous year (C8)

Amounts in EUR						
Budget line	Heading	CARRY OVER PREVIOUS YEAR BUDGET - C8 2021				
		Commitments carried over from previous year (RAL)	Payments made	% implementation	Cancellation of commitments which cannot be carried over	% cancellation
		1	2	(2/1)	3 (1-2)	(3/1)
1115	SECONDED NATIONAL EXPERTS AND VISITING EXPERTS	2,898,029.00	2,188,313.54	75.51%	709,715.46	24.49%
1116	TRAINEES	305,773.22	261,967.13	85.67%	43,806.09	14.33%
1181	ALLOWANCES AND EXPENSES ON ENTERING AND LEAVING THE SERVICE OR ON TRANSFER	201,076.86	143,874.70	71.55%	57,202.16	28.45%
1200	EXPENDITURE RELATING TO STAFF RECRUITMENT	2,055.22	1,256.09	61.12%	799.13	38.88%
1300	DUTY TRAVEL EXPENSES AND INCIDENTAL EXPENDITURE	14,292.05	3,168.73	22.17%	11,123.32	77.83%
1410	MEDICAL SERVICE	47,450.81	39,960.85	84.22%	7,489.96	15.78%
1420	MISCELLANEOUS WELFARE EXPENDITURE	324,100.00	318,091.48	98.15%	6,008.52	1.85%
1430	SOCIAL CONTACTS BETWEEN STAFF	179.00	179.00	100.00%	-	0.00%
1500	STAFF TRAINING	262,226.11	257,590.53	98.23%	4,635.58	1.77%
1601	INTERIM SERVICES	1,178,046.60	950,685.99	80.70%	227,360.61	19.30%
1602	ADMINISTRATIVE ASSISTANCE FROM THE EUROPEAN UNION INSTITUTIONS	5,637.00	5,539.46	98.27%	97.54	1.73%
1603	PROFESSIONAL SERVICE RELATING TO STAFF MANAGEMENT	52,050.00	52,050.00	100.00%	-	0.00%
1700	RECEPTIONS AND EVENTS	1,605.77	688.81	42.90%	916.96	57.10%
2010	INSURANCES	50,756.82	42,780.40	84.29%	7,976.42	15.71%
2030	MAINTENANCE AND CLEANING	286,740.61	270,885.26	94.47%	15,855.35	5.53%
2040	FITTING-OUT OF PREMISES	170,804.03	156,259.98	91.48%	14,544.05	8.52%
2050	SECURITY AND SURVEILLANCE OF BUILDINGS	162,415.80	157,440.38	96.94%	4,975.42	3.06%
2090	UTILITIES AND OTHER BUILDING CHARGES	90,890.40	59,346.51	65.29%	31,543.89	34.71%
2110	HARDWARE AND SOFTWARE	3,439,014.74	3,439,014.74	100.00%	-	0.00%
2114	MAINTENANCE AND SUPPORT OF APPLICATIONS	7,826,725.83	7,360,260.84	94.04%	466,464.99	5.96%
2115	IT CONSULTANCY AND DEVELOPMENT RELATED TO CORPORATE PROCESSES	1,101,446.64	982,546.74	89.21%	118,899.90	10.79%
2203	TECHNICAL EQUIPMENT AND INSTALLATIONS	426.82	426.82	100.00%	-	0.00%
2210	FURNITURE	621,485.53	621,485.53	100.00%	-	0.00%
2300	STATIONERY AND OFFICE SUPPLIES	1,495.00	1,495.00	100.00%	-	0.00%
2320	FINANCIAL CHARGES	76,093.66	76,093.66	100.00%	-	0.00%
2330	LEGAL EXPENSES AND ASSOCIATED COST	48,909.03	48,782.12	99.74%	126.91	0.26%
2359	OTHER OPERATING EXPENDITURE	3,082.29	634.52	20.59%	2,447.77	79.41%
2400	POSTAL AND DELIVERY SERVICES	2,713.45	2,605.62	96.03%	107.83	3.97%
2501	MEMBERSHIPS WITH PROFESSIONAL BODIES AND ORGANISATIONS	230.97	230.97	100.00%	-	0.00%
2600	RESTAURANT AND CATERING	142,048.91	121,257.84	85.36%	20,791.07	14.64%
2700	INFORMATION AND COMMUNICATION SERVICES	343,752.55	340,045.03	98.92%	3,707.52	1.08%
2800	BUSINESS CONSULTANCY AND AUDITS SERVICES	2,805,914.19	2,765,388.28	98.56%	40,525.91	1.44%
3000	REIMBURSEMENT OF PERSONS ATTENDING MEETINGS	4,000.00	3,708.00	92.70%	292.00	7.30%
3010	EVALUATION OF MEDICINAL PRODUCTS	28,466,995.00	27,428,705.00	96.35%	1,038,290.00	3.65%
3013	EVALUATION OF PHARMACOVIGILANCE PROCEDURES	4,685,474.95	4,678,607.65	99.85%	6,867.30	0.15%
3020	TRANSLATION CENTRE LUXEMBOURG	647,959.49	630,478.25	97.30%	17,481.24	2.70%
3030	SCIENTIFIC STUDIES AND SERVICES	5,985,537.85	4,556,617.30	76.13%	1,428,920.55	23.87%
3105	BUSINESS IT CONSULTANCY AND DEVELOPMENT	13,043,499.86	11,960,342.10	91.70%	1,083,157.76	8.30%
<b>Total</b>		<b>75,300,936.06</b>	<b>69,928,804.85</b>	<b>92.87%</b>	<b>5,372,131.21</b>	<b>7.13%</b>

#### 5.4.4. Implementation of external assigned revenue (R0)

Amounts in EUR

Budget line	Heading	EXTERNAL ASSIGNED REVENUE - R0 2021					
		Budget implementation					
		Appropriations	Commitments made	% Committed	Payments made	% Paid	Appropriation carried over
		1	2	(2/1)	3	(3/1)	4 (1-2)
1100 BASIC SALARIES		52,777.70	-	0.00%	-	0.00%	52,777.70
1300 DUTY TRAVEL EXPENSES AND INCIDENTAL EXPENDITURE		1,200.00	-	0.00%	-	0.00%	1,200.00
2000 RENT		2,850,000.00	150,000.00	5.26%	150,000.00	5.26%	2,700,000.00
2030 MAINTENANCE AND CLEANING		326,545.27	326,545.27	100.00%	326,545.27	100.00%	-
3000 REIMBURSEMENT OF PERSONS ATTENDING MEETINGS		253,719.00	-	0.00%	-	0.00%	253,719.00
<b>Total Expenditure</b>		<b>3,484,241.97</b>	<b>476,545.27</b>		<b>476,545.27</b>		<b>3,007,696.70</b>

#### 5.4.5. Implementation of internal assigned revenue (CL)

Amounts in EUR

Budget line	Heading	INTERNAL ASSIGNED REVENUE - CL 2021					
		Budget implementation					
		Appropriations	Commitments made	% Committed	Payments made	% Paid	Appropriation carried over
		1	2	(2/1)	3	(3/1)	4 (1-2)
2000 RENT		19,533,976.27	15,504,506.24	79.37%	15,504,506.24	79.37%	4,029,470.03
2010 INSURANCES		396,594.46	396,594.46	100.00%	396,594.46	100.00%	-
2090 UTILITIES AND OTHER BUILDING CHARGES		5,013,355.09	4,001,282.92	79.81%	4,001,282.92	79.81%	1,012,072.17
<b>Total Expenditure</b>		<b>24,943,925.82</b>	<b>19,902,383.62</b>		<b>19,902,383.62</b>		<b>5,041,542.20</b>