



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/95305/2024
Administration and Corporate Management Division

Annual accounts

Financial year 2023

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Certification of the annual 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')¹ and I hereby certify that the annual accounts of the European Medicines Agency for the year 2023 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 annual 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 annual accounts, I have a reasonable assurance that the annual 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

¹ COMMISSION DELEGATED REGULATION (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council.

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1. Introduction

1.1. Mission, legal mandate and principal activities of the Agency

Mission

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.

Legal mandate

The European Medicines Agency (“the Agency” or “EMA”) is the European Union (EU) agency responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products for human and veterinary use.

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

The EMA began operating on 26 January 1995 and it is based in Amsterdam, The Netherlands².

The EU rules governing veterinary and human medicines are set out in [Regulation \(EU\) 2019/6](#) and [Directive 2001/83/EC](#) respectively. They provide the legal framework for the authorisation, manufacture, and distribution of medicines in the EU. The centralised authorisation procedure for human and veterinary medicines is based on [Regulation \(EC\) No 726/2004](#), which established the European Medicines Agency (EMA), and Regulation (EU) 2019/6.

In 2010, a package of legislation was adopted the main aim of which was to reinforce pharmacovigilance in the EU. This was supplemented by further legislation in 2012. The main legal acts in this area were: [Regulation \(EU\) No 1235/2010](#) and [Regulation \(EU\) No 1027/2012](#) amending, as regards [pharmacovigilance](#), Regulation (EC) No 726/2004; [Directive 2010/84/EU](#) and [Directive 2012/26/EU](#) amending, as regards [pharmacovigilance](#), Directive 2001/83/EC; [Commission Implementing Regulation No 520/2012](#), which concerns operational aspects of implementing the new legislation.

In 2017, the Regulations on Medical Devices ([Regulation \(EU\) 2017/745](#)) and on In Vitro Diagnostic Devices ([Regulation \(EU\) 2017/746](#)) changed the European legal framework for medical devices, introducing new responsibilities for the European Medicines Agency and national competent authorities in the assessment of certain categories of medical device.

In 2018, a new legislation governing veterinary medicinal products and repealing Directive 2001/82/EC was adopted. The new Veterinary Medicines Regulation ([Regulation \(EU\) 2019/6](#)) modernises the existing rules on the authorisation and use of veterinary medicinal products in the European Union (EU). It became applicable on 28 January 2022. It contains new measures for increasing the availability and safety of veterinary medicinal products and to support the EU action against antimicrobial resistance. The Agency continues to work closely with the European Commission and other EU partners to finalise the implementation of the new Regulation.

In 2022, the Agency’s legal mandate was extended by [Regulation \(EU\) 2022/123](#) on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. This Regulation formalises and strengthens the Agency’s role in crisis response, provides a legal basis for the Agency’s activities on shortages of medicines and medical devices, and endows EMA

² 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

with the management of Expert Panels on Medical Devices. Lastly, the Regulation provides a legal basis for DARWIN EU®.

In 2022, the Regulation on Health Technology Assessment ([Regulation \(EU\) 2022/2282](#)) came into force, with a 3-year implementation period before application as of January 2025. This Regulation mandates the European Medicines Agency to collaborate with the newly established HTA Coordination Group, in the context of parallel Joint Scientific Consultation, exchange of information related to their Joint Clinical Assessment, as well as contribution to the identification of emerging technologies. Implementation activities are currently managed under an EMA/EUnetHTA 21 work plan, requested by the European Commission.

Principal activities

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 on the international level;
- Provides scientific support to the timely development of high-quality, safe and effective medicines during public health emergencies;
- Monitors and mitigates shortages of medicines and medical devices during a public health emergency;
- Ensures the functioning of expert panels to assess high-risk medical devices and In Vitro Diagnostic Medical Devices, and advises on crisis preparation and management;
- Provides scientific opinions related to the consultation procedures initiated by notified bodies on specific categories of medical devices, in accordance with the provisions of the revised legislative framework on medical devices and in vitro diagnostics (MDR/IVDR); e.g., companion diagnostics, devices incorporating a medicinal substance with ancillary action to that of the device, devices composed of substances that are systemically absorbed by the human body;

- Collaborates with the Health Technology Assessment Coordination Group in the context of parallel Joint Scientific Consultation, exchange of information related to their Joint Clinical Assessment, as well as contribution to the identification of emerging technologies.

Additional information can be found on the EMA's website 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 - which differs from cash-based accounting because of elements such as carryover, 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:

Item	Accrual	Budget
Fee revenue	Revenue recognized when services are provided	Cash received by the Agency during the year
Community contribution	Net amount after deduction of budget result for the year	Cash received by the Agency during the year
Fixed assets	Purchases of fixed assets are capitalised and their cost depreciated over the useful life of the assets	Total amount purchased during the year charged to the budget
Expenditure	Expenditure recognized when goods/services are received/provided	Actual amounts paid plus budgetary carry over

As the economic result and the budget result both cover the same underlying transactions, it is a useful control to ensure that they are reconcilable. The reconciliation between the budget result and 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.

The European Parliament, upon a recommendation from the Council, shall, before 15 May of year $n+2$ save where otherwise provided in the constituent act, give a discharge to the director in respect of the implementation of the budget for year n .

The discharge decision shall cover the accounts of all the revenue and expenditure of the Agency, the budget result and the assets and liabilities of the Agency shown in the financial statement.

2. Financial statements

2.1. Balance sheet

<i>Amounts in EUR</i>	Note	31.12.2023 Final	31.12.2022 Final
NON-CURRENT ASSETS			
Intangible fixed assets	4.1.1	71,639,419.55	75,398,242.64
Tangible fixed assets	4.1.2	15,286,872.33	17,873,539.31
Financial assets	4.1.3	-	1,937,097.30
Deferred expenditure	4.1.4	28,959,752.10	42,311,378.51
Recoverable from member states and the UK	4.2.2	2,250,000.00	2,400,000.00
TOTAL NON CURRENT ASSETS		118,136,043.98	139,920,257.76
CURRENT ASSETS			
Financial assets due within 1 year	4.1.3	2,028,896.18	3,833,205.55
Deferred expenditure due within 1 year	4.1.4	2,033,548.75	6,574,457.08
Receivables from exchange transactions	4.2.1	41,044,937.07	38,755,731.98
Recoverables from member states and the UK	4.2.2	1,933,912.59	1,122,643.91
Provision for impaired receivables and recoverables	4.2.2	(1,168,375.64)	(1,203,019.35)
Sundry receivables	4.2.3	53,106.34	74,270.00
Accrued marketing authorisation fees	4.2.4	67,027,322.19	59,883,447.06
Other accrued income	4.2.5	425,211.00	276,684.59
Prepaid expenses	4.2.6	13,462,977.25	12,300,242.59
Cash and cash equivalents	4.2.7	96,449,199.66	120,928,151.76
TOTAL CURRENT ASSETS		223,290,735.39	242,545,815.17
TOTAL ASSETS		341,426,779.37	382,466,072.93
NON-CURRENT LIABILITIES			
Deferred revenue	4.3.1	45,953,223.15	49,103,235.52
Provision for onerous contract	4.3.2	118,499,122.37	-
TOTAL NON CURRENT LIABILITIES		164,452,345.52	49,103,235.52
CURRENT LIABILITIES			
Deferred revenue due within 1 year	4.3.1	3,150,012.37	3,746,670.01
Provision for onerous contract due within 1 year	4.3.2	12,874,647.04	-
Payables and accrued charges under exchange transactions	4.4.1	76,194,241.86	74,084,147.81
Budgetary result payable to European Commission	4.4.2	20,938.59	10,459,043.14
Other prefinancing from EU entities	4.4.3	2,170,002.14	370,024.11
Payables with EU entities	4.4.4	49,265.02	149,368.81
Sundry payables	4.4.5	98,337.40	67,492.61
Deferred marketing authorisation fees	4.4.6	25,374,705.93	27,510,706.80
Other deferred income	4.4.7	1,541,402.45	3,947,729.63
TOTAL CURRENT LIABILITIES		121,473,552.80	120,335,182.92
TOTAL LIABILITIES		285,925,898.32	169,438,418.44
NET ASSETS		55,500,881.05	213,027,654.49
NET ASSETS			
Accumulated economic results previous years		213,027,654.49	209,919,486.20
Economic result of the year		(157,526,773.44)	3,108,168.29
NET ASSETS		55,500,881.05	213,027,654.49

2.2. Statement of financial performance

	Note	2023	2022
		Final	Final
<i>Amounts in EUR</i>			
OPERATING REVENUE			
Fees and charges related to marketing authorisations	4.5.1	399,010,495.93	358,760,501.03
Contribution from EU entities	4.5.2	51,203,352.62	39,855,811.89
Sundry revenue	4.5.3	203,988.37	320,292.86
Revenue from landlord incentives	4.5.4	3,561,929.65	3,556,958.00
Revenue from subletting	4.5.5	15,054,772.96	14,988,965.57
Revenue from external projects		1,658.97	-
Reversal of previous years provision		56.80	61,292.82
TOTAL OPERATING REVENUE		469,036,255.30	417,543,822.17
OPERATING EXPENDITURE			
Staff expenses	4.6.1	152,948,123.24	136,105,217.86
Administrative expenditure	4.6.2	89,559,673.56	69,609,884.46
Operating expenditure	4.6.3	212,505,457.16	184,630,335.68
Depreciation		26,648,270.95	23,349,666.78
Disposals and impairment of assets	4.1.4	15,178,504.38	33,997.96
Other adjustments		38.54	3,162.91
Provision for onerous contract	4.3.2	131,373,769.41	-
TOTAL OPERATING EXPENDITURE		628,213,837.24	413,732,265.65
Surplus (deficit) from operating activities		(159,177,581.94)	3,811,556.52
Surplus (deficit) from non-operating activities	4.7	1,650,808.50	(703,388.23)
ECONOMIC RESULT OF THE YEAR		(157,526,773.44)	3,108,168.29

2.3. Cash flow statement

<i>Amounts in EUR</i>	2023 Final	2022 Final
Economic result of the year	(157,526,773.44)	3,108,168.29
OPERATING ACTIVITIES		
Amortization (intangible fixed assets)	22,563,978.23	19,325,050.42
Depreciation (tangible fixed assets)	4,084,292.72	4,024,616.36
(Increase)/decrease in current receivable and accrued fees	(9,560,442.97)	4,304,139.76
(Increase)/decrease in other receivables	1,917,403.33	13,555,389.56
Increase/(decrease) in provision for doubtful debts	(34,643.71)	(81,962.64)
Increase/(decrease) in provision	131,373,769.41	-
Increase/(decrease) in deferred revenue	(5,882,670.88)	(2,446,164.42)
(Increase)/decrease in deferred expenditure	17,892,534.74	(1,938,380.52)
Increase/(decrease) in accounts payable	2,140,938.84	7,781,323.72
Increase/(decrease) in liabilities related to EU entities	(8,738,230.31)	(14,325,420.04)
(Gains)/losses on sale/disposal/derecognition of fixed assets	3,252.72	33,997.96
Increase/(decrease) in financial liabilities	-	(4,046,014.42)
Increase/(decrease) in prepaid income	(2,406,327.18)	(1,093,812.57)
Net cash flow from operating activities (a)	(4,172,918.50)	28,200,931.46
INVESTING ACTIVITIES		
(Purchase) of tangible and intangible fixed assets	(20,306,033.60)	(26,968,234.48)
Net cash flow from investing activities (b)	(20,306,033.60)	(26,968,234.48)
Net increase/(decrease) in cash and cash equivalents (a+b)	(24,478,952.10)	1,232,696.98
Cash and cash equivalents at the beginning of the period	120,928,151.76	119,695,454.78
Cash and cash equivalents at the end of the period	96,449,199.66	120,928,151.76

2.4. Statement of changes in net assets

<i>Amounts in EUR</i>	Accumulated surplus	Economic outturn for the year	Net assets
Balance as of 31 December 2022	209,919,486.20	3,108,168.29	213,027,654.49
Allocation of economic result 2022	3,108,168.29	(3,108,168.29)	-
Economic result 2023	-	(157,526,773.44)	(157,526,773.44)
Balance as of 31 December 2023	213,027,654.49	(157,526,773.44)	55,500,881.05

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, as disclosed in note 4.7.

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. At 31.12.2023 1 EUR = GBP 0.86905 (31.12.2022: 0.88693).

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.

Over the past two years, EMA has prioritised work to respond to the ongoing COVID-19 pandemic, which has had an unprecedented impact on many EMA activities. Nevertheless, the pandemic as such did not trigger significant estimations to be made in the preparation of the financial statements 2023. Over the last year, members of the EU Medicines Regulatory Network, including the European Medicines Agency took the decision to lift their respective COVID-19 business continuity measures. This coincided with the announcement from the World Health Organization (WHO), declaring the end of COVID-19 as a public health emergency of international concern.

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.

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.

On 2nd 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 (30 Churchill Place Tenant) 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.

In November 2023, the subtenant's ultimate parent company (We Work Inc) filed for protection under Chapter 11 of the U.S. Bankruptcy Code. The bankruptcy protection filing concerns the group's branches in the US and Canada only.

Following the filing for bankruptcy, WeWork Inc has been in contact with its landlords including EMA to re-negotiate their leases.

The negotiations were concluded in March 2024 with the submission of the subtenant's final position pertaining to the principles of the future occupancy of the former premises.

In accordance with the discussions held with the EU budgetary authorities and with the consent of its landlord, the Agency has agreed on an amendment of the existing sublease with the subtenant by way of rent reduction and including provisions for either the Agency or the subtenant to early terminate the sublease under certain conditions, before the scheduled expiry date in June 2039.

At the time these final accounts are issued the amendment of the existing sublease covering the relevant re-negotiated terms, clauses and conditions is on-going and the Agency's subtenant continues to carry on operations from its London premises.

The Agency's subtenant has met its contractual obligations for year 2023, with rental payments covering the period up to 31 December 2023.

The Agency has accepted the deferral of the rental payments covering the first three quarters of 2024, until the amendment of the existing sublease contract with the subtenant is signed.

Based on the latest evolutions of the case, management has made the following significant judgements in the application of the accounting policies:

- The operating lease on the Agency's former office premises in London meets the EU Accounting Rule (EAR) 10 definition and the recognition conditions of a provision for onerous contract as it is assessed probable that a net outflow of resources will be required to settle the related lease obligations.
- Before a separate provision for an onerous contract is established, the Agency recognises any impairment loss that has occurred on assets dedicated to that contract, more specifically in relation to the lease incentives granted to the subtenant, outlined in note 4.1.4.

The impairment loss on the lease incentive is measured as the sum of the net carrying amounts of the lease incentives granted to the subtenant in the form of rent-free period (€ 3.33 million of assets on 31 December 2023 – see note 4.1.4) and cash payments towards the rent (€ 11.84 million of assets on 31 December 2023 – see note 4.1.4).

The onerous contract provision is measured as the present value of the difference between the future cash outflows expected to be paid under the headlease and the cash inflows expected to be received under the sublease. The best estimate of the onerous lease contract provision amounts to € 131.37 million on 31 December 2023 (see note 4.3.2).

The carrying amount of this provision is exposed to significant adjustments in the future, knowing that the key sources of estimation uncertainty relate to the future cash inflows expected to be received by the Agency, namely:

- It is assumed that the current subtenant will meet its obligations under the amended contract and that the Agency will not early terminate the current sublease. Should the sublease be early terminated, other estimations would have to be made, including with respect to the period of vacancy of the premises as well as the sublease payments to be received under any new lease contract.
- In accordance with the amended sublease contract, lease payments are partially variable mainly depending on the occupancy of the premises, which requires estimations about the future rate of occupancy.
- It is expected that the Agency will remain contractually liable towards its Canary Wharf landlords until the end of the headlease. Reference is made to the comfort letter³ from the European Commission to the Canary Wharf Group, which will positively affect the future cash inflows expected to be received by the Agency. The letter “*provides full reassurance and comfort that the European Union and the bodies set up under European Union law will continue to honour their legal obligations*” and the Commission Decision states that “*The Canary Wharf Group will rely on the Commission comfort letter in case the sub-tenant would go bankrupt and in case EMA’s revenue would not be sufficient to face the financial implications of the EMA’s liability under the lease contract*”. The funding from the European Union (EU) is essential to protect the public health activities of both the Agency and the national competent authorities.

Management is closely monitoring the evolution of this file and may adapt its judgements in the future consistently with this evolution.

Since EMA remains a party to the headlease with its Canary Wharf landlords, should the subtenant not be able to meet its obligations and the sublease early terminated, 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 (€ 374.89 million) and any other financial obligation which would arise as a result of the vacant premises while waiting for the building floors being rented out to new subtenant(s), as for example commercial business rates collected by the UK local authorities, VAT and other operating costs and utilities. An estimated total amount of € 550 million is to be viewed as the maximum exposure of the Agency in case of a completely empty building for the period from 01 January 2024 until the expiry of the headlease in June 2039.

3.1.4. Application of new and amended European Union Accounting Rules (EAR)

New EAR adopted but not yet effective at 31 December 2023

There are no new EARs adopted but not yet effective at 31 December 2023.

3.2. Balance sheet and statement of financial performance

3.2.1. Intangible and tangible fixed assets

Intangible fixed assets

An intangible asset is an identifiable non-monetary asset without physical substance. An asset is identifiable if it is either separable (i.e. it is capable of being separated or divided from the entity, e.g. by being sold, transferred, licensed, rented, or exchanged, either individually or together with a related

³ COMMISSION DECISION C (2019) 5073 of 2 July 2019 approving, in the context of the relocation of the European Medicines Agency as a result of the notification of the withdrawal of the United Kingdom from the European Union, a comfort letter to Canary Wharf (BP4) T1 Limited, Canary Wharf (BP4) T2 Limited and Canary Wharf Management Limited

contract, identifiable asset or liability, regardless of whether the entity intends to do so), or arises from binding arrangements (including rights from contracts or other legal rights, regardless of whether those rights are transferable or separable from the entity or from other rights and obligations).

Acquired intangible assets are stated at historical cost less accumulated amortisation and impairment losses.

Internally generated intangible assets (i.e. computer software) are capitalised when the relevant criteria of the EU Accounting Rules are met and the expenses, if above the Agency's threshold of € 1,000,000, relate solely to the development phase of the asset.

The Agency transitioned from a programme and project approach into a new Agile way of working, where projects were replaced by Agile epics (an 'epic' means a container for a solution initiative, aligned with the EMA IT portfolio objectives). The epic lifecycle foresees approval of a solution idea at a first stage, called 'epic hypothesis'. The following stage aims the approval of an epic lean business case.

The capitalizable costs include all directly attributable costs, paid to third party consultants as well as internal staff cost, necessary to create, produce, and prepare the asset to be capable of operating in the manner intended by management. Costs associated with epic hypothesis, non-capitalizable development costs and maintenance costs are recognised as expenses as incurred.

Intangible assets are amortised on a straight-line basis over their estimated useful lives, as follows:

- Internally generated computer software 25%
- Other computer software 25%

Intangible assets under construction are not depreciated, as these assets are not yet available for use.

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.

The Agency's threshold for the capitalisation of computer hardware, equipment and furniture is € 1,500.

Tangible fixed assets are stated at historical cost less accumulated depreciation and impairment losses. Cost includes expenditure that is directly attributable to the acquisition, construction or transfer of the asset. Subsequent costs 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 or service potential associated with the item will flow to the Agency and its cost can be measured reliably. Repairs and maintenance costs are charged to the statement of financial performance during the financial period in which they are incurred.

Depreciation is calculated using the straight-line method over their estimated useful lives, as follows:

- Computer hardware 25%
- Equipment 12.5%-25%
- Furniture 10%
- Building, leasehold improvements and fitting out costs 4%-25%

Tangible assets under construction are not depreciated, as these assets are not yet available for use.

Impairment of intangible and tangible assets

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at least once per year. If the reasons for impairments recognised in previous years no longer apply, the impairment losses

are reversed accordingly. Gains or losses on disposals are charged to the statement of financial performance.

3.2.2. Leases

A lease is an agreement whereby the lessor conveys to the lessee, in return for a payment or series of payments, the right to use an asset for an agreed period.

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, with neither a leased asset nor a leasing liability presented in the balance sheet.

Leases where substantially all the risks and rewards incidental to ownership are transferred to the lessee are classified as financial leases. The Agency has not entered into financial leases.

3.2.3. Receivables

The EU Accounting Rules require a separate presentation of exchange and non-exchange transactions. The term 'receivables' is reserved for exchange transactions, i.e. fees charged by the Agency to applicants for services rendered in accordance with the applicable legislation and the lease receivables for the subletting of the Agency's former office premises at 30 Churchill Place, London. The term 'recoverables' is used for 'non-exchange transactions' and in the case of the Agency it represents the recoverables from Member States and the UK for value added tax (VAT) and incentives.

Receivables are financial assets measured at amortised cost. Please refer also to sections 3.5.1 on impairment of financial assets and 3.5.2 on write-off policy.

Recoverables from non-exchange transactions are carried at fair value as at the date of acquisition less write-down for impairment. The amount of the write-down is the difference between the asset's carrying amount and the recoverable amount. The amount of the write-down, if any, is recognised in the statement of financial performance.

3.2.4. Cash and cash equivalents

Cash and cash equivalents are financial assets measured at amortised cost and 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.

Present obligations arising under onerous contracts are recognized and measured as provisions. An onerous contract is considered to exist where the Agency has a contract under which the unavoidable costs of meeting the obligations under the contract exceed the economic benefits expected to be received under it. The unavoidable costs under a contract reflect the least net cost of exiting from the contract, which is the lower of the cost of fulfilling it and any compensation or penalties arising from failure to fulfill it. Before a separate provision for an onerous contract is established, the Agency recognises any impairment loss that has occurred on assets dedicated to that contract.

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.

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 reliably by the authorising officer on the basis of the budgetary carry over and the stage of completion of the service and recognised in the statement of financial performance. 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.

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 accrued charges. The amount is calculated as the additional amount that the Agency expects to pay as a result of the unused entitlement that has accumulated at the reporting date, applying the Agency's staff average cost and the specific country correction coefficient.

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 \(EC\) 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 2023/699](#) of 29 March 2023 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate⁴.

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

⁴ Following final adoption by the European Parliament and the Council, [REGULATION \(EU\) 2024/568 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL](#) on fees and charges payable to the European Medicines Agency has been published in the EU Official Journal and will become applicable as of 1 January 2025.

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 1st 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 1st January to 31st 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 11.1%⁵ 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

⁵ updated rate as of 1 July 2023, the weightings not being taken into account

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. A contingent liability is disclosed unless the possibility of an outflow of resources embodying economic benefits or service potential is remote.

3.5. Financial instruments

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

The financial assets and financial liabilities concerning the Agency are cash and cash equivalents, receivables and payables.

The analysis of the credit risk, the liquidity risk and the market risk of the Agency's financial instruments is presented in note 4.9.

3.5.1. Impairment of financial assets

For the impairment of financial assets an expected credit loss (ECL) model is applied. The ECL 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:

- exchange receivables
- non-current exchange receivables and lease receivables
- cash and cash equivalents.

For exchange receivables without a significant financing component (i.e. short-term trade receivables), 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, 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 ECL 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

This header 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, delivering new or enhanced IT systems in defined business areas, such as clinical trials, pharmacovigilance and veterinary medicines; EMA's approach to implementing the ISO IDMP standards through the management of master data on medicinal products in four domains: substance, product, organisation and referential (SPOR); and various EMA programmes and projects.

In 2023 it resulted in release of internally generated computer software in value of € 21.23 million, additional development costs in the value of € 18.80 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>	Internally generated computer software	Other computer software	Intangible asset under construction	Total
Gross carrying amounts 01.01.2023	159,082,764.52	8,784,911.30	29,105,687.02	196,973,362.84
Additions	-	-	18,805,155.14	18,805,155.14
Transfers	21,229,669.78	-	(21,229,669.78)	-
Gross carrying amounts 31.12.2023	180,312,434.30	8,784,911.30	26,681,172.38	215,778,517.98
Accumulated amortisation and impairment 01.01.2023	(113,135,004.25)	(8,440,115.95)	-	(121,575,120.20)
Amortisation	(22,388,289.11)	(175,689.12)	-	(22,563,978.23)
Accumulated amortisation and impairment 31.12.2023	(135,523,293.36)	(8,615,805.07)	-	(144,139,098.43)
Net carrying amounts 31.12.2023	44,789,140.94	169,106.23	26,681,172.38	71,639,419.55

4.1.2. Tangible fixed assets

Tangible assets include mainly 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 and the capitalisation of leasehold improvements, i.e. enhancements to the leased space paid for by the Agency with the financial incentive granted by the Dutch Government, as outlined in note 4.3.1.

Acquisitions for the year relates to networking equipment and new laptops. Disposals of computer hardware relates mainly to old laptops no longer in use. The table below summarises the accounting movements for the year.

<i>Amounts in EUR</i>	Leasehold improvements and fittings	Equipment	Furniture	Computer hardware	Total
Gross carrying amounts 01.01.2023	11,464,019.48	4,452,161.85	6,409,509.15	10,394,425.95	32,720,116.43
Additions	227,557.54	17,017.75	3,335.00	1,252,968.17	1,500,878.46
Disposals	-	-	(13,145.81)	(181,874.11)	(195,019.92)
Gross carrying amounts 31.12.2023	11,691,577.02	4,469,179.60	6,399,698.34	11,465,520.01	34,025,974.97
Accumulated depreciation and impairment 01.01.2023	(1,913,364.92)	(3,185,083.45)	(1,963,107.36)	(7,785,021.39)	(14,846,577.12)
Depreciation	(749,190.33)	(1,101,064.38)	(638,292.87)	(1,595,745.14)	(4,084,292.72)
Disposals	-	-	13,145.81	178,621.39	191,767.20
Accumulated depreciation and impairment 31.12.2023	(2,662,555.25)	(4,286,147.83)	(2,588,254.42)	(9,202,145.14)	(18,739,102.64)
Net carrying amounts 31.12.2023	9,029,021.77	183,031.77	3,811,443.92	2,263,374.87	15,286,872.33

4.1.3. Financial assets

This item relates to € 2.03 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. In respect of property-related obligations, please refer also to note 3.1.3 on key sources of estimation uncertainty and significant judgements, note 4.3.2 on provision for onerous contracts 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 (as reduction of revenue) against annual rents received from the subtenant (note 4.5.6). The release for the year amounts to € 6.58 million.

Sublease incentives (offered) for former office premises at 30 Churchill Place, Canary Wharf London, UK

30 Churchill Place, London

<i>Amounts in EUR</i>	Gross carrying amount 01.01.2023	Additions / Adjustments	Impairment	Gross carrying amount 31.12.2023	Accumulated expense release 01.01.2023	Release for the year	Accumulated release 31.12.2023	Net carrying amount 31.12.2023
Rent free period	6,348,873.63	-	(3,333,158.66)	3,015,714.97	1,904,662.08	1,111,052.89	3,015,714.97	-
Sub-tenant incentive (rent)	16,372,004.99	1,235,260.75	(11,842,093.00)	5,765,172.74	2,332,301.45	3,432,871.29	5,765,172.74	-
Sub-tenant incentive (fitting out)	35,452,343.65	2,624,929.09	-	38,077,272.74	5,050,423.13	2,033,548.76	7,083,971.89	30,993,300.85
Total	58,173,222.27	3,860,189.84	(15,175,251.66)	46,858,160.45	9,287,386.66	6,577,472.94	15,864,859.60	30,993,300.85
						<i>of which due within one year</i>		<i>2,033,548.75</i>

As disclosed in note 3.1.3 on key sources of estimation uncertainty and significant judgements, the operating lease on the Agency's former office premises in London meets the EAR 10 definition and the

recognition conditions of a provision for onerous contract as it is assessed probable that a net outflow of resources will be required to settle the related lease obligations.

As a result of said assessment, and before establishing a separate provision for onerous contract, the Agency has recognised a material impairment loss that has occurred on assets dedicated to that contract, namely the lease incentives offered to the subtenant in the form of rent-free period (€ 3.33 million net carrying amount on 31 December 2023) and cash payments towards rent (€ 11.84 million net carrying amount on 31 December 2023).

The net carrying amount of the cash lease incentive offered to the subtenant for the fitting out of the premises has not been impaired, on the basis of the expectation that the amended sublease contract will be executed until the end of the contract. The net carrying amount of such incentive not yet released at 31 December 2023 amounts to € 30.99 million.

In respect of property-related obligations, please refer also to note 4.3.2 on provision for onerous contracts 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 € 41.04 million of fees invoiced to marketing authorisation holders and applicants remaining open at 31 December 2023. Included in the amount is € 3.66 million of fees with deferred payment relating to applications by Micro, Small and Medium enterprises (SMEs) and for medicinal products to be used in a human pandemic situation.

The provision for short-term receivables of doubtful collection at 31 December 2023 amounts to € 205 thousand and it is presented in the balance sheet together with the provision referred to in note 4.2.2.

The policy for the impairment of short-term receivables is outlined at section 3.5.1. 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

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 tax recoverable from the Dutch authority as at 31 December 2023 amounts to € 19 thousand.

Because 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). The amount of UK VAT recoverable from the HMRC as at 31 December 2023 amounts to € 784 thousand.

In addition, € 981 thousand of VAT on goods and services invoiced by UK registered entities reclaimed from the UK Foreign Commonwealth and Development Office (FCDO) is past due at 31 December 2023 and a provision is presented on the balance sheet as at 31 December 2023.

This header includes also € 2.25 million of financial incentive granted by the Dutch Government remaining to be received as a reduction of the overall rent payable by equal yearly instalments of € 150 thousand over the 20 years duration of the lease, as outlined in note 4.3.1 on deferred revenue.

4.2.3. Sundry receivables

This header relates to a receivable from the European Directorate for the Quality of Medicines and Healthcare (EDQM) in the context of the annual sampling and testing programme for centrally authorised medicines.

4.2.4. Accrued marketing authorisation fees

This item includes fees that have been earned as at 31 December but that have not yet been invoiced to the applicants.

It mainly relates to annual fees which are due on the first and each subsequent anniversary of the notification of the marketing authorisation decision and revenue is accrued as a pro-rata basis in relation to the time passed since the previous anniversary date.

The accounting policy for the recognition of fees revenue is outlined in note 3.2.8.

4.2.5. Other accrued income

Other accrued income includes bank interest earned at 31 December 2023, for which the corresponding remuneration is paid in the Agency's bank account in January.

4.2.6. Prepaid expenses

This item includes payments made in advance for services or goods that have not yet been received. Accordingly, the expense is deferred and recognised in the subsequent accounting period.

<i>Amounts in EUR</i>	31.12.2023	31.12.2022
Rent and service charges EMA head-lease, London	3,892,363.33	3,947,729.62
Prepaid expenditure for evaluation services	3,809,963.65	3,216,415.81
Other prepaid expenditure	5,760,650.27	5,136,097.16
Total	13,462,977.25	12,300,242.59

Other prepaid expenditure relates mainly to annual maintenance contracts for facilities and IT services.

4.2.7. Cash and cash equivalents

Cash and cash equivalents balances comprise the following:

<i>Amounts in EUR</i>	31.12.2023	31.12.2022
EUR account ABN AMRO NL - current account	11,024,734.73	8,886,151.52
EUR account ING Bank - deposit of surplus	74,903,406.09	99,633,129.93
EUR account ING Bank - current account	10,485,355.31	10,474,163.41
GBP account ABN AMRO NL	27,984.75	1,923,733.09
GBP account ABN AMRO UK	7,718.77	10,973.81
Total	96,449,199.66	120,928,151.76

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 (received) for office premises at Domenico Scarlattilaan 6, Amsterdam, The Netherlands

Domenico Scarlattilaan 6, Amsterdam							
<i>Amounts in EUR</i>	Gross carrying amount 01.01.2023	Additions / Adjustments	Gross carrying amount 31.12.2023	Accumulated release 01.01.2023	Release for the year	Accumulated release 31.12.2023	Net carrying amount 31.12.2023
Rent free period	3,170,662.00	-	3,170,662.00	475,599.30	158,533.10	634,132.40	2,536,529.60
Landlord incentive (rent)	3,000,000.00	-	3,000,000.00	450,000.00	150,000.00	600,000.00	2,400,000.00
Landlord inducement (enhancements)	14,918,703.58	-	14,918,703.58	3,699,783.87	1,233,261.30	4,933,045.17	9,985,658.41
Total	21,089,365.58	-	21,089,365.58	4,625,383.17	1,541,794.40	6,167,177.57	14,922,188.01
						<i>of which due within one year</i>	<i>945,136.75</i>

In accordance with its 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 allocated € 15 million to the enhancement of the leased space and to the purchase of IT equipment (note 4.1.2). This incentive is released as annual revenue (€ 1.23 million, note 4.5.4) over the life of the lease (20 years). The remaining € 3 million is offset against the yearly rental payments (note 4.2.2) and released as annual revenue in equal yearly instalments (€ 150 thousand, note 4.5.4) over the life of the lease.

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 (€ 3.17 million) and released (as reduction of expenditure) against annual rents paid to the landlord (€ 158.5 thousand, note 4.6.2) over the life of the lease.

The net carrying amount of lease incentives not yet released as revenue at 31 December 2023 amounts to € 14.92 million.

Lease incentives (received) for former office premises at 30 Churchill Place, Canary Wharf London, UK

Lease incentives received by the Agency in 2014 consisted of a rent free period, corresponding to € 9.00 million released (as reduction of expenditure) against annual rents paid to the landlord (€ 362.62 thousand, note 4.6.2) over the life of the lease (25 years); a cash contribution of € 46.00 million corresponding to 37 months of rent free period, released as annual revenue (€ 1.84 million, note 4.5.4) over the life of the lease and a cash contribution of € 14.00 million for 'Category A' fit out which has been fully released in line with the depreciation of the fitout costs (4 years). The net carrying amount of lease incentives not yet released as revenue at 31 December 2023 amount to € 34.18 million.

30 Churchill Place, London							
<i>Amounts in EUR</i>	Gross carrying amount 01.01.2023	Additions	Gross carrying amount 31.12.2023	Accumulated release 01.01.2023	Release for the year	Accumulated release 31.12.2023	Net carrying amount 31.12.2023
Rent free period	9,065,559.00	-	9,065,559.00	3,082,289.88	362,622.36	3,444,912.24	5,620,646.76
Landlord inducement	59,984,695.72	-	59,984,695.72	29,582,041.72	1,842,253.26	31,424,294.98	28,560,400.74
Total	69,050,254.72	-	69,050,254.72	32,664,331.60	2,204,875.62	34,869,207.22	34,181,047.50
						<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, note 4.3.2 on provision for onerous contracts and note 4.8 on other significant disclosures, dealing with operating leases and contingent liabilities.

4.3.2. Provision for onerous contracts

We also refer to note 3.1.3 on key sources of estimation uncertainty and significant judgements in the application of accounting policies.

On 29 March 2017, the United Kingdom (UK) formally notified the European Council of its intention to withdraw from the European Union (EU), a process commonly referred to as 'Brexit.' This development prompted a decision by EU Member States on 20 November 2017 to relocate the EMA from London to Amsterdam.

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.

Effective 2nd July 2019, the Agency reached an agreement over its premises at 30 Churchill Place, London, 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.

In November 2023, the subtenant's ultimate parent company (We Work Inc) filed for protection under Chapter 11 of the U.S. Bankruptcy Code. The bankruptcy protection filing concerns the group's branches in the US and Canada only.

Following the filing for bankruptcy, WeWork Inc has been in contact with its landlords including EMA to re-negotiate their leases.

The negotiations were concluded in March 2024 with the submission of the subtenant's final position pertaining to the principles of the future occupancy of the former premises.

In accordance with the discussions held with the EU budgetary authorities and with the consent of its landlord, the Agency has agreed on an amendment of the existing sublease with the subtenant by way of rent reduction and including provisions for either the Agency or the subtenant to early terminate the sublease under certain conditions, before the scheduled expiry date in June 2039.

At the time these final accounts are issued the amendment of the existing sublease covering the relevant terms, clauses and conditions is on-going and the Agency's subtenant continues to carry on operations from its London premises.

The Agency's subtenant has met its contractual obligations for year 2023, with rental payments covering the period up to 31 December 2023.

The Agency has accepted the deferral of the rental payments covering the first three quarters of 2024, until the amendment of the existing sublease contract with the subtenant is signed.

Based on the above elements, the Agency concluded that the operating lease on the Agency's former office premises in London meets the EAR 10 definition and the recognition conditions of a provision for onerous contract.

The best estimate of the onerous contract provision, amounting at € 131.37 million on 31 December 2023, has been made for the net present value of the future contractual cash flows expected to be paid (€ 280.37 million) and received (€ 149 million) under the headlease and sublease, respectively.

As outlined in note 3.1.3 on key sources of estimation uncertainty and significant judgements, the estimate of the onerous contract provision has been based on the most probable outcome that the current subtenant will meet its obligations under the amended contract until the end of the term and that the Agency will not early terminate the current sublease. Should the sublease be early terminated,

other estimations would have to be made, including with respect to the period of vacancy of the premises as well as the sublease payments to be received under any new lease contract.

In addition, future contractual lease payments expected to be received from the subtenant under the amended sublease are based on fixed and variable elements, the latter being a turnover rent linked to the subtenant's turnover, therefore depending on the occupancy of the premises at 30 Churchill Place, which requires estimations about the future rate of occupancy. The estimates made by the Agency with respect to the future rate of occupancy have been based on historical occupancy data of said premises, adjusted with annual percentage growth rate to reflect the latest trends and forecast in office occupancy levels.

As the contractual cash flows are denominated in GBP, the discount rate amounting to 3.918% was determined by reference to a risk-free discount rate in GBP linked to the interest rate of UK government bonds as at 31.12.2023 for similar duration as the lease contracts (15 years).

A change of 100 basis points in the interest rate at the reporting date would have increased (decreased) the provision by the amounts shown in the sensitivity analysis below and consequently affected the economic result by said amounts, holding all the other assumptions constant.

Sensitivity analysis of the discount rate	31.12.2023	- 100 bps	+ 100 bps
<i>Amounts in EUR</i>	3.918%	2.918%	4.918%
Net present value of expected cash outflows	280,376,976.91	300,801,440.12	261,992,663.46
Net present value of expected cash inflows	149,003,207.50	161,179,637.76	138,100,716.46
Net present value of the provision	131,373,769.41	139,621,802.36	123,891,947.00
Increase/(decrease) of provision at 31.12.2023 for a change of 100 basis points		8,248,032.95	(7,481,822.41)

4.4. Current liabilities

4.4.1. Payables and accrued charges under exchange transactions

Current payables represent amounts accrued for goods and services due at 31 December 2023 for a total of € 76.19 million. It also includes accrued charges of € 7.35 million for employees accumulated compensated absences (untaken leave) and other miscellaneous staff payables.

<i>Amounts in EUR</i>	31.12.2023	31.12.2022
Accounts payable and accrued charges	23,840,524.18	25,803,405.54
Accrued expenditure for evaluation services	44,997,499.73	40,029,063.46
Accrued charges for untaken leave and other staff payables	7,356,217.95	8,251,678.81
Total	76,194,241.86	74,084,147.81

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 2023 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 2023 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 are the initial prefinancing of € 2.14 (out of a ten million euros grant agreement) received from the European Commission to support regulatory systems at national and regional level in Africa, and in particular for the setting up of the African Medicines Agency (AMA), in collaboration with African, European and international actors and the Instrument for Pre-Accession Assistance (IPA) funding remaining open at 31 December.

4.4.4. Payables with EU entities

Included under this header are the accounts payables with EC consolidated entities as at 31 December 2023.

4.4.5. Sundry payables

Included under this header are the contribution received by Agency in relation to the Innovative Medicines Initiative (IMI) programme and other minor miscellaneous payables.

4.4.6. 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.

4.4.7. Other deferred income

This item relates to the payment received from the subtenant for the first quarter 2023 service charges of the premises at 30 Churchill Place, London.

4.5. Operating revenue

4.5.1. Fees and charges relating to marketing authorisations

The Agency charges fees for applications for marketing authorisation, for variations and other changes to marketing authorisations, and annual fees for authorised medicines as well as procedural fees to marketing authorisation holders for the assessment of pharmacovigilance procedures, i.e. periodic safety update reports (PSURs), post-authorisation safety studies (PASS), referrals initiated as a result of the evaluation of pharmacovigilance data in respect of medicinal products for human use.

In addition, the Agency charges annual fees to support its activities with 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 98 of Regulation (EU, Euratom) 2018/1046.

<i>Amounts in EUR</i>	2023	2022
Fees for scientific advice	31,143,392.86	34,377,662.31
Fees for initial applications	32,348,951.24	26,997,803.84
Post authorization variations and inspection fees	153,890,422.10	139,295,613.18
Annual maintenance fees	138,911,468.53	118,428,964.81
Other administrative fees	1,444,267.73	1,782,010.00
Fees for pharmacovigilance activities	27,780,513.47	26,259,356.89
Processing Parallel Distribution notifications	9,471,060.00	8,049,860.00
Processing Export Certificates	4,020,420.00	3,569,230.00
Total	399,010,495.93	358,760,501.03

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>	2023	2022
European Commission general subsidy	14,421,263.00	32,416,399.18
EU orphan medicinal products contribution	10,733,120.00	12,895,240.00
Balance of budget outturn from previous years	24,982,177.86	4,368,320.96
Balance of budget outturn 2023 to be returned to the EC in 2024	(20,938.59)	(10,459,043.14)
Other pre-financing received from EC	1,087,730.35	634,894.89
Total	51,203,352.62	39,855,811.89

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 2023 such contribution amounted to € 10.73 million of revenue for orphan medicinal products.

It also includes the recognition of the pre-financing received by the European Commission for the implementation of the EU Common Standard for electronic product information (ePI) and for the IPA programme, for which related expenses have been booked in the statement of financial performance.

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

4.5.3. Sundry revenue

This item includes recoveries of amounts wrongly paid in previous years, and other miscellaneous revenue.

4.5.4. Revenue from landlord incentives

This item comprises € 3.56 million of recognized revenue related the landlord incentive received as part of the contractual arrangements for the premises at 30 Churchill Place, London (€ 1.84 million, note 4.3.1) and the incentives received from the Dutch government (€ 1.38 million, note 4.3.1). It also includes a yearly rebate on the maintenance costs (€ 336 thousand).

4.5.5. Revenue from subletting

This item includes € 21.62 million revenue earned in relation to the subletting of the Agency's former office premises at 30 Churchill Place, London, reduced by the yearly release of the incentive offered to the subtenant (€ 6.57 million, note 4.1.4). In respect of property-related obligations, please refer also to note 3.1.3 on key sources of estimation uncertainty and significant judgements, note 4.3.2 on provision for onerous contracts and note 4.8 on other significant disclosures, dealing with operating leases and contingent liabilities.

4.6. Operating expenditure

4.6.1. Staff expenses

As at 31 December 2023, the Agency's headcount included a total of 664 temporary agents, 216 contract agents, 47 national experts on secondment, 134 interims and 53 trainees (2022: 658, 207, 31, 107 and 40). Compared to 2022, the total headcount had increased by 6.8% from 1043 to 1114.

Such increase is reflected in the staff expenses, amounting to € 152.94 million at 31 December 2023 (2022: € 136.10 million). The header also includes the estimated cost for employee accumulated compensated absences (untaken leave) at year-end, referred to in note 4.4.1.

The intermediate salary update of basic salary/allowances with effect of 1 January 2023 was 1.7%, the Netherlands remuneration correction coefficient increased from 109.8 to 111.8.

The annual update of the basic salary/allowances with effect of 1 July 2023 was 1.0%, the Netherlands remuneration correction coefficient increased from 111.8% to 114.6%. The employee's pension contribution increased from 10.1% to 11.1% of the basic salary.

4.6.2. Administrative expenditure

This item comprises the expenditure related to the Agency 's building and IT infrastructure and administrative costs.

The increase in the Amsterdam building occupancy costs, namely restaurant and catering costs, maintenance and cleaning, utilities, is mainly due to the return of the Agency's staff to the office.

The maintenance, support and the IT consultancy for development of corporate applications has increased significantly compared to the previous year, due to the continuous investment in the context of the Agency's digitalisation strategy for its corporate processes as well as the implementation of the IT cloud strategy which foresees the Agency transition fully to the cloud by 2025.

<i>Amounts in EUR</i>	2023	2022
Rent for EMA head-lease, Amsterdam	10,929,307.90	10,711,898.90
Service charges and building occupancy costs EMA head-lease, Amsterdam	7,209,448.76	5,343,348.63
Rent for EMA head-lease, London	15,263,557.37	15,852,186.28
Service charges and other building expenses EMA head-lease, London	5,811,578.08	4,937,527.73
Maintenance, support, IT consultancy for corporate processes and applications	43,676,958.78	28,488,401.81
Business consultancy and audit services	3,279,038.04	1,444,786.86
Information and communication services and other administrative expenditure	3,389,784.63	2,831,734.25
Total	89,559,673.56	69,609,884.46

4.6.3. Operating expenditure

This item comprises:

<i>Amounts in EUR</i>	2023	2022
Share of evaluation and annual fees to NCAs	144,173,452.58	136,349,620.84
Share of evaluation of pharmacovigilance procedures fees to NCAs	12,399,366.83	11,697,987.84
Reimbursement of delegates attending meetings	4,901,433.67	2,303,046.86
Translations	4,102,312.90	3,995,335.90
Scientific studies and services	18,127,275.29	12,163,689.32
Data management	2,049,757.83	6,728,070.28
External experts	53,100.00	77,850.00
IT consultancy and development related to business applications	26,698,758.06	11,314,734.64
Total	212,505,457.16	184,630,335.68

The increase in reimbursement costs for delegates attending meetings compared to the previous year is due to the reinstatement of face-to-face scientific committees meeting at the Agency.

IT consultancy and development expenditures relate to costs incurred for the support of large pan-European operational IT applications released in the previous years and to development costs which are expensed because falling below the Agency's threshold of € 1,000,000 for capitalisation of internally generated intangible asset. Note 4.1.1. outlines the intangible asset movements of the year. The significant increase in IT consultancy and development as well as in scientific studies and services costs compared to the previous year, are mainly related to the implementation of the Agency's extended mandate (Regulation 2022/123) from 1 March 2022, bringing considerable changes to the Agency's activities, processes and also expenditure e.g. Darwin EU, Expert panel, IT databases.

4.7. Non-operating activities

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

<i>Amounts in EUR</i>	2023	2022
Remuneration earned on bank accounts balances	1,584,958.70	252,501.31
Financial charges	(16,004.88)	(421,978.82)
Exchange gain (loss) on non-Euro currency transactions	81,854.68	(533,910.72)
Total	1,650,808.50	(703,388.23)

The European Central Bank (ECB) interest rate has been increasing steadily, leading to remuneration being paid on cash balances deposited in banks.

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 2023 of the

financial assets and liabilities held by the Agency in pound sterling and other exchange differences on transactions 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:

Amounts in EUR	Domenico Scarlattilaan 6, Amsterdam - Lease payments			Total
	<1 year	1-5 years	> 5 years	
Rent	9,895,897.89	52,528,623.03	122,027,942.66	184,452,463.58
Building service charge	1,413,699.70	7,504,089.00	17,432,563.24	26,350,351.94
Total	11,309,597.59	60,032,712.03	139,460,505.90	210,802,815.52

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 is 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 1st 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.

The schedule for the estimated future payments to the Canary Wharf landlords in relation to this non-cancellable operating lease (i.e. headlease obligations, namely: rent, service charges and insurance) is as follows:

Amounts in EUR	30 Churchill Place, London - Lease payments			Total
	<1 year	1-5 years	> 5 years	
Rent	16,346,347.16	85,222,064.32	161,921,922.21	263,490,333.70
Building service charge	3,905,036.53	21,354,338.65	50,412,015.42	75,671,390.60
Estate service charge	1,418,523.68	7,757,070.36	18,312,420.46	27,488,014.50
Landlord insurance	458,645.65	2,434,543.47	5,346,992.69	8,240,181.81
Total	22,128,553.02	116,768,016.80	235,993,350.79	374,889,920.60

On 2nd 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.

In November 2023, the subtenant's ultimate parent company (We Work Inc) filed for protection under Chapter 11 of the U.S. Bankruptcy Code. The bankruptcy protection filing concerns the group's branches in the US and Canada only.

Following the filing for bankruptcy, WeWork Inc has been in contact with its landlords including EMA to re-negotiate their leases.

The negotiations were concluded in March 2024 with the submission of the subtenant's final position pertaining to the principles of the future occupancy of the former premises.

In accordance with the discussions held with the EU budgetary authorities and with the consent of its landlord, the Agency has agreed on an amendment of the existing sublease with the subtenant by way of rent reduction and including provisions for either the Agency or the subtenant to early terminate the sublease under certain conditions, before the scheduled expiry date in June 2039.

At the time these final accounts are issued the amendment of the existing sublease covering the relevant terms, clauses and conditions is on-going and the Agency's subtenant continues to carry on operations from its London premises.

The Agency's subtenant has met its contractual obligations for year 2023, with rental payments covering the period up to 31 December 2023.

The Agency has accepted the deferral of the rental payments covering the first three quarters of 2024, until the amendment of the existing sublease contract with the subtenant is signed.

Based on the above elements, the Agency concluded that the operating lease on the Agency's former office premises in London meets the EAR 10 definition and the recognition conditions of a provision for onerous contract (see note 4.3.2).

Before establishing a separate provision for onerous contract, the Agency has recognised a material impairment loss that has occurred on assets dedicated to that contract, namely the lease incentives offered to the subtenant in the form of rent-free period (€ 3.33 million of assets on 31 December 2023 – see note 4.1.4) and cash payments towards rent (€ 11.84 million of assets on 31 December 2023 – see note 4.1.4).

4.8.2. Contingent assets and liabilities

The total amounts payable under the headlease contracts for the EMA former office premises at 30 Churchill Place, London are disclosed in note 4.8.1 on operating leases. In addition, we refer note 3.1.3 on key sources of estimation uncertainty and significant judgements and note 4.3.2 with respect to onerous contract provisions.

Since EMA remains a party to the headlease with its Canary Wharf landlords, should the subtenant not be able to meet its obligations and the sublease early terminated, 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 (€ 374.89 million) and any other financial obligation which would arise as a result of the vacant premises while waiting for the building floors being rented out to new subtenant(s), as for example commercial business rates collected from the leaseholders by the UK local authorities, VAT and other operating costs and utilities,. An estimated total amount of € 550 million is to be viewed as the maximum exposure of the Agency in case of a completely empty building for the period from 01 January 2024 until the expiry of the headlease in June 2039.

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 € 16.01 million, equivalent to the budgetary carry over or RAL i.e. "Reste a liquider", representing the open commitments as at 31 December 2023 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 € 12.86 million.

4.9. Financial assets and financial liabilities risk analysis

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

Cash and cash equivalents are carried in the balance sheet at cost i.e. financial assets measured at amortised cost. They include cash in hand, deposits held at call and short-term deposits with banks.

The Agency implements rigorous cash management, taking account of assigned revenue, in order to ensure that its cash balances are limited to duly justified requirements.

Treasury and payment operations are highly automated and rely on modern information systems.

Specific procedures are applied to guarantee system security and to ensure segregation of duties in line with the Financial Regulation, the Agency's internal control standards, and audit principles.

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

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 4.2.7 and the financial assets referred to in note 4.1.3.

Credit quality analysis

Amounts in EUR	Cash and cash equivalent	Other financial assets
2023		
Counterparties with external credit rating :		
Prime and high grade	96,449,199.66	2,028,896.18
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 (€ 41.04 million) and in note 4.2.3 (€ 53 thousand) and the accrued marketing authorisation fees at note 4.2.4 (€ 67.03 million). Regarding the recoverability of receivables from pharmaceutical companies, there has been no significant reductions in collection or increase in risk in 2023.

In respect of property-related obligations and lease receivable, please refer also to note 3.1.3 on key sources of estimation uncertainty and significant judgements, note 4.3.2 on provision for onerous contracts and note 4.8 on other significant disclosures, dealing with operating leases and contingent liabilities.

31.12.2023	Receivables gross carrying amount	Impairment (-)	Net receivables
Not past due	102,632,920.53		102,632,920.53
Past due 0-30 days	3,612,596.53		3,612,596.53
Past due 31-90 days	709,714.12		709,714.12
Past due 91 days - 1 year	447,353.10		447,353.10
Past due > 1 year	722,781.32	(205,069.62)	517,711.70
Total	108,125,365.60	(205,069.62)	107,920,295.98

Recoverables outside the scope of EAR 11

As outlined in note 4.2.2, because 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). The amount of UK VAT recoverable from the HMRC as at 31 December 2023 amounts to € 784 thousand.

In addition, € 981 thousand of VAT on goods and services invoiced by UK registered entities reclaimed from the UK Foreign Commonwealth and Development Office (FCDO) is past due at 31 December 2023 and a provision is presented on the balance sheet as at 31 December 2023.

The Agency is proactively engaging with the UK FCDO to recuperate the outstanding amount.

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>	31.12.2023	<1 year	1-5 years
Payables with EU entities	2,289,278.13	-	-
Other payables with third parties	76,243,506.88	-	-

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 2023.

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 2023. 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. 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.

Amounts in EUR

31.12.2023	GBP EUR equivalent	EUR	Total EUR
Financial assets	2,064,599.71	204,333,792.11	206,398,391.82
Receivables excluding receivables with EU entities		107,920,295.98	107,920,295.98
Cash and cash equivalent	35,703.53	96,413,496.13	96,449,199.66
Other financial assets	2,028,896.18		2,028,896.18
Financial liabilities	4,810.72	78,527,974.29	78,532,785.01
Payables with third parties	4,810.72	76,238,696.16	76,243,506.88
Payables with EU entities	-	2,289,278.13	2,289,278.13
Net position	2,059,788.99	125,805,817.82	127,865,606.81

Financial assets include € 2.06 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 € 206 thousand. 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.

The Agency's Executive Director is the highest-ranking staff member of the Agency (AD14). The grades of the members of the Executive Board range between A13 and AD12. 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 4.3.2 on provision for onerous contracts and note 4.8 on

other significant disclosures, dealing with operating leases and contingent liabilities. Management is closely monitoring the evolution of this file and may adapt its judgements in the future consistently with this evolution.

The war in Ukraine 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, 2023

<i>Amounts in EUR</i>	2023 Final	2022 Final
REVENUE		
Balancing Commission subsidy	50,136,560.86	49,679,960.14
Other subsidy from Commission	2,887,708.38	750,000.00
Fees and charges related to marketing authorisations	387,090,033.71	364,882,044.13
Other income	21,410,264.29	20,628,237.13
TOTAL REVENUE (a)	461,524,567.24	435,940,241.40
EXPENDITURE		
Title 1 - Staff expenditure		
Payments	149,457,900.29	132,820,479.75
Carry over	9,080,101.39	6,182,261.25
Sub-total	158,538,001.68	139,002,741.00
Title 2 - Administrative expenditure		
Payments	77,366,319.64	59,852,277.29
Carry over	18,170,928.30	17,761,165.03
Sub-total	95,537,247.94	77,613,442.32
Title 3 - Operating Expenditure		
Payments	145,828,227.91	130,849,178.67
Carry over	71,258,494.97	87,286,345.22
Sub-total	217,086,722.88	218,135,523.89
Total Payments	372,652,447.84	323,521,935.71
Total Carry Over	98,509,524.66	111,229,771.50
TOTAL EXPENDITURE (b)	471,161,972.50	434,751,707.21
OUTTURN FOR THE FINANCIAL YEAR (a-b)	(9,637,405.26)	1,188,534.19
Appropriation from previous year which lapses	5,174,935.87	4,455,177.77
Adjustment for carry-over from the previous year of appropriations available at 31.12 arising from assigned revenue	4,401,553.29	5,349,238.90
Exchange differences for the year (gain +/-loss -)	81,854.69	(533,910.72)
BALANCE OF THE OUTTURN ACCOUNT FOR THE FINANCIAL YEAR	20,938.59	10,459,040.14
Balance year N-1	10,459,043.14	24,982,180.86
Positive balance from year N-1 reimbursed in year N to the Commission	(10,459,043.14)	(24,982,177.86)
Balance remaining open to be reimbursed to the Commission in year n+1	20,938.59	10,459,043.14

5.2.1. Reconciliation of economic result with budget result

Amounts in EUR	2023 Final
Economic result (a)	(157,526,773.44)
Adjustments for accrual items (not in budget result)	
Adjustments for expenditure accrual cut-off (reversal 31.12.2022)	(65,886,595.14)
Adjustments for expenditure accrual cut-off (31.12.2023)	67,437,312.86
Payments made from payment appropriations carried over from previous year	101,653,282.34
Other expenditure accrual movements not included in the budget result	38.54
Depreciation of intangible and tangible assets	26,648,270.95
Value reductions	15,178,504.38
Provisions	131,373,712.61
New prefinancing received in year 2023 and remaining open as at 31.12.2023	20,938.59
Recovery orders issued in 2023 not cashed at 31.12.2023	(39,459,119.91)
Adjustments for revenue accrual cut-off (reversal 31.12.2022)	25,134,438.70
Adjustments for revenue accrual cut-off (31.12.2023)	(31,786,843.89)
Other revenue accrual movements not included in the budget result	<u>(555,742.37)</u>
Total accrual items adjustment (b)	229,758,197.66
Adjustments for budgetary items (not in economic result)	
Fixed asset acquisitions (less unpaid amounts)	(20,306,033.60)
Recovery orders issued before year 2023 and cashed in year 2023	37,028,583.46
Payment appropriations carried over to 2024	(98,509,524.65)
Cancellation of unused carry overs payment appropriations from previous year	5,174,935.87
Adjustment for carry-over from the previous year of appropriations available at 31.12 arising from assigned revenue	<u>4,401,553.29</u>
Total budgetary items adjustment (c)	(72,210,485.63)
Budgetary result (a+b+c)	20,938.59
<i>Amount of exchange rate differences included in the budgetary result</i>	<i>81,854.69</i>

5.2.2. Notes to the budget result

In 2023 the Agency had a positive budgetary result for € 20,938.59, to be reimbursed to the Commission in 2024.

The budget result consists of the difference between all the revenue collected in respect of that financial year (€ 461.52 million) and the amount of payments made against appropriations for that financial year (€ 372.65 million) increased by the amount of the appropriations for the same financial year carried over to the following year (€ 98.51 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 (€ 5.17 million) and the adjustment for carry-over from the previous year of appropriations available at 31 December arising from assigned revenue (€ 4.40 million) and, on the other hand, increased or decreased by the balance resulting from exchange gains and losses during the financial year, both realised and non-realised (€ 82 thousand).

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

As the economic result and the budget result both cover the same underlying transactions, it is a useful control to ensure that they are reconcilable. Adjustments for accrual items which are included in the economic result and not in the budgetary result mainly consist of:

- accruals made at year-end for eligible expenses incurred by Agency's for which an invoice has not yet been received;
- the budgetary payments made in the current year from carry-overs from previous years and the reversal of previous year accrued expenses;
- different elements such as asset depreciation and movement in provisions;
- the invoices issued to customers in the current year but not yet collected;
- accruals made at year end for earned revenue for which an invoice has not yet been issued, or, deferrals for invoices issued in relation to revenue to be earned in future;
- 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 2023 budget

In the initial adopted budget, adopted by the EMA management board on 15 December 2022, the amount of appropriations was € 458 million. The revenue and expenditure estimates in the initial budget are typically adjusted during the budgetary year, such modification presented in Amending Budgets. During 2023 one amending budget and ten transfers were adopted, resulting in a final adopted budget of € 448.60 million.

Revenue

<i>Amounts in EUR</i>	Initial adopted budget	Amending budgets and transfers	Final adopted budget	% over total final adopted budget
EC subsidy	50,027,000.00	-	50,027,000.00	11.15%
Fees	407,609,000.00	(9,400,000.00)	398,209,000.00	88.77%
Other revenue	367,000.00	-	367,000.00	0.08%
Total	458,003,000.00	(9,400,000.00)	448,603,000.00	

Expenditure

<i>Amounts in EUR</i>	Initial adopted budget	Amending budgets and transfers	Final adopted budget	Automatic carry over from 2022
I - Staff	158,385,000.00	(500,000.00)	157,885,000.00	6,021,430.30
II - Administrative	72,741,000.00	(153,000.00)	72,588,000.00	13,783,423.80
III - Operating	226,877,000.00	(8,747,000.00)	218,130,000.00	87,023,364.11
Total	458,003,000.00	(9,400,000.00)	448,603,000.00	106,828,218.21

5.3.1. Summary of the implementation of income appropriations

The Agency's revenue consists of subsidy received from the European Commission (EC), fees paid by the pharmaceutical industry for services provided, miscellaneous revenue and assigned revenue.

The Agency has collected total revenue for € 461.52 million. Fees collected in 2023 were € 387.09 million, corresponding to 90.36% of the entitlements established. The Agency has received € 50.14 million subsidy from the European Commission (EC), of which € 20,938.59 million will be reimbursed to the EC in 2024.

<i>Amounts in EUR</i>	Total income appropriations	Entitlements established	Revenue collected	%	Outstanding
EC subsidy	50,027,000.00	50,136,560.86	50,136,560.86	100.00%	-
Fees	398,209,000.00	428,374,863.14	387,090,033.71	90.36%	41,284,829.43
Other revenue	367,000.00	1,638,744.04	1,584,681.43	96.70%	54,062.61
Total	448,603,000.00	480,150,168.04	438,811,276.00		41,338,892.04

Assigned revenue amounted at € 22.71 million, corresponding to 90.46% of the entitlements established.

<i>Amounts in EUR</i>	Total income appropriations	Entitlements established	Revenue collected	%	Outstanding
Assigned revenue	-	25,109,413.16	22,713,291.24	90.46%	2,396,121.92
Sub-total	-	25,109,413.16	22,713,291.24		2,396,121.92

Details of the Agency income for 2023, 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 € 443.25 million corresponding to 98.81% of the total appropriations for the current year budget. Appropriations lapsing amount at € 4.56 million (1.02% of the total appropriations).

<i>Amounts in EUR</i>	Total commitment appropriations	Commitments made	%	Carry over by decision to next year	Appropriations lapsing	%
I - Staff	157,885,000.00	157,063,463.43	99.48%	-	821,536.57	0.52%
II - Administrative	72,588,000.00	71,363,992.14	98.31%	350,000.00	874,007.86	1.20%
III - Operating	218,130,000.00	214,819,672.39	98.48%	450,000.00	2,860,327.61	1.31%
Total	448,603,000.00	443,247,127.96	98.81%	800,000.00	4,555,872.04	1.02%

Payments made were € 347.82 million corresponding to 78.47% of the total commitments. A total of € 95.43 million, corresponding to 21.53% of the total commitments made (21.27% of the final adopted budget), are carried over automatically to the following year.

<i>Amounts in EUR</i>	Commitments made	Payments made	%	Commitments carried over to next year	% of commitments	% of final adopted budget
I - Staff	157,063,463.43	149,381,830.28	95.11%	7,681,633.15	4.89%	4.87%
II - Administrative	71,363,992.14	53,623,733.39	75.14%	17,740,258.75	24.86%	24.44%
III - Operating	214,819,672.39	144,814,908.60	67.41%	70,004,763.79	32.59%	32.09%
Total	443,247,127.96	347,820,472.27	78.47%	95,426,655.69	21.53%	21.27%

Details of the implementation of the Agency current year budget for 2023, 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 95.16% of the appropriations carried over automatically from the previous year.

<i>Amounts in EUR</i>	Total appropriations carried over automatically from previous year	Payments made	%	Appropriations lapsing	%
I - Staff	6,021,430.30	5,584,729.24	92.75%	436,701.06	7.25%
II - Administrative	13,783,423.80	13,090,984.24	94.98%	692,439.56	5.02%
III - Operating	87,023,364.11	82,977,568.86	95.35%	4,045,795.25	4.65%
Total	106,828,218.21	101,653,282.34	95.16%	5,174,935.87	4.84%

Details of the implementation of the Agency carry overs for 2023, 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 (R0) relates to the yearly incentive received by the Dutch government as a reduction of the overall annual rent amount over the life of the lease (20 years); to a contribution received against the maintenance cost and to the prefinancing received by the EC for special projects and programmes (AMA, IMA, IPA, ePI).

<i>Amounts in EUR</i>	Total appropriations	Commitments made	%	Payments made	%	Commitment Appropriations carried over to next year	Payment appropriations carried over to next year
I - Staff	1,474,538.25	83,109.97	5.64%	76,070.01	0.00%	1,391,428.28	1,398,468.24
II - Administrative	2,951,738.10	486,415.10	16.48%	486,415.10	100.00%	2,465,323.00	65,323.00
III - Operating	1,817,050.49	1,033,361.49	56.87%	1,013,319.31	98.06%	783,689.00	803,731.18
Total	6,243,326.84	1,602,886.56	25.67%	1,575,804.42		4,640,440.28	2,267,522.42

Internal assigned revenue (CL) relates to the payments received in relation to the subletting of the Agency's former office premises at 30 Churchill Place, London which is implemented by corresponding equal payments made to the Agency's landlords.

<i>Amounts in EUR</i>	Total appropriations	Commitments made	%	Payments made	%	Commitment Appropriations carried over to next year	Payment appropriations carried over to next year
I - Staff	-	-	-	-	-	-	-
II - Administrative	23,271,517.70	23,256,171.15	99.93%	23,256,171.15	100.00%	15,346.55	15,346.55
III - Operating	-	-	-	-	-	-	-
Total	23,271,517.70	23,256,171.15	99.93%	23,256,171.15		15,346.55	15,346.55

Details of the implementation of the Agency assigned revenue received for 2023 are provided in sections 5.4.4 and 5.4.5 below.

5.4. Details of the implementation of budget revenue 2023 and budget expenditure 2023

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

Amounts in EUR

Budget line	Title	Income appropriations			Entitlements established		
		Initial adopted budget	Amending budgets and transfers	Final adopted budget	Current Year	Carried over	Total
		1	2	3=1+2	4	5	6=4+5
1000	FEES COLLECTED	376,228,000.00	(8,400,000.00)	367,828,000.00	361,938,188.32	38,093,263.20	400,031,451.52
1001	FEES COLLECTED PHARMACOVIGILANCE	31,381,000.00	(1,000,000.00)	30,381,000.00	27,757,844.70	585,566.92	28,343,411.62
2000	EU BASIC CONTRIBUTION	10,633,000.00	3,677,100.00	14,310,100.00	14,421,263.00		14,421,263.00
2010	SPECIAL CONTRIBUTION FOR ORPHAN MEDICINAL PRODUCTS	14,411,000.00	(3,677,100.00)	10,733,900.00	10,733,120.00		10,733,120.00
5200	REVENUE FOR ADMINISTRATIVE ACTIVITIES	27,000.00		27,000.00	1,359,529.40		1,359,529.40
7000	BALANCE OF OUTTURN ACCOUNT OF PREVIOUS YEARS	24,983,000.00		24,983,000.00	24,982,177.86		24,982,177.86
9000	MISCELLANEOUS REVENUE	340,000.00		340,000.00	203,988.37	75,226.27	279,214.64
	Total CURRENT YEAR budget	458,003,000.00	(9,400,000.00)	448,603,000.00	441,396,111.65	38,754,056.39	480,150,168.04
6000	EXTERNAL ASSIGNED REVENUE FOR PROJECTS AND PROGRAMME	-	-	-	3,259,514.78	2,550,000.00	5,809,514.78
6010	INTERNAL ASSIGNED REVENUE	-	-	-	19,299,477.26	421.12	19,299,898.38
	Total ASSIGNED REVENUE budget	-	-	-	22,558,992.04	2,550,421.12	25,109,413.16
	Total REVENUE budget	458,003,000.00	(9,400,000.00)	448,603,000.00	463,955,103.69	41,304,477.51	505,259,581.20

Amounts in EUR

Budget line	Title	Revenue				
		On entitlements of current year	On entitlements carried over	Total	Receipts as % of budget	Outstanding
		7	8	9=7+8	10=9/3	11=6-9
1000	FEES COLLECTED	322,881,131.63	36,334,338.12	359,215,469.75	97.66%	40,815,981.77
1001	FEES COLLECTED PHARMACOVIGILANCE	27,405,009.74	469,554.22	27,874,563.96	91.75%	468,847.66
2000	EU BASIC CONTRIBUTION	14,421,263.00		14,421,263.00	100.78%	-
2010	SPECIAL CONTRIBUTION FOR ORPHAN MEDICINAL PRODUCTS	10,733,120.00		10,733,120.00	99.99%	-
5200	REVENUE FOR ADMINISTRATIVE ACTIVITIES	1,359,529.40		1,359,529.40	5035.29%	-
7000	BALANCE OF OUTTURN ACCOUNT OF PREVIOUS YEARS	24,982,177.86		24,982,177.86	100.00%	-
9000	MISCELLANEOUS REVENUE	150,882.03	74,270.00	225,152.03	66.22%	54,062.61
	Total CURRENT YEAR budget	401,933,113.66	36,878,162.34	438,811,276.00	97.82%	41,338,892.04
6000	EXTERNAL ASSIGNED REVENUE FOR PROJECTS AND PROGRAMME	3,259,514.78	150,000.00	3,409,514.78	N/A	2,400,000.00
6010	INTERNAL ASSIGNED REVENUE	19,303,355.34	421.12	19,303,776.46	N/A	(3,878.08)
	Total ASSIGNED REVENUE budget	22,562,870.12	150,421.12	22,713,291.24	-	2,396,121.92
	Total REVENUE budget	424,495,983.78	37,028,583.46	461,524,567.24		43,735,013.96

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

Amounts in EUR		CARRY OVER PREVIOUS YEAR BUDGET - C8 2023				
Budget line	Heading	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	1,243,105.65	1,219,088.85	98.07%	24,016.80	1.93%
1116	TRAINEES	542,469.65	481,842.04	88.82%	60,627.61	11.18%
1181	ALLOWANCES AND EXPENSES ON ENTERING AND LEAVING THE SERVICE OR ON TRANSFER	25,581.23	25,579.62	99.99%	1.61	0.01%
1200	EXPENDITURE RELATING TO STAFF RECRUITMENT	19,235.87	18,719.97	97.32%	515.90	2.68%
1300	DUTY TRAVEL EXPENSES AND INCIDENTAL EXPENDITURE	90,766.04	57,689.22	63.56%	33,076.82	36.44%
1410	MEDICAL SERVICE	95,870.00	94,274.00	98.34%	1,596.00	1.66%
1420	MISCELLANEOUS WELFARE EXPENDITURE	52,862.50	52,709.60	99.71%	152.90	0.29%
1430	SOCIAL CONTACTS BETWEEN STAFF	61,436.14	47,680.74	77.61%	13,755.40	22.39%
1500	STAFF TRAINING	347,714.42	330,892.79	95.16%	16,821.63	4.84%
1601	INTERIM SERVICES	3,462,793.15	3,206,560.36	92.60%	256,232.79	7.40%
1602	ADMINISTRATIVE ASSISTANCE FROM THE EUROPEAN UNION INSTITUTIONS	49,591.30	19,687.70	39.70%	29,903.60	60.30%
1700	RECEPTIONS AND EVENTS	11,243.35	11,243.35	100.00%	-	0.00%
1701	OPEN ACCESS PUBLICATIONS	18,761.00	18,761.00	100.00%	-	0.00%
2010	INSURANCES	10,821.20	6,460.16	59.70%	4,361.04	40.30%
2030	MAINTENANCE AND CLEANING	345,142.15	336,050.99	97.37%	9,091.16	2.63%
2040	FITTING-OUT OF PREMISES	116,170.07	114,488.91	98.55%	1,681.16	1.45%
2050	SECURITY AND SURVEILLANCE OF BUILDINGS	304,948.48	296,845.44	97.34%	8,103.04	2.66%
2090	UTILITIES AND OTHER BUILDING CHARGES	273,065.03	257,745.64	94.39%	15,319.39	5.61%
2110	HARDWARE AND SOFTWARE	1,096,169.96	1,096,169.96	100.00%	-	0.00%
2114	MAINTENANCE AND SUPPORT OF APPLICATIONS	6,956,763.30	6,456,342.70	92.81%	500,420.60	7.19%
2115	IT CONSULTANCY AND DEVELOPMENT RELATED TO CORPORATE PROCESSES	2,065,250.16	2,043,519.67	98.95%	21,730.49	1.05%
2203	TECHNICAL EQUIPMENT AND INSTALLATIONS	1,331.82	1,331.82	100.00%	-	0.00%
2210	FURNITURE	3,335.00	-	0.00%	3,335.00	100.00%
2300	STATIONERY AND OFFICE SUPPLIES	1,842.31	576.66	31.30%	1,265.65	68.70%
2320	FINANCIAL CHARGES	1,500.00	1,473.00	98.20%	27.00	1.80%
2330	LEGAL EXPENSES AND ASSOCIATED COST	286,329.49	246,233.44	86.00%	40,096.05	14.00%
2359	OTHER OPERATING EXPENDITURE	5,103.66	4,441.80	87.03%	661.86	12.97%
2400	POSTAL AND DELIVERY SERVICES	1,167.18	944.79	80.95%	222.39	19.05%
2501	MEMBERSHIPS WITH PROFESSIONAL BODIES AND ORGANISATIONS	24,015.00	24,000.00	99.94%	15.00	0.06%
2600	RESTAURANT AND CATERING	181,421.03	149,404.72	82.35%	32,016.31	17.65%
2700	INFORMATION AND COMMUNICATION SERVICES	361,048.76	321,175.34	88.96%	39,873.42	11.04%
2800	BUSINESS CONSULTANCY AND AUDITS SERVICES	1,716,814.20	1,702,594.20	99.17%	14,220.00	0.83%
2801	AUDIT SERVICES	31,185.00	31,185.00	100.00%	-	0.00%
3000	REIMBURSEMENT OF PERSONS ATTENDING MEETINGS	145,864.06	126,973.01	87.05%	18,891.05	12.95%
3003	OTHER EXPENDITURE IN RELATION TO MEETINGS	8,385.00	1,935.00	23.08%	6,450.00	76.92%
3010	EVALUATION OF MEDICINAL PRODUCTS	31,623,386.36	31,034,901.36	98.14%	588,485.00	1.86%
3013	EVALUATION OF PHARMACOVIGILANCE PROCEDURES	3,421,974.06	3,413,592.06	99.76%	8,382.00	0.24%
3020	TRANSLATION CENTRE LUXEMBOURG	357,421.20	357,421.20	100.00%	-	0.00%
3030	SCIENTIFIC STUDIES AND SERVICES	18,495,973.49	16,594,534.74	89.72%	1,901,438.75	10.28%
3031	DATA MANAGEMENT	1,124,836.30	1,046,216.11	93.01%	78,620.19	6.99%
3032	EXTERNAL EXPERTS	1,392,750.00	78,075.00	5.61%	1,314,675.00	94.39%
3105	BUSINESS IT CONSULTANCY AND DEVELOPMENT	30,452,773.64	30,323,920.38	99.58%	128,853.26	0.42%
	Total	106,828,218.21	101,653,282.34	95.16%	5,174,935.87	4.84%

5.4.4. Implementation of external assigned revenue (R0)

Amounts in EUR

Budget line	Heading	EXTERNAL ASSIGNED REVENUE - R0 2023						
		Budget implementation						
		Appropriations	Commitments made	% Committed	Payments made	% Paid	Commitment Appropriation carried over	Payment Appropriation carried over
		1	2	(2/1)	3	(3/1)	4 (1-2)	5 (1-3)
1100	BASIC SALARIES	920,980.28	-	0.00%	-	0.00%	920,980.28	920,980.28
1300	DUTY TRAVEL EXPENSES AND INCIDENTAL EXPENDITURE	384,538.97	1,658.97	0.43%	1,658.97	0.43%	382,880.00	382,880.00
1500	STAFF TRAINING	55,256.00	-	0.00%	-	0.00%	55,256.00	55,256.00
1601	INTERIM SERVICES	103,943.00	81,451.00	78.36%	74,411.04	71.59%	22,492.00	29,531.96
1700	RECEPTIONS & EVENTS	9,820.00	-	0.00%	-	0.00%	9,820.00	9,820.00
2000	RENT	2,550,000.00	150,000.00	5.88%	150,000.00	5.88%	2,400,000.00	-
2030	MAINTENANCE AND CLEANING	336,415.10	336,415.10	100.00%	336,415.10	100.00%	-	-
2700	INFORMATION & COMMUNICATION SERVICES	39,622.00	-	0.00%	-	0.00%	39,622.00	39,622.00
2800	BUSINESS CONSULTANCY AND AUDIT SERVICES	25,701.00	-	0.00%	-	0.00%	25,701.00	25,701.00
3000	REIMBURSEMENT OF PERSONS ATTENDING MEETINGS	413,884.00	172,268.00	41.62%	152,225.82	36.78%	241,616.00	261,658.18
3003	OTHER MEETINGS EXP	96,377.00	-	0.00%	-	0.00%	96,377.00	96,377.00
3020	TRANSLATION CENTRE LUXEMBOURG	32,345.00	-	0.00%	-	0.00%	32,345.00	32,345.00
3030	SCIENTIFIC STUDIES & SERVICES	179,904.00	-	0.00%	-	0.00%	179,904.00	179,904.00
3032	EXTERNAL EXPERTS	233,447.00	-	0.00%	-	0.00%	233,447.00	233,447.00
3105	BUSINESS IT CONSULTANCY & DEVELOPMENT	861,093.49	861,093.49	100.00%	861,093.49	100.00%	-	-
Total Expenditure		6,243,326.84	1,602,886.56		1,575,804.42		4,640,440.28	2,267,522.42

5.4.5. Implementation of internal assigned revenue (CL)

Amounts in EUR

Budget line	Heading	INTERNAL ASSIGNED REVENUE - CL 2023						
		Budget implementation						
		Appropriations	Commitments made	% Committed	Payments made	% Paid	Commitment Appropriation carried over	Payment Appropriation carried over
		1	2	(2/1)	3	(3/1)	4 (1-2)	5 (1-3)
2000	RENT	15,626,179.73	15,626,179.73	100.00%	15,626,179.73	100.00%	-	-
2010	INSURANCES	465,770.45	465,770.45	100.00%	465,770.45	100.00%	-	-
2090	UTILITIES AND OTHER BUILDING CHARGES	7,179,567.52	7,164,220.97	99.79%	7,164,220.97	99.79%	15,346.55	15,346.55
Total Expenditure		23,271,517.70	23,256,171.15		23,256,171.15		15,346.55	15,346.55