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Executive Director

## Report on budgetary and financial management

Financial year 2021

### Contents

<b>1. Introduction .....</b>	<b>2</b>
<b>2. 2021 work programme vs. budget.....</b>	<b>3</b>
<b>3. Financial management in general .....</b>	<b>4</b>
3.1. Performance against KPIs.....	4
3.2. Budget overview .....	4
3.3. Revenue (recovery orders and cash).....	5
3.4. Expenditure (commitments and payments) .....	6
3.5. Implementation of appropriations carried forward from 2020 to 2021 .....	9
3.6. Appropriations carried forward from 2021 to 2022.....	9
3.7. Budget transfers .....	9
3.8. Amending budget .....	10
3.9. Cancellation of appropriations.....	11
3.10. Payment of interest on late payments .....	11
<b>4. Financial management by chapter .....</b>	<b>12</b>
4.1. Revenue.....	12
4.2. Expenditure.....	13
5. Appropriations from assigned revenue, fund sources R0 & CL .....	13
Annex I – Budget evolution .....	15
Annex III – Summary of transfers.....	19



# 1. Introduction

This report summarises the outcomes of the budgetary and financial management carried out by the European Medicines Agency during the financial year 2021. It outlines the financial situation, budget evolution and the events which had a significant influence on activities during the year.

It provides qualitative and quantitative information on the operational performance of the past financial year, reports in more detail on any difficulties in the implementation of the budget and provides additional, useful information for the budgetary authority and the European Court of Auditors.

It is issued in accordance with Art. 64 of Regulation (EC) No726/2004 of the European Parliament and of the Council, of 31 March 2004, and Article 103 of the EMA's Financial Regulation of 1 July 2019.

The European Medicines Agency is a fee-funded agency, with 89.37% of its 2021 revenue stemming from fees paid by the pharmaceutical industry for services provided.

## Highlights for 2021

- ✓ The COVID-19 pandemic continued to have a profound impact on the Agency's activities, also in 2021, with staff working from home and most meetings conducted online. Thanks to the resilience of the Agency's IT infrastructure, and, not least its staff, the Agency was able to continue delivering on its core responsibilities.
- ✓ Due to the unpredictability of restrictions linked to the pandemic, funds were maintained to cover expenditure which could be affected by these restrictions. At the end of the year, budgetary savings were thus seen on several budget lines, in particular related to meeting and duty travel expenditure, some staff related measures as well as some expenditure on building/facilities where activities could not go ahead.
- ✓ The draft financial outturn, a surplus of approx. EUR 24.98 million, representing 6.13% of total revenue, was caused partly by higher than budgeted fee-related income being collected at the end of the year, and partly by under-consumption of expenditure appropriations, across all three expenditure titles. Annex I has more details.
- ✓ The agency managed to achieve outcomes close to the guidance ceilings for amounts carried forward (C1 to C8): title I (10%), title II (20%) and title III (30%), with the following percentages realised: title I: 5.75%, title II: 24.31%, title III: 37.59%. More details can be found under point 3.6 below.
- ✓ 11 transfers were carried out in 2021. Transferred appropriations mainly funded an increase in IT projects and activities and an increase in activities related to scientific applications (rapporteurs and scientific studies). Point 3.7 below provides more details.
- ✓ The adopted budget was decreased through an amending budget (AB01), which reduced the amount of provisional appropriations earmarked for activities related to the Agency's extended mandate, while increasing expected fee revenue. The increased fee revenue provided more funds to cover expected staff cost, IT projects and activities, and an increase in assessment activities related to scientific applications. In agreement with the European Commission, the funding for the extended mandate was postponed until 2022 and 2023. Point 3.8 below provides more information.
- ✓ The Agency received external assigned revenue stemming from incentives from the Dutch government and internal assigned revenue stemming from the sub-letting of its former

headquarters in London. In accordance with the Financial Regulation, these funds are managed outside the adopted budget. Detailed reporting is included under point 5 below.

This report should be read in conjunction with other reports in order to have the full picture of the agency's budgetary and financial management. For information about the agency's business objectives and the level of achievement, please refer to the Annual Activity Report and the Annual Report. For further financial information, please refer to the financial accounts.

## **2. 2021 work programme vs. budget**

The 2021 budget should be considered in conjunction with the 2021 work programme in that it sets out the financial and human resources necessary for the implementation of the work programme.

### **Constraints**

2021 saw a number of constraints impacting the realisation of the Agency's work programme, with business continuity planning in place throughout due to the COVID-19 pandemic. This resulted in some activities being put on hold, delayed or scaled back, with knock-on effects on the implementation of the budget.

The establishment plan saw a considerable increase by 61 temporary agent (TA) posts to 657, up from 596 in 2020, an increase of 9.28%. 40 short-term TA posts were justified by the additional workload caused by the pandemic, while 21 TA posts were earmarked for activities related to the implementation of the agency's extended mandate.

There was a small net decrease in the number of contract agents (CA), from 228 to 226. While 8 new CA positions were allocated for activities related to the extended mandate, there was a reduction by 10 CA positions earmarked for 'Brexit', of a total of 40 initially allocated in 2019 and gradually being reduced.

As an indicator of the increase in core activities, please note that fee income increased by 7.80%, with a corresponding impact on scientific assessments.

Despite the additional resources available in the establishment plan, the workload caused by the pandemic continued to put human resources under considerable pressure. A number of interim contractors was deployed in an attempt to address this.

### **Mid-year review**

The mid-year review of the work programme and budget resulted in the identification of additional fee revenue which was allocated to activities identified by the Agency's Executive Board (EXB), mainly in the areas of IT projects and rapporteur assessments. Moreover, the review concluded that the preparatory activities foreseen for the implementation of the Agency's extended mandate could not proceed in 2021 and, as a consequence, the available appropriations would not be implemented in full.

The mid-year review therefore resulted in an amending budget, adopted by the Management Board in September. Point 3.8 below provides more details.

## 3. Financial management in general

### 3.1. Performance against KPIs

The key performance indicators (KPIs) applicable to the implementation of the budget are listed in the table below:

**Table 1: KPIs for budget implementation**

		target	2021 result	2020 result
1.	Implementation of expenditure appropriations, C1	95%	96.38%	98.83%
2.	Implementation of payment appropriations, C1 and C8	95%	95.80%	98.41%
		<b>guidance</b>		
3.	Implementation of revenue appropriations	95-105%	99.87%	104.30%
4	Maximum rate of carryover to year N+1 of total commitments within title			
4.a	Title I, staff expenditure	10%	5.75%	4.62%
4.b	Title II, infrastructure and operating expenditure	20%	24.31%	20.71%
4.c	Title III, operational expenditure	30%	37.59%	31.47%
	Average		24.92%	20.61%

These performance indicators are important measurements of the Agency's budget management, used internally and are also subject to scrutiny by the European Commission and the budget authority (Council and European Parliament).

Moreover, failure to meet the targets for the implementation of appropriations (KPIs 1 and 2 above), can have consequences for the amount of EU contribution paid to the Agency's budget in the subsequent year, causing a 2% reduction in the amount of the contribution for each KPIs missed (i.e. a total reduction of 4%, but only on the contribution received from the EU budget).

The ceilings under KPI 4 are those applied by the European Court of Auditors for their audit work and are for guidance only.

Carry-forward to 2022 (C8) has increased for all titles, but particularly for titles II and III. The Agency is reviewing internal procedures in order to bring these values back down. See also point 3.6 below.

### 3.2. Budget overview

Authorised appropriations in the initial budget totalled EUR 385,919,000, representing a 7.78% increase over the 2020 initial budget (EUR 358,071,000).

One amending budget was processed in 2021 in order to increase expected revenue from scientific applications, decrease revenue from the 2021 EU contributions to match revised expectations for activities related to the Agency's extended mandate, and increase miscellaneous revenue in order to enable regularisation of payments related to the subletting of 30CP. The resulting final budget amounted to EUR 379,288,000. See also point 3.8 below.

A table summarising the evolution of the budget can be found at Annex I, which compares the outturn against the initially adopted budget and against the 2020 outturn.

Annex II provides details of the implementation of assigned revenue and Annex III details of transfers carried out in 2021.

### 3.3. Revenue (recovery orders and cash)

As stipulated in the Financial Regulation, budget revenue is based on cash received in terms of fees for applications for marketing licenses for pharmaceutical products and for post-authorisation activities, contributions from the European Union, as well as for various administrative activities.

Total C1 cash revenue entered in the accounts as of 31 December 2021 amounted to EUR 382,156,343.70 (2020: EUR 376,246,022.54).

Of total C1 income, 89.40% derived from the evaluation of medicines and other business-related activities, 9.85% from the European Union budget to fund various public health and harmonisation activities, and 0.75% from various sources (2020: 84.22%/15.65%/0.13%).

Assigned revenue (external, R0, and internal, CL), which is handled outside the adopted budget, totalled EUR 25.45 million, cf. point 5 below for more details.

The chart below provides the breakdown by type of revenue in the adopted budget, i.e. fund source C1.

**Figure 1: breakdown of C1 revenue by type**

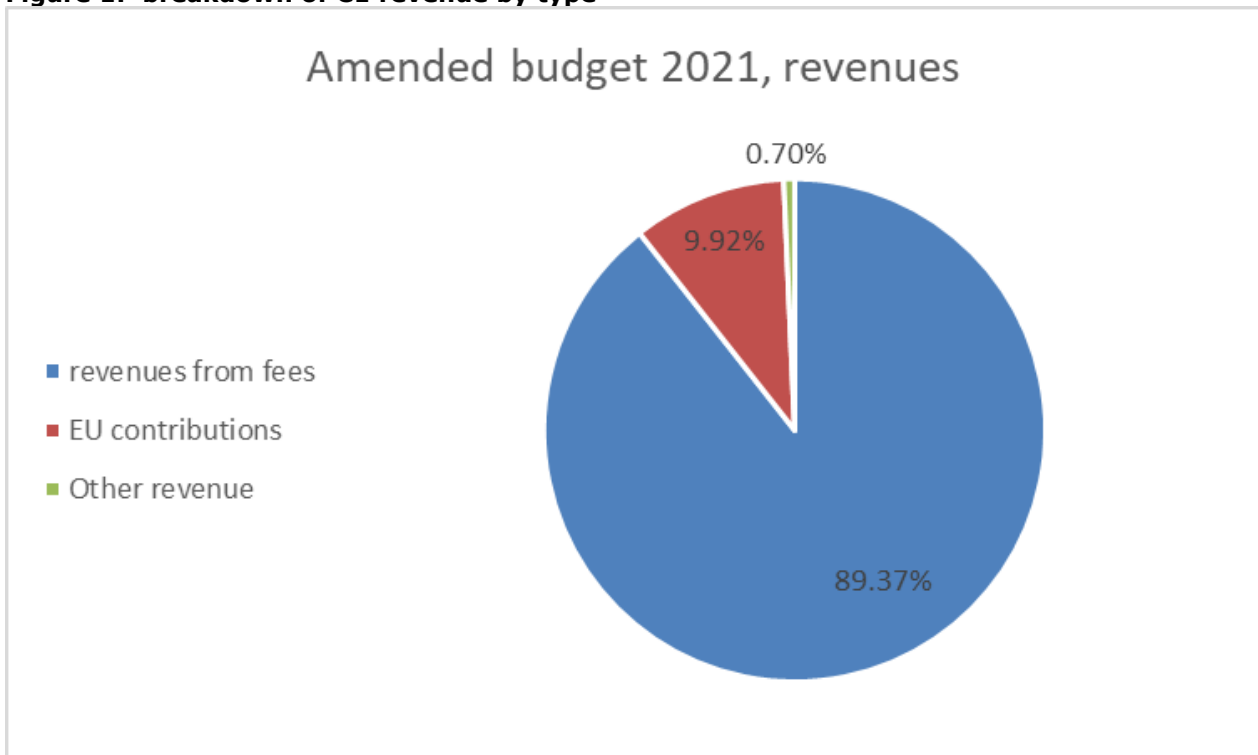


Table 2 below details the implementation of the revenue budget of the European Medicines Agency.

**Table 2: implementation of 2021 revenue appropriations**

Appropriation type	EUR or %
<b>I. Appropriations in general</b>	
Initial appropriations	385,919,000.00
Amending budget	-6,691,000.00
Final appropriations	379,228,000.00
<b>II. Use of appropriations</b>	
Recovery orders 2021 and earlier	458,988,914.91
Representing in % of final appropriations	121.03%
Cash-receipts against recovery orders 2021 and earlier, C1 & C11	382,156,343.70
Representing in % of final recovery orders	83.26%
<b>III. Amounts established in 2021</b>	
Recovery orders 2021 only	378,744,244.70
Representing in % of final appropriations	99.87%
Cash-receipts against recovery orders 2021 only	356,805,594.31
Representing in % of final recovery orders	94.21%
<b>IV. Amounts unpaid from 2021 to be paid in 2022 or later</b>	
Recovery orders for the evaluation of medicinal products (fees)	48,662,567.66
Other recovery orders	2,724,117.31
<b>V. Amounts unpaid in 2020 or earlier, paid in 2021</b>	
Recovery orders for the evaluation of medicinal products (fees)	43,774,871.59
Other recovery orders	6,871,764.04
<b>VI. Total revenue, C1 and C11</b>	<b>382,156,343.70</b>
<b>VII. Waivers and cancellations of amounts receivable</b>	
Recovery orders waived or cancelled by the authorising officer in accordance with Article 66 Financial Regulation	109,161.92
<b>VIII. Waivers of fees and charges (excluding waivers for orphan medicines )</b>	
Reductions deriving from paediatric or micro, small- and medium sized enterprises, advanced therapies and variations legislation	35,213,428.56
Other reductions in accordance with Article 9 of the Fee Regulation	10,834,351.00

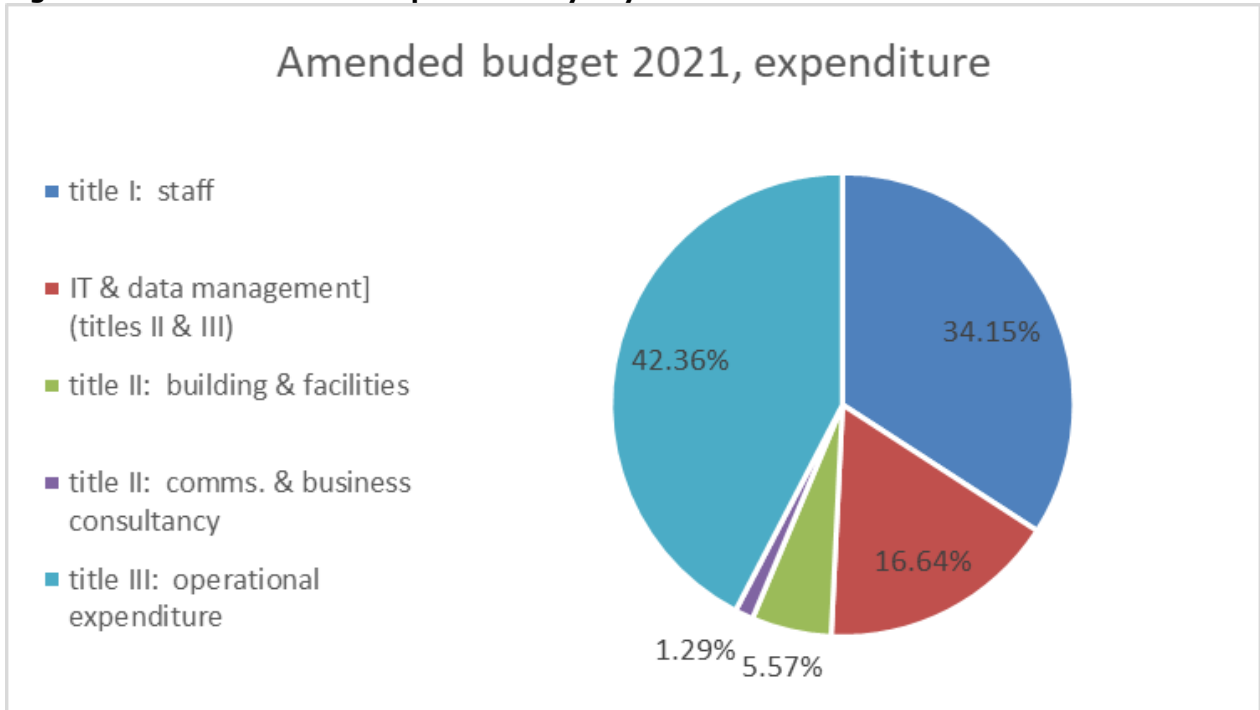
### **3.4. Expenditure (commitments and payments)**

Of the adopted budget, i.e. fund source C1, commitments totalled EUR 365,490,700.73, or 96.38% of final appropriations (2020: 98.83%). Payments totalled EUR 274,400,002.19, or 75.08% of commitments (2020: 79.39%). For details on the implementation of expenditure see table 3 below.

The chart below provides a breakdown of types of expenditure by business area.

The use of expenditure appropriations stemming from assigned revenue (R0 and CL) is detailed under point 5 below.

**Figure 2: breakdown of C1 expenditure by key business area**



**Table 3: implementation of 2021 expenditure appropriations**

<b>Appropriation type</b>	<b>EUR or %</b>
<b>I. Appropriations in general</b>	
Initial appropriations	385,919,000.00
Amending budget	-6,691,000.00
Final appropriations	379,228,000.00
<b>II. Use of 2021 appropriations</b>	
Commitments	365,490,700.73
Representing of final appropriations	96.38%
Payments	274,400,002.19
Representing of final commitments	75.08%
<b>III. Carry-over from 2021 to 2022</b>	
<i>Carry-over of administrative appropriations</i>	18,825,656.56
<i>Carry-over of operational appropriations</i>	72,265,041.98
Total automatic carry-over	91,090,698.54
Representing of final appropriations	24.02%
Representing of final commitments	24.92%
<b>IV. Cancellation of 2021 appropriations</b>	
Appropriations cancelled	13,737,299.27
Representing of final appropriations	3.62%
<b>V. Carry-over from 2020 to 2021</b>	
<b>Automatic carry-over, C8</b>	
<i>Carry-over of administrative appropriations</i>	22,467,468.91
<i>Carry-over of operational appropriations</i>	52,833,467.15
Total automatic carry-over	75,300,936.06
Payment against carry-over	69,928,804.85
Total automatic carry-over unused	5,372,131.21
Representing of carry-over	92.87%
<b>VI. Total expenditure, C1 and C8</b>	<b>365,490,700.73</b>

### 3.5. Implementation of appropriations carried forward from 2020 to 2021

Automatic carry-forward from financial year 2020 to 2021, i.e., fund source C8, totalled EUR 75,300,936.06. Payments against these appropriations equalled EUR 69,928,804.85 (92.87%) of appropriations (2020: 95.49%) and EUR 5,372,131.21 were cancelled.

**Table 4: automatic carry-forward from 2020 to 2021, per title**

Title	Total commitments	of which carried over	
	EUR	EUR	%
1: Staff expenditure	114,634,112.13	5,292,521.64	4.62%
2: infrastructure and operating expenditure	82,926,883.31	17,174,947.27	20.71%
3: Operational expenditure	167,872,236.49	52,833,467.15	31.47%
<b>Total</b>	<b>365,433,231.93</b>	<b>75,300,936.06</b>	<b>20.61%</b>

### 3.6. Appropriations carried forward from 2021 to 2022

Automatic carry-forward to financial year 2022, C1 to C8, totalled EUR 91,090,698.54, or 24.92% of appropriations.

**Table 5: automatic carry-over from 2021 to 2022, per title**

Title	Total commitments	of which carried over	
	EUR	EUR	%
1: Staff expenditure	125,481,672.60	7,215,451.81	5.75%
2: infrastructure and operating expenditure	47,758,404.57	11,610,204.75	24.31%
3: Operational expenditure	192,250,623.56	72,265,041.98	37.59%
<b>Total</b>	<b>365,490,700.73</b>	<b>91,090,698.54</b>	<b>24.92%</b>

As a guideline, carry-forward should remain below ceilings of 10%, 20% and 30%, for titles 1, 2 and 3, respectively.

Carry forward in title 3, operational expenditure, increased mainly as a consequence of commitments and contracts being put in place towards the end of the year, for work and services to be delivered mainly in 2022, which resulted in the relevant commitments being carried forward.

### 3.7. Budget transfers

In line with Art. 26 of the Financial Regulation, the Executive Director may make unlimited transfers within a title and of up to 10% of appropriations from one title to another. Transfers *per se* are not an indication of deficiencies in budget management but are a necessary tool to adjust the budget in a changing environment, e.g. resigning staff members receiving allowances related to their departure rather than their salaries, increased expenditure due to exchange rate fluctuation, etc.

During 2021 one transfer exceeded the 10% ceiling for transfer between titles, thus requiring Management Board approval. Of the eleven transfers, all involved expenditure appropriations and one also revenue appropriations.

The transferred expenditure appropriations were primarily needed to cover additional commitments for rapporteur payments and scientific studies, due to the increase in the number of scientific applications and the COVID-19 pandemic, as well as IT project development, data management and interim contractor services, as approved by the EXB.

Annex III provides details of all transfers carried out in 2021.

### **3.8. Amending budget**

The mid-year review of the work programme and budget resulted in the identification of an increase of revenue from scientific applications, estimated at EUR 8,522,000.

The budget as initially adopted included appropriations for activities related to the implementation of the Agency's extended mandate. When it became apparent that some of these activities would not commence in 2021, it was agreed that the Agency would not claim the full amount available in 2021, but only in 2022 and 2023, when the activities would start. With the agreement of DG SANTE, a total of EUR 17,811,000 was deferred to 2022 (EUR 14,000,000) and 2023 (EUR 3,811,000).

Finally, appropriations for miscellaneous revenue was increased by EUR 2,660,000 in order to regularise a one-off payment related to the Agency's subletting of its previous headquarters in London as well as an insurance pay-out and other minor regularisations.

As such, the amending budget decreased revenue by a net total of EUR 6,691,000.

The EXB decided to allocate the expenditure appropriations to a number of activities:

Title I, staff expenditure

- various salary budget lines to cover the expected increase in staff numbers and the impact of the annual salary adjustment;
- estimated increase in cost related to the secondment of national experts;
- estimated cost of input from the Commission's DIGIT to work related to a project on real world data;

Title II, infrastructure and operating expenditure

- estimated cost of cyber security activities;
- estimated cost of impact of negative bank interests;

Title III, operational expenditure

- estimated increase in payments to rapporteurs, as a consequence of the expected increase in scientific application, following the July review of the fee forecast;
- estimated increase in cost of translations, including expected increase in workload caused by the pandemic;

Title IX, provisional appropriations

- provisional appropriations were reduced in line with the plan for activities related to the Agency's extended mandate.

**Table 6: amending budget 01-21**

	budget line	fund source	comment	amount
	1000R	C1	Fees collected (Reg. (EU) 297/95)	8,735,000
	1001R	C1	Fees collected (Regulation (EU) 658/2014)	-213,000
	2000R	C1	European Union and EEA contribution	-15,620,155
	2010R	C1	Special contribution for OMPs and EEA contribution	-2,190,845
	5200R	C1	Revenue from administrative activities and ancillary services	-62,000
	9000R	C1	Miscellaneous revenue	2,660,000
<b>TOTAL</b>				<b>-6,691,000</b>
	1100	C1	Basic salaries	307,000
	1115	C1	Seconded national experts & visiting experts	386,000
	1190	C1	Weightings	1,639,000
	1601	C1	Interim services	1,312,000
	1602	C1	Administrative assistance from EU institutions	650,000
	2114	C1	Maintenace & support of applications	2,500,000
	2320	C1	Financial charges	200,000
	3010	C1	Evaluation of medicinal products	3,626,000
	3020	C1	Translation Centre, Luxembourg	500,000
	9000	C1	Provisional appropriations	-17,811,000
<b>TOTAL</b>				<b>-6,691,000</b>

### **3.9. Cancellation of appropriations**

Expenditure appropriations should be understood as estimates of requirements, and not as an entitlement to create the corresponding commitments. Being reliant on fee income, as the agency is, this means that the level of cancelled expenditure appropriations does not indicate delays in the implementation of the work programme, but should rather be considered the result of stringent monitoring of actual revenue and adjustments to the expenditure.

Of the amended budget, expenditure appropriations totalling EUR 13,737,299.27 remained unused, corresponding to 3.62% of final appropriations (2020: EUR 4,315,768.07, 1.17%).

The underuse of commitment appropriations is considered to be within the acceptable range, with 3.19% of appropriations cancelled in title I (staff expenditure), 11.91% in title II (infrastructure and operating expenditure) and 1.61% in title III (operational expenditure). Details can be found in Annex I.

### **3.10. Payment of interest on late payments**

In compliance with the Agency's standard contract, established in accordance with Art. 77 of the Financial Regulation, the terms of payment are 30 days upon receipt of a valid invoice. If these terms are not respected, from day 31 until the actual day of payment, default interest accrues at the rate

applied by the European Central Bank to its principal refinancing operations, as published in the C series of the Official Journal of the European Union, increased by 8%<sup>1</sup>. The default interest accrued is paid automatically to the supplier/contractor if it amounts to more than EUR 200 at the time of payment of the valid invoice.

In 2021, 886 payments out of a total of 26,076, i.e. 3.40% of all payments, were made later than 30 days after receipt of a valid invoice (2020: 4.35% of all payments). This resulted in default interest of EUR 5,095.00 being paid to suppliers and contractors (2020: EUR 12,638.45).

**Table 7: breakdown of late payments and default interest**

	Payments		Of which late payments		Interest accrued	Interest =>
	Number	EUR	Number	EUR	EUR	EUR 200
Supply and other services	18,558	226,346,802	99	2,777,377	8,096	5,095
Evaluation services (NCAs)	7,503	128,975,956	787	11,536,815		

## 4. Financial management by chapter

Hereafter follows further analysis of the evolution of revenue (based on cash collected) and expenditure (based on commitments) in 2021. It contains information at title/chapter/article level for revenue and expenditure. Detailed information per chapter, for both revenue and expenditure, can be found in Annex I.

### 4.1. Revenue

#### 4.1.1. Stable vs. cyclical revenue

In budgetary terms, EUR 148.3 million (38.82% of total 2021 revenues) represent the proportion which can be considered stable, since it relates to annual product maintenance fees received for both human and veterinary medicines activities, and EU contributions. In contrast, 60.43% of total revenue depended on cyclical business activities.

**Table 8: Stable and cyclical sources of revenue**

	2020 Actual	% of total	2021 Actual	% of total
Stable revenue for the Agency	147,032,842	39.08%	148,337,314	38.82%
<i>EU subsidies and contributions</i>	45,078,000	11.98%	37,636,730	9.85%
<i>Annual fees</i>	101,954,842	27.10%	110,700,584	28.97%
Cyclical business revenue	214,933,977	57.13%	230,937,468	60.43%
Revenue from miscellaneous activities	14,279,204	3.80%	2,881,562	0.75%
<b>Total revenue</b>	<b>376,246,023</b>	<b>100.00%</b>	<b>382,156,344</b>	<b>100.00%</b>

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

Art. 66 of the Financial Regulation stipulates that recoveries established can, under certain, well-defined circumstances, be partly or fully waived by the authorising officer.

In 2021, recovery orders for a total of EUR 109,161.92<sup>2</sup> were waived.

<sup>1</sup> Cf. Article 116 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council

<sup>2</sup> Cf. Article 101 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council; any waiver for an amount above a value of €60,000 must be reported separately.

One waiver amounted to EUR 91,909.23 and related to interest charged on a late payment from the sub-tenant of 30CP, which was waived in line with UK economic support measures for tenants in place during the lock-down.

The remaining waivers covered multiple debtors and invoices for parallel distribution charges and pharmacovigilance fees where the insolvency of the debtors had been confirmed in writing or there was evidence of the status of the company in the national register; and a small amount of outstanding debt older than five years.

## 4.2. Expenditure

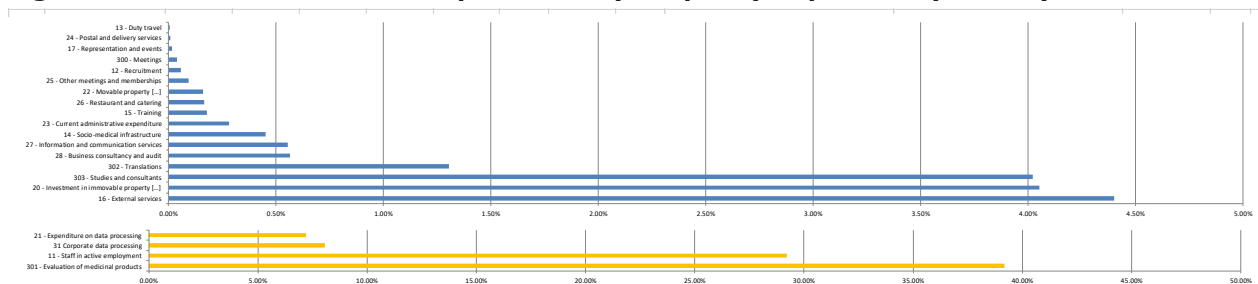
### 4.2.1. Details on expenditure items

In 2021 the four chapters and articles with the highest amounts committed accounted for 83.64% of total commitments (2020: top three chapters and articles accounted for 88.28% of total commitments). They were:

- Article 301 'Evaluation of medicinal products', 39.17% (2020: 36.55%),
- Chapter 11 'Staff in active employment', 29.22% (2020: 28.73%),
- Chapter 31 'Expenditure on business related IT development', 8.06% (2020: 5.60%),
- Chapter 21 'Information and communication technology', 7.19% (2020: 8.85%).

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

**Figure 3: Distribution of 2021 expenditure by chapter (chapter 30 by article):**



## 5. Appropriations from assigned revenue, fund sources R0 & CL

The Agency's available appropriations in 2021 included external and internal assigned revenue. In accordance with the revised Financial Regulation which came into effect on 1 July 2019, this revenue, matched by expenditure appropriations, is managed outside the adopted budget and under separate fund sources, i.e. R0 for external assigned revenue, and CL for internal assigned revenue.

The vast majority of the assigned revenue relates to the Agency's office buildings, with the remainder relating to grants received from the EU budget to fund projects within the IMI and IPA programmes. Due to the restrictions imposed by the pandemic, these programmes saw no activities in 2021, and hence no expenditure was incurred.

**Table 9: Assigned revenue, 2021**

<b>I. External assigned revenue, R0</b>	
Recovery orders	3,201,960.42
Cash receipts against recovery orders	501,960.42
Representing in % of recovery orders	15.68%
Recovery orders carried forward	2,700,000.00
<b>Total revenue, R0</b>	<b>501,960.42</b>
<b>II. Internal assigned revenue, CL</b>	
Recovery orders	24,960,246.86
Cash receipts against recovery orders	24,943,925.82
Representing in % of recovery orders	99.93%
Recovery orders carried forward	16,321.04
<b>Total revenue, CL</b>	<b>24,943,925.82</b>
<b>III. Total revenue, R0, CL</b>	<b>25,445,886.24</b>

**Table 10: Assigned revenue, 2021, expenditure appropriations**

<b>I. External assigned revenue, R0, expenditure appropriations</b>	784,241.70
Payments	476,545.27
<i>Carried forward to 2022</i>	<i>307,696.43</i>
<b>II. Internal assigned revenue, CL, expenditure appropriations</b>	<b>24,943,925.82</b>
Payments	19,902,383.62
<i>Carried forward to 2022</i>	<i>5,041,542.20</i>
<b>III. Total expenditure, R0, CL</b>	<b>20,378,928.89</b>

**Background information**

External assigned revenue (R0) stems mainly from inducements related to the Agency's new headquarters in Amsterdam. In 2021, EUR 501,960.42 were received.

Internal assigned revenue (CL) stems from payments of rent, service and other charges received from the sub-tenant of the Agency's former headquarters in London. This revenue matches the payments made to the Agency's landlord in London. In 2021, EUR 24.9 million were received, and expenditure amounting to EUR 19.9 million incurred.

While R0 and CL appropriations do not expire, the revenue and expenditure must balance over time.

Further details on the implementation of both fund sources can be found at Annex II.

## Annex I – Budget evolution

### Revenue, deviation from adopted budget and comparison against 2020 revenue

Item	Heading	2020	2021	2021	2021	Change, 2020-2021		2021 budget vs. recovery orders	Deviation, 2021 budget vs. implementation	Evolution, 2021 vs. 2020	
		recognised income	adopted budget	final budget	recognised income	EUR	%	EUR			%
1000	Fees collected (Regulation (EU) 297/95)	291,631,351.43	302,127,000.00	310,862,000.00	314,344,159.26	22,712,807.83	7.79%	3,482,159.26	1.12%	Appropriations were increased by EUR 8,735,000 through amending budget 01-21, to match expected fee income in accordance with the outcome of the mid-year review.	Fee income from evaluation services is the main source of revenue for the agency, representing 82.26% of 2021 revenue (2020: 77.51%). The value of recovery orders / invoices for fees, reflecting the level of activities, rose by 7.99% when compared to 2020, whereas the value of cash-receipts increased by 7.79%.
1001	Fees collected (Regulation (EU) 658/2014)	25,257,467.08	28,282,000.00	28,069,000.00	27,293,085.61	2,035,618.53	8.06%	- 775,914.39	-2.76%	Fees are charged for PSUR, PASS and referral procedures and involve more than approx. 4,000 companies across Europe. Appropriations were reduced by EUR 213,000 through amending budget 01-21 and in accordance with expectations following the mid-year review.	The chapter accounted for 7.14% of revenue in 2021 (2015: 6.71%). Appropriations were reduced by EUR 213,000 through amending budget 01-21.
2000	European Union contribution	33,703,605.00	41,070,000.00	25,449,845.00	25,449,575.00	-8,254,030.00	-24.49%	- 270.00	0.00%	Recovery of general EU contribution was increase by the amount not requested under BL2010R, thus ensuring that all available funds were recovered. AB01-21 reduced the appropriations in order to reflect the fact that some activities related to the Agency's extended mandate, and covered by the 2021 contribution, would not be able to start in 2021. In agreement with the European Commission, whose budget is the source of these contributions, €14 million were delayed until 2022 and €3,811,000 until 2023.	This article accounted for 6.66% of 2021 revenues (2020: 8.96%). The contribution from the European Union budget decreased by 24.49% between 2020 and 2021.
2010	Special contribution for orphan medicinal products	11,374,395.00	14,378,000.00	12,187,155.00	12,187,155.00	812,760.00	7.15%	-	0.00%	The amount of contribution claimed to cover orphan medicinal products (OMP) fee reductions matches the sales orders issued in response to applications from industry. The amount not requested was transferred to BL2000R.	This article accounted for 3.19% of 2021 revenue (2020: 3.02%). The total amount of available EU contributions (general and OMP) was claimed.
5200	Revenue from administrative operations and ancillary services	0.00	62,000.00	0.00	3,039.00	3,039.00	n/a	3,039.00	0.00%	Chapter 52 includes the income from administrative activities as well as bank interest. In 2021 interest on bank deposits remained negative.	The chapter accounted for less than 0.01% of 2021 revenues (2020: 0.00%).
7000	Balance of outturn account of previous year	13,802,754.48	0.00	0.00	0.00	-13,802,754.48	-100.00%	-	0.00%	Any surplus (positive outturn) from the previous budget year is posted here. In 2019 the outturn was negative, hence no appropriations were entered on this line in 2021.	This chapter accounted for 0.00% of 2021 revenues (2020: 3.67%).
9000	Miscellaneous revenue	476,449.55	0.00	2,660,000.00	2,878,523.05	2,402,073.50	504.16%	218,523.05	8.22%	The bulk of the income stems from the regularisation of a payment from the sub-tenant of the Agency's former headquarters in London, relating to 2020 charges, which could not be offset against new payments, in accordance with the financial regulation.	This chapter accounted for 0.75% of 2021 revenues (2020: 0.13%).
<b>Total</b>		<b>376,246,022.54</b>	<b>385,919,000.00</b>	<b>379,228,000.00</b>	<b>382,155,536.92</b>	<b>5,909,514.38</b>	<b>1.57%</b>	<b>2,927,536.92</b>	<b>0.77%</b>		

## Expenditure, deviation from adopted budget and comparison against 2020 expenditure

Chapter	Heading	2020	2021	2021	2021	Change 2020-2021		2021 budget v/commitments		Deviation, 2021 budget vs. implementation	Evolution, 2021 vs. 2020
		EUR commitments	EUR adopted budget	EUR final budget	EUR commitments	EUR	%	EUR	%		
11	Staff in active employment	104,979,006.27	112,009,000.00	110,059,000.00	106,812,413.71	1,833,407.44	1.75%	-3,246,586.29	-2.95%	The lower than budgeted consumption was due to a lower salary adjustment, including duty station weighting, than initially expected. Vacancy rates for TAs of 1.98% and for CAs, 8.85% were achieved. A net total of EUR 1,950,000 was transferred out of the chapter.	Chapter 11 accounted for 29.22% of 2021 expenditure (2020: 28.73%), constituting the second largest share of expenditure. 59.02% of chapter 11 expenditure related to items 1100 'basic salaries' and 1114 'CA salaries' and 8.33% to 1190 'weightings' (2020: 56.07% and 8.12%). For these three items 2021 commitments amounted to EUR 71,937,409.46.
12	Staff recruitment	199,235.04	300,000.00	284,000.00	211,242.21	12,007.17	6.03%	-72,757.79	-25.62%	Recruitment was carried out with little or no travel by candidates, due to restrictions related to the pandemic, resulting in lower than budgeted consumption. EUR 16,000 was transferred out of the chapter.	This chapter accounted for 0.06% of 2021 expenditure (2020: 0.05%).
13	Missions and duty travel	137,782.04	750,000.00	146,000.00	24,508.37	-113,273.67	-82.21%	-121,491.63	-83.21%	A total of 20 duty trips were carried out in 2021 (2020: 204 trips). The low activity level was caused by travel restrictions related to the pandemic. A total of EUR 604,000 was transferred out of the chapter.	This chapter accounted for 0.01% of 2021 expenditure (2020: 0.04%) with a total of 20 duty trips carried out (2020: 204 trips).
14	Socio-medical infrastructure	1,695,263.40	2,734,000.00	2,115,000.00	1,646,279.19	-48,984.21	-2.89%	-468,720.81	-22.16%	A total of EUR 619,000.00 was transferred out of the chapter. Lower than budgeted expenditure was due to the impact of the pandemic.	This chapter accounted for 0.45% of 2021 expenditure (2020: 0.46%).
15	Training	555,731.22	770,000.00	680,000.00	648,765.01	93,033.79	16.74%	-31,234.99	-4.59%	Access to training was reduced due to restrictions related to the pandemic. A total of EUR 90,000 was transferred out of the chapter.	This chapter accounted for 0.18% of 2021 expenditure (2020: 0.15%).
16	External services	7,000,918.29	11,438,000.00	16,206,000.00	16,084,185.53	9,083,267.24	129.74%	-121,814.47	-0.75%	The increase was caused by higher use of interim contractors and higher use of Commission services. A total of EUR 4,768,000 was transferred into the chapter.	Chapter 16 accounted for 4.40% of 2021 expenditure (2020: 1.92%).
17	Representation and events	66,175.87	125,000.00	125,000.00	54,278.58	-11,897.29	-17.98%	-70,721.42	-56.58%	Lower expenditure was caused by the impact of the pandemic, which caused most events to be cancelled.	Chapter 17 accounted for 0.01% of 2021 expenditure (2020: 0.01%).
<b>Title I</b>		<b>114,634,112.13</b>	<b>128,126,000.00</b>	<b>129,615,000.00</b>	<b>125,481,672.60</b>	<b>10,847,560.47</b>	<b>9.46%</b>	<b>-4,133,327.40</b>	<b>-3.19%</b>		
Chapter	Heading	2020	2021	2021	2021	Change 2020-2021		2021 budget v/commitments		Deviation, 2021 budget vs. implementation	Evolution, 2021 vs. 2020
		EUR	EUR	EUR	EUR	EUR	%	EUR	%		
20	Investment in immovable property, renting of buildings [...]	41,541,361.61	15,397,000.00	15,672,000.00	14,813,190.06	-26,728,171.55	-64.34%	-858,809.94	-5.48%	Appropriations were reinforced by EUR 275,000 through transfer, to provide appropriations for fitting-out work to the building not originally foreseen in the budget. Savings were achieved on insurances not renewed, and on maintenance and cleaning, due to lower occupancy of the office building.	Chapter 20 accounted for 4.05% of 2021 expenditure, compared to 11.37% in 2020.
21	Information and communication technology	32,334,229.36	29,382,000.00	28,346,000.00	26,268,793.72	-6,065,435.64	-18.76%	-2,077,206.28	-7.33%	The lower than budgeted expenditure was caused by revised project plans and adjustment of license costs. A total of EUR 1,036,000 was transferred out of the chapter.	Chapter 21 accounted for 7.19% of 2021 expenditure (2020: 8.85%).
22	Movable property [...]	1,221,640.78	648,000.00	604,000.00	588,233.45	-633,407.33	-51.85%	-15,766.55	-2.61%	Lower expenditure in particular on printing, due to limited staff presence in the building and move to paperless working. EUR 44,000 was transferred out of the chapter.	Chapter 22 accounted for 0.16% of 2021 expenditure (2020: 0.33%).
23	Current administrative expenditure	886,939.65	3,890,000.00	3,360,000.00	1,025,312.38	138,372.73	15.60%	-2,334,687.62	-69.48%	Funds budgeted to cover potential legal expenditure were not required, and savings were achieved on the running of the Agency's reception. EUR 530,000 was transferred out of the chapter.	This chapter accounted for 0.28% of 2021 expenditure (2020: 0.24%).
24	Postal and delivery services	35,404.32	60,000.00	54,000.00	31,097.72	-4,306.60	-12.16%	-22,902.28	-42.41%	Savings achieved mainly through a shift away from using surface mail. A total of EUR 6,000 as transferred out of the chapter.	This chapter accounted for 0.01% of 2021 expenditure (2020: 0.01%).
25	Other meetings and memberships	269,685.89	320,000.00	350,000.00	342,247.70	72,561.81	26.91%	-7,752.30	-2.21%	EUR 30,000 were transferred into the chapter to provide appropriations to cover the cost of memberships.	This chapter accounted for 0.09% of 2021 expenditure (2020: 0.07%).
26	Restaurant and catering	1,703,201.05	1,061,000.00	955,000.00	601,622.38	-1,101,578.67	-64.68%	-353,377.62	-37.00%	EUR 106,000 were transferred out of the chapter. Lower staff presence and meeting activity in the building caused by the pandemic resulted in lower expenditure.	This chapter accounted for 0.16% of 2021 expenditure (2020: 0.47%).
27	Information and communication services	1,240,950.49	2,567,000.00	2,311,000.00	2,027,511.14	786,560.65	63.38%	-283,488.86	-12.27%	Lower than budgeted expenditure stemming from some postponed activities and revised cost of database subscriptions. EUR 256,000 were transferred out of the chapter.	This chapter accounted for 0.55% of 2021 expenditure (2020: 0.34%).
28	Business consultancy and audit services	3,693,470.16	2,850,000.00	2,565,000.00	2,060,396.02	-1,633,074.14	-44.22%	-504,603.98	-19.67%	Lower than budgeted expenditure on consultancy related to initiatives and projects, some of which were postponed. No audit-related expenditure was incurred for an audit covering the Agency's COVID-19 response. EUR 285,000 were transferred out of the chapter.	This chapter accounted for 0.56% of 2021 expenditure (2020: 1.01%).
<b>Title II</b>		<b>82,926,883.31</b>	<b>56,175,000.00</b>	<b>54,217,000.00</b>	<b>47,758,404.57</b>	<b>-35,168,478.74</b>	<b>-42.41%</b>	<b>-6,458,595.43</b>	<b>-11.91%</b>		

Chapter	Heading	2020	2021	2021	2021	Change 2020-2021		2021 budget v/commitments		Deviation, 2021 budget vs. implementation	Evolution, 2021 vs. 2020
		EUR commitments	EUR adopted budget	EUR final budget	EUR commitments	EUR	%	EUR	%		
300	Meetings	1,309,091.79	7,000,000.00	158,000.00	143,394.46	-1,165,697.33	-89.05%	-14,605.54	-9.24%	Lower meeting activities were caused by restrictions imposed due to the pandemic. A total of EUR 6,842,000 was transferred out of the article.	Article 300 accounted for 0.04% of 2021 expenditure (2020: 0.36%).
301	Evaluation of medicinal products	133,570,796.06	134,042,000.00	145,331,000.00	143,175,359.12	9,604,563.06	7.19%	-2,155,640.88	-1.48%	Appropriations were increased by EUR 11,289,000 through transfer and amending budget, to provide for rapporteur payments linked to higher numbers of scientific applications. Increasing activity was seen in particular for type II variations, rolling reviews (related to initial applications) and scientific advice applications. Appropriations were also allocated to NCA payments related to new activities under the Agency's extended mandate.	Article 301 accounted for 39.17% of 2021 expenditure (2020: 36.55%). Between 2020 and 2021 expenditure in absolute terms increased by approx. EUR 9.6 million.
302	Translations	5,046,745.99	5,184,000.00	4,842,000.00	4,772,548.10	-274,197.89	-5.43%	-69,451.90	-1.43%	The decrease in expenditure is linked to a revised pricing structure and fewer translations of arbitrations/referrals and renewals. A total of EUR 342,000 was transferred out of the article.	Article 302 accounted for 1.31% of 2021 expenditure (2020: 1.38%).
303	Scientific studies and services	7,490,375.67	7,400,000.00	15,565,000.00	14,706,873.73	7,216,498.06	96.34%	-858,126.27	-5.51%	The increase in expenditure reflects activities related to COVID-19 vaccines and medicines and to the Agency's extended mandate. The article was reinforced by a total of EUR 8,165,000 through transfer.	This article accounted for 4.02% of 2021 expenditure (2020: 2.05%).
31	Business related IT projects	20,455,226.98	22,600,000.00	29,500,000.00	29,452,448.15	8,997,221.17	43.98%	-47,551.85	-0.16%	The chapter was reinforced through transfer by a total of EUR 6,900,000. This increase reflects the revision of the budget commentary in order to include on the budget line the cost related to maintenance and support, so as to simplify contract management. Development projects included: clinical trials programme, veterinary medicinal products, RBOP (regulatory business optimisation programme) and SPMS (substance and product management system). In addition, appropriations were allocated to preparatory work linked to IT aspects of the Agency's extended mandate.	This chapter accounted for 8.06% of 2021 expenditure (2020: 5.60%).
<b>Title III</b>		<b>167,872,236.49</b>	<b>176,226,000.00</b>	<b>195,396,000.00</b>	<b>192,250,623.56</b>	<b>24,378,387.07</b>	<b>14.52%</b>	<b>-3,145,376.44</b>	<b>-1.61%</b>		
Chapter	Heading	2020	2021	2021	2021	Change 2020-2021		2021 budget v/commitments		Deviation, 2021 budget vs. implementation	Evolution, 2021 vs. 2020
		EUR commitments	EUR adopted budget	EUR final budget	EUR commitments	EUR	%	EUR	%		
900	Provisional appropriations	0.00	25,392,000.00	0.00	0.00	0.00	n/a	0.00	n/a	The 2021 budget included provisional appropriations amounting to EUR 25,392,000. In accordance with the Financial Regulation, these appropriations can only be implemented after transfer into the budget line where the expenditure will be incurred. Transfer 09-21, as adopted by the Management Board, transferred EUR 7,581,000 into budget lines 3010 (rapporteurs), 3030 (scientific studies) and 3105 (business IT development) to cover expenditure linked to activities under the Agency's extended mandate. The remaining appropriations were transferred into 2022 (EUR 14 million) and 2023 (EUR 3,811,000) to cover activities related to the extended mandate which to be undertaken during those years.	The 2020 budget included no provisional appropriations.
<b>Title IX</b>		<b>0.00</b>	<b>25,392,000.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>		
<b>Total</b>		<b>365,433,231.93</b>	<b>385,919,000.00</b>	<b>379,228,000.00</b>	<b>365,490,700.73</b>	<b>57,468.80</b>	<b>0.02%</b>	<b>-13,737,299.27</b>	<b>-3.62%</b>		

## Annex II – Details of assigned revenue, fund sources R0 and CL

### Fund source R0, JAN-DEC 2021

Budget item	Heading	Current appropriations	Total recoveries	Invoices not yet cashed	Cash received
<b>REVENUE</b>					
6000	External assigned revenue	351,960	3,201,960	2,700,000	501,960
<b>TOTAL</b>		<b>351,960</b>	<b>3,201,960</b>	<b>2,700,000</b>	<b>501,960</b>
Budget item	Heading	Current appropriations	Total commitments		Payments and regularisations
<b>EXPENDITURE</b>					
1100	Basic salaries	52,778	0		0
1300	Duty travel expenses [..]	1,200	0		0
2000	Rent	2,850,000	150,000		150,000
2030	Maintenance and cleaning	326,545	326,545		326,545
3000	Reimbursement of persons attending meetings	253,719	0		0
<b>TOTAL</b>		<b>3,484,242</b>	<b>476,545</b>		<b>476,545</b>

### Fund source CL, JAN-DEC2021

Budget item	Heading	Current appropriations	Total recoveries	Invoices not yet cashed	Cash received*
<b>REVENUE</b>					
6010	Internal assigned revenue from lettings	24,943,926	24,960,247	16,321	24,943,926
<b>TOTAL</b>		<b>24,943,926</b>	<b>24,960,247</b>	<b>16,321</b>	<b>24,943,926</b>
Budget item	Heading	Current appropriations	Total commitments		Payments and regularisations
<b>EXPENDITURE</b>					
2000	Rent	19,533,976	15,504,506		15,504,506
2010	Insurances	396,594	396,594		396,594
2090	Utilities and other building charges	5,013,355	4,001,283		4,001,283
<b>TOTAL</b>		<b>24,943,926</b>	<b>19,902,384</b>		<b>19,902,384</b>

\* EUR 2,093,666.08 was regularised to fund source C1 in 2022, in line with the Financial Regulation

## Annex III – Summary of transfers

No.	From/To item	Item No.	Fund source	Item Heading	Amount of receiving item	Amount of donating item
01	from	1420	C1	Miscellaneous welfare expenditure	0	377,000
	to	1604	C1	Contributions to European schools	377,000	0
02	from	1601	C1	Interim services		15,000
	to	1603	C1	Professional services relating to staff management	15,000	
03	from	3000	C1	Reimbursement of persons attending meetings		1,300,000
	to	3030	C1	Scientific studies & services	1,300,000	
04	from	1130	C1	Employer's social security contributions		350,000
	from	1300	C1	Duty travel		300,000
	from	1420	C1	Miscellaneous welfare expenditure		150,000
	from	2114	C1	Maintenance & support of applications		5,274,000
	from	3000	C1	Reimbursement of persons attending meetings		4,100,000
	from	3003	C1	Other expenditure in relation to meetings		250,000
	to	1190	C1	Weightings	800,000	
	to	2040	C1	Fitting-out of premises	680,000	
	to	2110	C1	Hardware & software	1,400,000	
	to	2115	C1	IT development related to corporate processes	850,000	
	to	2320	C1	Financial charges	194,000	
	to	3105	C1	Business IT development	6,500,000	
	05	from	3031	C1	Data management	
to		3030	C1	Scientific studies & services	258,000	
06	from	1300	C1	Duty travel		80,000
	to	1141	C1	Travel expenses from place of employment to place of origin	80,000	

No.	From/To item	Item No.	Fund source	Item Heading	Amount of receiving item	Amount of donating item
07	from	1100	C1	Basic salaries		351,000
	from	1101	C1	Family allowances		87,000
	from	1102	C1	Expatriation & foreign residence allowances		177,000
	from	1114	C1	Basic salaries & allowances for contract agents		500,000
	from	1115	C1	Seconded national experts & visiting experts		500,000
	from	1130	C1	Employer's social security contributions		380,000
	from	1181	C1	Allowances on entering & leaving the service & on transfer		179,000
	from	1300	C1	Duty travel		20,000
	from	1420	C1	Miscellaneous welfare expenditure		92,000
	from	1500	C1	Training		120,000
	from	2030	C1	Maintenance & cleaning		170,000
	from	2090	C1	Utilities & other building charges		47,000
	from	2110	C1	Hardware & software		186,000
	from	2115	C1	IT development related to corporate processes		190,000
	from	2330	C1	Legal expenses & associated costs		388,000
	from	3000	C1	Reimbursement of persons attending meetings		900,000
	from	3031	C1	Data management		100,000
	to	1601	C1	Interim services	3,000,000	
	to	1602	C1	Administrative assistance from the European Union institutions	286,000	
	to	2040	C1	Rent	1,000	
	to	2320	C1	Financial charges	100,000	
	to	3105	C1	Business IT development	1,000,000	
08	from	1101	C1	Family allowances		307,000
	from	1115	C1	Seconded national experts & visiting experts		386,000
	from	1190	C1	Weightings		307,000
	from	2203	C1	Technical equipment & installations		43,000
	from	2210	C1	Furniture		1,000
	from	2300	C1	Stationery & office supplies		4,000
	from	2330	C1	Legal expenses & associated costs		260,000
	from	2400	C1	Postal & delivery services		6,000
	to	3031	C1	Data management	1,314,000	

No.	From/To item	Item No.	Fund source	Item Heading	Amount of receiving item	Amount of donating item
09	from	9000	C1	Provisional appropriations		7,581,000
	to	3010	C1	Evaluation of medicinal products	3,180,000	
	to	3030	C1	Scientific studies & services	3,401,000	
	to	3105	C1	Business IT development	1,000,000	
10	from	1100	C1	Basic salaries		97,000
	from	1300	C1	Duty travel		101,000
	from	2030	C1	Maintenance & cleaning		65,000
	from	2330	C1	Legal expenses & associated costs		265,000
	from	3010	C1	Evaluation of medicinal products		1,017,000
	from	3013	C1	Evaluation of pharmacovigilance products		500,000
	from	3020	C1	Translation centre, Luxembourg		498,000
	to	1101	C1	Family allowances	97,000	
	to	1116	C1	Trainees	101,000	
	to	2050	C1	Security & surveillance of buildings	65,000	
	to	2501	C1	Memberships with professional bodies & organisations	30,000	
	to	3031	C1	Data management	2,250,000	
11	from	2010R	C1	Special contribution for Orphan medicinal Products from the EU budget and EEA contribution		2,190,845
	to	2000R	C1	European Union and EEA contributions	2,190,845	
	from	1100	C1	Basic salaries		1,047,000
	from	1101	C1	Family allowances		101,000
	from	1102	C1	Expatriation & foreign residence allowances		92,000
	from	1181	C1	Allowances on entering & leaving the service & on transfer		70,000
	from	1190	C1	Weightings		532,000
	from	1200	C1	Staff recruitment		16,000
	from	1300	C1	Duty travel		103,000
	from	1601	C1	Interim services		820,000
	from	1602	C1	Administrative assistance from the European Union institutions		37,000
	from	2040	C1	Fitting-out of premises		88,000
	from	2050	C1	Security & surveillance of buildings		101,000
	from	2115	C1	IT development related to corporate processes		136,000
	from	2320	C1	Financial charges		69,000
	from	2359	C1	Other operating expenditure		38,000
	from	2600	C1	Restaurant & catering		106,000
	from	2700	C1	Information & communication services		256,000
	from	2800	C1	Business consultancy & audit services		285,000
	from	3000	C1	Reimbursement of persons attending meetings		248,000
	from	3003	C1	Other expenditure in relation to meetings		44,000
	from	3020	C1	Translation centre, Luxembourg		246,000
	from	3021	C1	Other translations		98,000
	from	3105	C1	Business IT development		1,600,000
	to	1130	C1	Employer's social security contributions	103,000	
	to	1500	C1	Training	30,000	
	to	3010	C1	Evaluation of medicinal products	6,000,000	
				<b>Total amount of transfers</b>	<b>36,602,845</b>	<b>36,602,845</b>