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Report on the annual accounts of the European Medicines Agency (EMA) for the financial year 2019

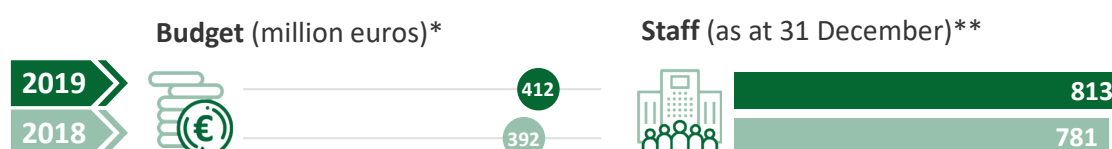
together with the Agency's reply

Introduction

01 The European Medicines Agency (“the Agency”, or “EMA”), which has relocated to Amsterdam, was established by Council Regulation (EEC) No 2309/93, which was replaced by Regulation (EC) No 726/2004 of the European Parliament and of the Council¹. The Agency operates through a pan-EU network and coordinates the scientific resources made available by the national authorities in order to ensure the evaluation and supervision of medicinal products for human or veterinary use.

02 *Graph 1* presents key figures for the Agency².

Graph 1: Key figures for the Agency



* Budget figures are based on the total payment appropriations available during the financial year.

** “Staff” includes EU officials, EU temporary agents, EU contract staff and seconded national experts, but excludes interim workers and consultants.

Source: Consolidated annual accounts of the European Union for the financial year 2018 and Provisional consolidated annual accounts of the European Union Financial year 2019; Staff figures provided by the Agency.

Information in support of the statement of assurance

03 The audit approach taken by the Court comprises analytical audit procedures, direct testing of transactions and an assessment of key controls of the Agency’s supervisory and control systems. This is supplemented by evidence provided by the work of other auditors and an analysis of information provided by the Agency’s management.

¹ OJ L 214, 24.8.1993, p. 1, and OJ L 136, 30.4.2004, p. 1. In accordance with the latter Regulation, the Agency’s original name, the European Agency for the Evaluation of Medicinal Products, was changed to the European Medicines Agency.

² More information on the Agency’s competences and activities is available on its website: www.ema.europa.eu.

The Court's statement of assurance provided to the European Parliament and the Council – Independent auditor's report

Opinion

04 We have audited:

- (a) the accounts of the Agency which comprise the financial statements³ and the reports on the implementation of the budget⁴ for the financial year ended 31 December 2019 and
- (b) the legality and regularity of the transactions underlying those accounts

as required by Article 287 of the Treaty on the Functioning of the European Union (TFEU).

Reliability of the accounts

Opinion on the reliability of the accounts

05 In our opinion, the accounts of the Agency for the year ended 31 December 2019 present fairly, in all material respects, the financial position of the Agency at 31 December 2019, the results of its operations, its cash flows, and the changes in net assets for the year then ended, in accordance with its Financial Regulation and with accounting rules adopted by the Commission's accounting officer. These are based on internationally accepted accounting standards for the public sector.

Emphasis of matter

06 We draw attention to note 3.1.3 of the Agency's provisional accounts, which describes the uncertainty of the lease agreement for the Agency's previous premises in London which lasts until 2039, with no provision for early termination. However, the premises can be sublet with the landlord's consent. In July 2019, the Agency reached an agreement with its landlord and has sublet its former office

³ The financial statements comprise the balance sheet, the statement of financial performance, the cash flow statement, the statement of changes in net assets and a summary of significant accounting policies and other explanatory notes.

⁴ The reports on implementation of the budget comprise the reports which aggregate all budgetary operations and the explanatory notes.

premises to a subtenant from July 2019, under conditions that are consistent with the terms of the head lease. The sublease term lasts until the expiry of the EMA's lease in June 2039. Since the EMA remains a party to the rental contract, the Agency could be held liable for the entire amount remaining payable under the rental contract if the subtenant fails to meet its obligations. This is described in note 4.8.1 on operating leases and note 4.8.2 on contingent assets and liabilities. As of 31 December 2019, the total estimated outstanding rent, associated service charges and landlord insurance to be paid by the EMA until the end of the lease term is 417 million euros. Our opinion is not qualified in respect of this matter.

Legality and regularity of the transactions underlying the accounts

Revenue

Opinion on the legality and regularity of revenue underlying the accounts

07 In our opinion, revenue underlying the accounts for the year ended 31 December 2019 is legal and regular in all material respects.

Payments

Opinion on the legality and regularity of payments underlying the accounts

08 In our opinion, payments underlying the accounts for the year ended 31 December 2019 are legal and regular in all material respects.

Basis for opinions

09 We conducted our audit in accordance with the IFAC International Standards on Auditing (ISAs) and Codes of Ethics and the INTOSAI International Standards of Supreme Audit Institutions (ISSAIs). Our responsibilities under those standards are further described in the 'Auditor's responsibilities' section of our report. We are independent, in accordance with the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants (IESBA Code) and with the ethical requirements that are relevant to our audit, and we have fulfilled our other ethical responsibilities in accordance with these requirements and the IESBA Code. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Responsibilities of management and those charged with governance

10 In accordance with Articles 310 to 325 of the TFEU and the Agency's Financial Regulation, the Agency's management is responsible for the preparing and presenting the Agency's accounts on the basis of internationally accepted accounting standards for the public sector and for the legality and regularity of the transactions underlying them. This includes the design, implementation and maintenance of internal controls relevant to the preparation and presentation of financial statements that are free from material misstatement, whether due to fraud or error. The Agency's management is also responsible for ensuring that the activities, financial transactions and information reflected in the financial statements comply with the official requirements, which govern those statements. The Agency's management bears the ultimate responsibility for the legality and regularity of the transactions underlying the Agency's accounts.

11 In preparing the accounts, the Agency's management is responsible for assessing the Agency's ability to continue as a going concern. It must disclose, as applicable, any matters affecting the Agency's status as a going concern, and use the going concern basis of accounting, unless management either intends to liquidate the entity or to cease operations, or has no realistic alternative but to do so.

12 Those charged with governance are responsible for overseeing the Agency's financial reporting process.

The auditor's responsibilities for the audit of the accounts and underlying transactions

13 Our objectives are to obtain reasonable assurance about whether the accounts of the Agency are free from material misstatement and the transactions underlying them are legal and regular, and to provide, on the basis of our audit, the European Parliament and the Council or the other respective discharge authorities with statements of assurance as to the reliability of the Agency's accounts and the legality and regularity of the transactions underlying them. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit will always detect a material misstatement or non-compliance when it exists. These can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these accounts.

14 For revenue, we verify subsidies received from the Commission or cooperating countries and assess the Agency's procedures for collecting fees and other income, if any.

15 For expenditure, we examine payment transactions when expenditure has been incurred, recorded and accepted. This examination covers all categories of payments (including those made for the purchase of assets) other than advances at the point they are made. Advance payments are examined when the recipient of funds provides justification for their proper use and the Agency accepts the justification by clearing the advance payment, whether in the same year or later.

16 In accordance with the ISAs and ISSAIs, we exercise our professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the accounts and of material non-compliance of the underlying transactions with the requirements of the legal framework of the European Union, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement or non-compliance resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the overriding of internal controls.
- Obtain an understanding of internal controls relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal controls.
- Evaluate the appropriateness of the accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Agency's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the accounts or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause an entity to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the accounts, including the disclosures, and whether the accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the Agency to express an opinion on the accounts and transactions underlying them. We are responsible for the direction, supervision and performance of the audit. We remain solely responsible for our audit opinion.
- Considered the audit work of the independent external auditor performed on the Agency's accounts as stipulated in Article 70(6) of the EU Financial Regulation, where applicable.

We communicate with the management regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal controls that we identify during our audit. From the matters on which we communicated with the Agency, we determine those matters that were of most significance in the audit of the accounts of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

17 The observations which follow do not call the Court's opinion into question.

Observation on the legality and regularity of transactions

18 At the time of our audit, there were 119 on-site consultants providing services at the EMA's premises. They were employed by a number of providers, some of them from other Member States (mostly from Belgium) and some based in the Netherlands. The Agency was unable to confirm to the auditors whether the temporary-work agency staff providing services on its premises qualified for posted worker status under the provisions of Netherlands law concerning the transposition of the Posting of Workers Directive (Directive 96/71/EC of the European Parliament and of the Council⁵)

⁵ OJ L 18, 21.1.1997, p. 1.

and the Enforcement Directive (Directive 2014/67/EU of the European Parliament and of the Council⁶).

We consider that in the context of calls for tenders for acquisition of services, the EMA, as contracting authority, has the responsibility to verify the declarations of compliance with EU and national social and labour law made by contractors (including legislation concerning the posting of workers) as required by the Financial Regulation applicable to the general budget of the Union. By way of example, the EMA could have fulfilled this requirement by asking its contractor for a list of these workers and asking it to submit evidence that it complied with the national legislation in the host Member State (e.g. proof that the contractor had notified the host Member State about the posted workers). However, at the time of our audit, it had not done so. Nor had it taken any further such steps to ensure compliance with the requirements imposed by the Financial Regulation in this connection.

The EMA also needs to be aware of its host Member State's national legislation concerning posted workers, and to comply with any obligation that this legislation imposes on the receiver of services (i.e. the EMA) provided by posted workers.

Observations on sound financial management

19 When running a public procurement procedure, contracting authorities must divide contracts into lots, if appropriate, with due regard to the need to facilitate broad competition. Technical specifications must allow bidders equal access to procurement procedures, and may not have the effect of creating unjustified obstacles to open competition.

20 In March 2019, the EMA launched a procurement procedure. The procedure covered two items: the supply of printers, and the management of the goods loading bay at the Agency's new premises in Amsterdam. These two items are completely unrelated. But they were nevertheless combined into a single same lot, with an estimated value of 6 200 000 euros over a maximum period of 6 years. Only two offers were received for this tender.

By combining the procurement procedures for the supply of printers and the provision of loading bay management services, the Agency may have limited the number of potentially interested tenderers from submitting an offer for either set of services, thus impairing fair competition.

⁶ OJ L 159, 28.5.2014, p. 11.

In addition, the Agency extended the duration of contract from four to six years. Extending contracts in this way is only allowed by the Financial Regulations in exceptional and substantiated cases. The life span of the equipment in the contract and the significant amount which the contractor would have to invest to acquire the printers are not sufficient grounds for such an extension.

21 In October 2019, the EMA concluded a framework contract with three companies for the supply of temporary workers. The combined maximum value of the contract was 15 450 000 euros. According to the tender specifications, the price element had a weighting factor of 40 %. It was stipulated in those specifications that this element must include an all-inclusive hourly rate conversion factor applied to the gross hourly remuneration of the temporary workers in specific staff categories. Based on the offers received, especially in the categories FGII and FGIII, which had the highest weighting factor in the overall price element, the conversion factor ranged from 1.85 to 1.95. However, the EMA did not request an estimate of the gross staff cost for the interim workers in each requested staff category (e.g. employer's contributions, and other expenses covered by the employer according to Netherlands labour law).

As a result, the EMA could have been in a better position to evaluate whether the service provider's mark-up or gross profit was reasonable in relation to similar contracts.

22 In March 2019, the EMA relocated from London to Amsterdam in preparation for the United Kingdom's withdrawal from the European Union. To facilitate the transition, the Agency granted an additional travel allowance to each member of staff who relocated to Amsterdam, and the members of their household. The amount of this additional allowance (1 227 euros for each person who received it) was calculated as a flat-rate amount according to the price of a business-class ticket instead of the economy-class fare as stated in the Staff Regulations.

If the Agency had calculated the amount of this additional travel allowance on the basis of an economy-class fare, the normal class of travel for journeys made within the EU, it would have delivered the same result more economically. This applies even if the Agency had purchased additional luggage allowance for each person who received the allowance, to make it equivalent to the luggage allowance permitted in business class. We conclude that the EMA gave little consideration to the principle of economy in calculating the amount of the additional travel allowance.

By 31 December 2019, the EMA had paid both the statutory and this exceptional travel allowance to 481 EMA staff members and 524 members of their households. The total amount disbursed by that date was 1 263 305 euros, instead of 30 562 euros in the

case only the statutory allowance had been applied. Together with 245 000 euros reserved for further such payments, the amount expected to be spent on the exceptional travel allowance is 1 477 743 euros.

Follow-up of previous years' observations

23 An overview of the action taken in response to the Court's observations from previous years is provided in the **Annex**.

This Report was adopted by Chamber IV, headed by Mr Alex Brenninkmeijer, Member of the Court of Auditors, in Luxembourg on 22 September 2020.

For the Court of Auditors

A handwritten signature in black ink, appearing to read 'K-H Le', written in a cursive style.

Klaus-Heiner Lehne
President

Annex - Follow-up of previous years' observations

Year	Court's observations	Status of corrective action (Completed / Ongoing / Outstanding / N/A)
2014	The Agency's fee regulation provides due dates for the collection of fees. These due dates were not respected for most of the transactions audited.	Completed
2016- 2017-2018	The Agency has been tasked by Parliament and Council with the implementation of the Regulations on Pharmacovigilance (1027/2012) and Clinical Trials (536/2014), requiring the development and implementation of two major pan-European IT systems. In the absence of the necessary own internal resources, the Agency used consultants to an extent that it became critically dependent on external expertise. There was no adequate control over project development and implementation and project delays and costs escalated. The Agency should speed up the implementation of the mitigating action not only for the completion of the ongoing IT projects but also to get ready for significant new projects.	Ongoing
2016	The founding Regulation requires an external evaluation of the Agency and its operations by the Commission only every ten years.	Outstanding (Not under the Agency's control)

Year	Court's observations	Status of corrective action (Completed / Ongoing / Outstanding / N/A)
2017	There is a need to strengthen the accounting officer's independence by making her directly responsible to the Agency's Director (administrative) and Management Board (functional).	Completed
2017	The Agency publishes vacancy notices on its website, but not on the website of the European Personnel Selection Office (EPSO).	Completed
2017	E-procurement: by the end of 2017, the Agency had introduced e-tendering for certain procedures, but not e-invoicing and e-submission.	E-submission: Completed E-invoicing: Outstanding

The Agency's reply

The European Medicines Agency ("the Agency" or "EMA") welcomes the Court's positive opinion on the reliability of the 2019 accounts and on the legality and regularity of the transactions underlying the accounts.

As highlighted by the Court, 2019 was again a challenging year with the relocation to Amsterdam and the necessity to operate under a business continuity plan.

06. The issue of London premises arose due to United Kingdom (UK) unilateral decision to leave the European Union. The topic was initially included in the EU negotiation position but later was excluded.

As a result, following the EU institutional approach, the Agency has sought for an alternative solution and has sublet the premises in line with the limits set by the EU budgetary authority.

The Agency and its Management Board are concerned that the Agency, instead of focusing its full effort on its mission of protecting and promoting public health, now must manage commercial property in the soon-to-be third country diverting its human and financial resources from its public health responsibilities for the EU citizens.

This focus of the Agency and consequently of the EU institutions will have to be maintained for another 19 years, till 2039.

Despite negotiated guarantee measures, the subletting solution is not without risks, magnified by the current COVID 19 crisis. It is therefore necessary to manage this topic at the right political level, involving the UK government, and find the long-term resolution during the negotiations between the EU and the UK.

18. The Agency notes the observation of the Court in respect of the monitoring of posted workers and acknowledges the importance of ensuring that compliance with applicable Union and national legislation on this matter is fully observed.

In order to ensure compliance with Dutch employment and labour law the Agency has started implementing changes to its contract templates and template for technical specifications to include information about the Posted Workers directive.

If necessary, further actions will be taken after a thorough legal analysis has been completed.

19. The Agency notes the comment of the Court.

20. Considering that the loading bay management service at the Agency's new premises in Amsterdam represents two out of nine FTEs foreseen in the Framework Contract and that the emphasis is on the quality of the procedural aspects of this service, it would have not been practical nor efficient to tender such service in isolation.

The initiative to extend the contract duration was to prevent the lack of interest from prospective tenderers, due to the large fleet (45 MDFs) the Agency would require to be supplied, installed and maintained at its new premises.

It is worth to note that following the Advisory Committee on Procurement and Contracts the contract duration scheme is 4+1+1 meaning that after 4 years the contract can be ended if needed.

21. The Agency has been operating in a new country (the Netherlands) since March 2019, where market conditions are also new for the Agency. Therefore, a market research was carried out in order to understand the local (Dutch) market conditions for interim workers.

As part of such research and cooperation among EU bodies, EMA has taken into account information provided by other EU agencies which have been located in the Netherlands much longer such as JRC Petten (57 years) and Eurojust (16 years). In addition, the Agency also consulted a Dutch law firm to review and comment the draft technical specifications and draft contract for the interim services to ensure they are compliant and aligned with local legislation.

The price was assessed in its globality and the Agency considers that the high diligence applied produced a favourable result. However, the Agency notes the ECA recommendation.

22. The Agency introduced social measures under Article 1e of the Staff Regulations (SR) in the context of the Agency's relocation from London to Amsterdam as a consequence of the UK's decision to leave the EU.

For the purpose of an effective social measure aiming at staff support and staff retention in the extraordinary situation of staff relocating (while continuing to deliver the Agency's mandate at all times) as well as staff's families, from UK to the Netherlands, the principle of economy should not be considered in isolation and merely by reference to the cost of an economy-class flight, but other factors should be also taken into account.

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