



EUROPEAN
COURT
OF AUDITORS

Report on the annual accounts
of the European Medicines Agency
for the financial year 2015

together with the Agency's reply

INTRODUCTION

1. The European Medicines Agency (hereinafter “the Agency”, aka “EMA”), which is located in London, 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 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.

2. *Table 1* presents key figures for the Agency²

TABLE 1: KEY FIGURES FOR THE AGENCY

	2014	2015
Budget (million euro)	272	304
Total staff as at 31 December ³	752	775

Source: data provided by the Agency.

INFORMATION IN SUPPORT OF THE STATEMENT OF ASSURANCE

3. 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 management representations.

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.

³ Staff includes officials, temporary and contract staff and seconded national experts.

STATEMENT OF ASSURANCE

4. Pursuant to the provisions of Article 287 of the Treaty on the Functioning of the European Union (TFEU), the Court has audited:

- (a) the annual accounts of the Agency, which comprise the financial statements⁴ and the reports on the implementation of the budget⁵ for the financial year ended 31 December 2015, and
- (b) the legality and regularity of the transactions underlying those accounts.

The management's responsibility

5. The management is responsible for the preparation and fair presentation of the annual accounts of the Agency and the legality and regularity of the underlying transactions⁶:

- (a) The management's responsibilities in respect of the Agency's annual accounts include designing, implementing and maintaining an internal control system relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies on the basis of the accounting rules adopted by the Commission's accounting officer⁷; making accounting estimates that are reasonable in the circumstances. The Executive Director approves the annual accounts of the Agency after its accounting officer has prepared them on the basis of all available information and established a note to accompany the accounts in which he declares, inter alia, that he has reasonable assurance that they present a true and fair view of the financial position of the Agency in all material respects.

⁴ These include the balance sheet and the statement of financial performance, the cash flow table, the statement of changes in net assets and a summary of the significant accounting policies and other explanatory notes.

⁵ These comprise the budgetary outturn account and the annex to the budgetary outturn account.

⁶ Articles 39 and 50 of Commission Delegated Regulation (EU) No 1271/2013 (OJ L 328, 7.12.2013, p. 42).

⁷ The accounting rules adopted by the Commission's accounting officer are derived from the International Public Sector Accounting Standards (IPSAS) issued by the International Federation of Accountants or, where relevant, the International Accounting Standards (IAS)/International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board.

- (b) The management's responsibilities in respect of the legality and regularity of the underlying transactions and compliance with the principle of sound financial management consist of designing, implementing and maintaining an effective and efficient internal control system comprising adequate supervision and appropriate measures to prevent irregularities and fraud and, if necessary, legal proceedings to recover funds wrongly paid or used.

The auditor's responsibility

6. The Court's responsibility is, on the basis of its audit, to provide the European Parliament and the Council⁸ with a statement of assurance as to the reliability of the annual accounts and the legality and regularity of the underlying transactions. The Court conducts its audit in accordance with the IFAC International Standards on Auditing and Codes of Ethics and the INTOSAI International Standards of Supreme Audit Institutions. These standards require the Court to plan and perform the audit to obtain reasonable assurance as to whether the annual accounts of the Agency are free from material misstatement and the transactions underlying them are legal and regular.

7. The audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the accounts and the legality and regularity of the underlying transactions. The procedures selected depend on the auditor's judgement, which is based on an assessment of the risks of material misstatement of the accounts and material non-compliance by the underlying transactions with the requirements in the legal framework of the European Union, whether due to fraud or error. In assessing these risks, the auditor considers any internal controls relevant to the preparation and fair presentation of the accounts, as well as the supervisory and control systems that are implemented to ensure the legality and regularity of underlying transactions, and designs audit procedures that are appropriate in the circumstances. The audit also entails evaluating the appropriateness of accounting policies, the reasonableness of accounting estimates and the overall presentation of the accounts. In preparing this report and Statement of Assurance, the Court considered the audit work of the independent external auditor performed on the Agency's accounts as stipulated in Article 208(4) of the EU Financial Regulation⁹.

⁸ Article 107 of Regulation (EU) No 1271/2013.

⁹ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council (OJ L 298, 26.10.2012, p. 1).

8. The Court considers that the audit evidence obtained is sufficient and appropriate to provide a basis for its statement of assurance.

Opinion on the reliability of the accounts

9. In the Court's opinion, the Agency's annual accounts present fairly, in all material respects, its financial position as at 31 December 2015 and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its Financial Regulation and the accounting rules adopted by the Commission's accounting officer.

Opinion on the legality and regularity of the transactions underlying the accounts

10. In the Court's opinion, the transactions underlying the annual accounts for the year ended 31 December 2015 are legal and regular in all material respects.

Other matter – event after balance sheet date

11. On 23 June 2016, the citizens of the United Kingdom (UK) voted to leave the European Union. Article 50 of the Treaty on European Union provides that a Member State which decides to withdraw from the Union shall notify the European Council of its intention and the Union shall negotiate and conclude an agreement with that State, setting out the arrangements for its withdrawal. The accounts and related notes of the Agency, which is located in London (UK), were prepared using the information available at the date of signing of these accounts when the results of the referendum were not yet known and the formal notification of the triggering of Article 50 has not been presented¹⁰.

FOLLOW-UP OF PREVIOUS YEARS' COMMENTS

12. An overview of the corrective actions taken in response to the Court's comments from previous years is provided in **Annex I**.

¹⁰ The Agency's accountant signed the accounts on 1 June 2016.

This Report was adopted by Chamber IV, headed by Mr Baudilio TOMÉ MUGURUZA, Member of the Court of Auditors, in Luxembourg at its meeting of 4 October 2016.

For the Court of Auditors

Klaus-Heiner LEHNE

President

Annex I**Follow-up of previous years' comments**

Year	Court's comment	Status of corrective action (Completed / Ongoing / Outstanding / N/A)
2014	The Agency's fee regulation provides due dates for the collection of fees from applicants and the Agency's related payments to National Competent Authorities ¹ . These due dates were not respected for most of the transactions audited by the Court.	Ongoing
2014	In 2014, the Agency carried out an administrative procedure against its Information, Communication and Technology (ICT) manager. Significant weaknesses in management control were reported, implying considerable operational and financial risks to the Agency. An action plan to address the issue was established and implemented. However, the effectiveness of the measures taken has yet to be evaluated by the Agency.	Ongoing
2014	One of the Agency's tasks is to distribute appropriate pharmacovigilance information to Member States and to the general public. This information is collected from individual national authorities and verified with the pharmaceutical companies concerned. However, the Agency is largely dependent on controls and inspections carried out by Member States' authorities. These determine the completeness and accuracy of information disseminated to the public.	Ongoing
2014	In 2014 the Agency concluded a 15 million euro framework contract (covering the years 2014 to 2017) for high-level management consultancy services. The objectives and activities to be carried out were not sufficiently specific to justify the procurement decision or the volume of the contract. There is no evidence that the Management Board had been consulted on the procurement decision, which would have been appropriate given the nature and value of the contract, even though the Financial Regulation does not require it.	N/A

¹ Agency's fee regulation, Articles 10(1) and 11(1).

THE AGENCY'S REPLY

The Agency has taken note of the Court's report.