EUROPEAN
COURT
OF AUDITORS

Report on the annual accounts of the European Medicines Agency for the financial year 2014

together with the Agency's reply

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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 Council[1]. 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].

INFORMATION IN SUPPORT OF THE STATEMENT OF ASSURANCE

2. 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.

STATEMENT OF ASSURANCE

3. 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 statements[3] and the reports on the implementation of the budget[4] for the financial year ended 31 December 2014, and

(b) the legality and regularity of the transactions underlying those accounts.

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[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] ***Annex II*** summarises the Agency's competences and activities. It is presented for information purposes.

[3] 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.

[4] These comprise the budgetary outturn account and the annex to the budgetary outturn account.

The management's responsibility

4. 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 transactions[5]:

(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 officer[6]; 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.

(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

5. The Court's responsibility is, on the basis of its audit, to provide the European Parliament and the Council[7] 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

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

[6] 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.

[7] Article 107 of Regulation (EU) No 1271/2013.

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.

6. 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 Regulation[8].

7. 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

8. In the Court's opinion, the Agency's annual accounts present fairly, in all material respects, its financial position as at 31 December 2014 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

9. In the Court's opinion, the transactions underlying the annual accounts for the year ended 31 December 2014 are legal and regular in all material respects.

10. The comments which follow do not call the Court's opinions into question.

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

COMMENTS ON THE LEGALITY AND REGULARITY OF TRANSACTIONS

11. 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[9]. These due dates were not respected for most of the transactions audited by the Court.

COMMENTS ON INTERNAL CONTROLS

12. 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.

OTHER COMMENTS

13. 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.

14. 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.

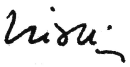
[9] Agency's fee regulation, Articles 10(1) and 11(1).

FOLLOW-UP OF PREVIOUS YEARS' COMMENTS

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

This Report was adopted by Chamber IV, headed by Mr Milan Martin CVIKL, Member of the Court of Auditors, in Luxembourg at its meeting of 8 September 2015.

For the Court of Auditors



Vítor Manuel da SILVA CALDEIRA

President

Annex I

Follow-up of previous years' comments

Year	Court´s comment	Status of corrective action (Completed / Ongoing / Outstanding / N/A)
2012	In addition to the education allowances provided for in the Staff Regulations[1], the Agency pays education contributions directly to schools for staff whose children attend primary or secondary school without having contracts with schools in place. Total 2012 education contributions amounted to some 389 000 euro. Such expenditure is not covered by the Staff Regulations and irregular.	**Completed**

[1] Article 3 of Annex VII provides for twice the basic allowance of 252,81 euro = 505,62 euro.

Annex II

European Medicines Agency

(London)

Competences and activities

Areas of Union competence deriving from the Treaty *(Article 168 of the Treaty on the Functioning of the European Union)*	**Collection of information** A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.
Competences of the Agency *(Regulation (EC) No 726/2004 of the European Parliament and of the Council)*	**Objectives** – To coordinate the scientific resources that the Member States' authorities make available to the Agency for the authorisation and supervision of medicinal products for human and veterinary use; – to provide the Member States and the institutions of the European Union with scientific advice on medicinal products for human or veterinary use. **Tasks** – To coordinate the scientific evaluation of medicinal products which are subject to Union marketing authorisation procedures; – to coordinate the supervision of medicinal products which have been authorised within the Union (*Pharmacovigilance*); – to advise on the maximum limits for residues of veterinary medicinal products which may be accepted in foodstuffs of animal origin; – to coordinate verification of compliance with the principles of good manufacturing practice, good laboratory practice and good clinical practice; – to record the status of marketing authorisations granted for medicinal products.
Governance	The **Committee for Medicinal Products for Human Use** (CHMP) is responsible for preparing the Agency's opinions on all questions concerning medicines for human use. The CHMP consists of one member and one alternate from each Member State, one member and an alternate nominated by Iceland and by Norway and up to five co-opted members. The **Committee for Medicinal Products for Veterinary Use** (CVMP) is responsible for preparing the Agency's opinions on all questions concerning

	veterinary medicines. The CVMP consists of one member and one alternate from each Member State, one member and an alternate nominated by Iceland and by Norway and up to five co-opted members. The **Committee on Orphan Medicinal Products** (COMP) is responsible for reviewing applications from people or companies seeking orphan medicinal product designation. The COMP consists of one member from each Member State, three members nominated by the European Commission representing patients' organisations, three members nominated by the European Commission on the Agency's recommendation, one member nominated by Iceland, one by Liechtenstein and one by Norway, and one European Commission representative. The **Committee on Herbal Medicinal Products** (HMPC) is responsible for preparing the Agency's opinions on herbal medicines. The HMPC consists of one member and one alternate from each Member State and from Iceland and Norway, and up to five co-opted members. The **Paediatric Committee** (PDCO) is responsible for assessing the content of applications for paediatric investigation plans, waivers, deferrals and compliance checks, and adopting opinions on them. The PDCO consists of five members of the CHMP and their five alternates, one member and one alternate from each Member State which is not represented by the five above, and six members and alternates appointed by the European Commission representing healthcare professionals and patients' associations. The **Committee for Advanced Therapy** (CAT) is responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products (ATMPs) and following scientific developments in the field. The CAT consists of five members of the CHMP and their five alternates, one member and one alternate from each Member State which is not represented by the five above, and four members and four alternates appointed by the European Commission representing patients' associations and clinicians. The **Pharmacovigilance Risk Assessment Committee** (PRAC) is responsible for assessing and monitoring safety issues for human medicines. The PRAC consists of one member and one alternate from each Member State, one member and an alternate nominated by Iceland and by Norway, six independent scientific experts nominated by the European Commission and two members and two alternates nominated by the European Commission to represent healthcare professionals and patients' organisations. The **Management Board** consists of one member and one alternate from each Member State, two representatives of the Commission, two representatives of the European Parliament and two representatives from patients' organisations, one representative from doctors' organisations and one representative from veterinarians' organisations. The Board adopts the work programme and the annual report. The **Executive Director** is appointed by the Management Board on a proposal from the Commission. **Internal audit** European Commission Internal Audit Service (IAS) & EMA Internal Audit Capability (IAC).

	External audit European Court of Auditors. **Discharge authority** European Parliament, acting on a recommendation from the Council.
Resources made available to the Agency in 2014 *(2013)*	**Final Budget** 282,47 *(251,56)* million euro[1]; Union contribution: 8,2 % *(13,0 %)*[2] **Staff as at 31 December 2014** 599 *(611)* posts in the establishment plan, of which occupied: 580 *(583)* 210 *(144)* other staff (contract staff, seconded national experts, employment agency staff) Total staff: 790 *(727)* undertaking the following tasks: operational: 621 *(590)*, administrative: 169 *(137)*
Products and services in 2014 *(2013)*	**Medicinal Products for Human Use** – Applications for marketing authorisations: 100 *(80)* – Favourable opinions: 82 *(80)* – Average evaluation time: 179 *(200)* days – Opinions after authorisation: 5 958 *(5 447)* – Pharmacovigilance (CAP EEA and non-EEA ADR reports): 691 897 *(679 413)* reports – Periodic safety update reports (PSUR): 471[3] *(525)* – Scientific advice finalised: 532 *(474)* – Mutual Recognition Procedures and Decentralised Procedures[4]: started 7 231 *(6 293)*; ended 6 412 *(6 242)* – Applications for paediatric procedures at the PDCO: 485 *(480)*[5] **Medicinal Products for Veterinary Use** – Applications for marketing authorisations: 12 *(23)* – Applications for variations: 340 *(315)* – Applications for line extensions: 6 *(5)* **Inspections** Inspections: 506 *(480)* **Herbal Medicinal Products** Herbal monographs: 11 *(9)* List of herbal substances, preparations and combinations thereof: 1 *(0)* **Orphan Medicinal Products** – Designation applications: 329 *(201)* – Favourable Orphan designation opinions: 196 *(136)* **SMEs** – Requests for SME status 499 *(401)*

	– Applications for fee reduction or deferrals 333 *(336)*

[1] This is the final budget, not the actual total of the budgetary outturn account.

[2] This is the percentage of the budgeted EU contribution (excluding special contribution for orphan fee reductions and excluding the use of surplus n-2) in relation to the final budget.

[3] The figures take into account the PSURs finalised as of end of 2014.

[4] Includes initial MRP/DCP, type IA, IB, II and worksharing variations.

[5] Data for 2014 (and for *2013*) are reported now for all PDCO procedures, including first PIP applications, modifications of agreed PIP, waiver applications, and compliance check applications.

Source: Annex supplied by the Agency.

THE AGENCY'S REPLY

11. During 2013-2014, the Agency has redesigned and streamlined its main operational processes including financial authorisations and fee collections. The further planned automation of the latter was delayed because of the Agency's reorganisation in 2014. To ensure compliance with the Agency's fee regulation concerning due dates, this automation is now planned to be implemented by the end of 2015.

12. Whilst weaknesses in management control were detected, no considerable financial risks were reported in the administrative enquiry report to the Executive Director.
The effectiveness of the measures taken by the Agency is to be evaluated through the already planned audits in 2015 by the Internal Audit Service of the EC and the Internal Audit Capability of the Agency.

13. The agency takes note of the Court's comment. The regulation of medicinal products in the European Union is based on a network model. EMA coordinates the EU pharmacovigilance network system and manages key information systems to support data exchange in pharmacovigilance, in particular EudraVigilance and the Article 57 database of medicinal products. We will continue to work with our stakeholders/partners to ensure adequate protection to the EU citizen in this area.

14. An inter-service consultation was conducted prior to the launch of the procurement procedure for a framework contract leading to an estimate of 15 000 person days over four years. The consultation sought to identify for the departments from the perspective of the time certain objectives, estimated profiles, and person days, as well as the assumed nature of services and approximate timing. Given the advance nature of the required estimates the Agency cannot share the Court's comments. Furthermore, as the Court acknowledges, the Agency was not required to consult the Management Board prior to launch of the tender.