049401/EU XXV. GP
Eingelangt am 05/12/14

Council of the
European Union

Brussels, 4 December 2014
(OR. en)

16453/14

FIN 925

COVER NOTE

From:	Mr Vítor CALDEIRA, President of the European Court of Auditors
date of receipt:	14 October 2014
To:	Mr Linas LINKEVICIUS, President of the Council of the European Union
Subject:	Report on the annual accounts of the European Medicines Agency for the financial year 2013 together with the Agency's replies

Delegations will find attached the European Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2013.

This report is accompanied by the Agency's replies and will shortly be published in the *Official Journal of the European Union*.

Encl.: Report on the annual accounts of the European Medicines Agency for the financial year 2013 together with the Agency's replies.[1]

[1] In English only. The other languages of this report are available on the European Court of Auditors' website: http://eca.europa.eu/.

www.parlament.gv.at

ЕВРОПЕЙСКА СМЕТНА ПАЛАТА
TRIBUNAL DE CUENTAS EUROPEO
EVROPSKÝ ÚČETNÍ DVŮR
DEN EUROPÆISKE REVISIONSRET
EUROPÄISCHER RECHNUNGSHOF
EUROOPA KONTROLLIKODA
ΕΥΡΩΠΑΪΚΟ ΕΛΕΓΚΤΙΚΟ ΣΥΝΕΔΡΙΟ
EUROPEAN COURT OF AUDITORS
COUR DES COMPTES EUROPÉENNE
CÚIRT INIÚCHÓIRÍ NA HEORPA

EUROPSKI REVIZORSKI SUD
CORTE DEI CONTI EUROPEA
EIROPAS REVĪZIJAS PALĀTA
EUROPOS AUDITO RŪMAI

EURÓPAI SZÁMVEVŐSZÉK
IL-QORTI EWROPEA TAL-AWDITURI
EUROPESE REKENKAMER
EUROPEJSKI TRYBUNAŁ OBRACHUNKOWY
TRIBUNAL DE CONTAS EUROPEU
CURTEA DE CONTURI EUROPEANĂ
EURÓPSKY DVOR AUDÍTOROV
EVROPSKO RAČUNSKO SODIŠČE
EUROOPAN TILINTARKASTUSTUOMIOISTUIN
EUROPEISKA REVISIONSRÄTTEN

Report on the annual accounts of the European Medicines Agency for the financial year 2013

together with the Agency's replies

12, RUE ALCIDE DE GASPERI
L - 1615 LUXEMBOURG
TELEPHONE (+352) 43 98 – 1
TELEFAX (+352) 43 93 42
E-MAIL: eca-info@eca.europa.eu
INTERNET: http://eca.europa.eu

www.parlament.gv.at

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[2]. 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[3].

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 (where relevant) 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:

---

[2] 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.

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

(a) the annual accounts of the Agency, which comprise the financial statements[4] and the reports on the implementation of the budget[5] for the financial year ended 31 December 2013, and

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

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[6]:

(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[7]; making accounting estimates that are reasonable in the circumstances. The 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

---

[4] These include the balance sheet and the economic outturn account, 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.

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[8] 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.

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

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

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.

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 2013 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 2013 are legal and regular in all material respects.

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

FOLLOW-UP OF PREVIOUS YEARS' COMMENTS

11. 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 1 July 2014.

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)
2011	There is scope for improving the transparency of procurement procedures.	**Completed**
2011	The Court identified a need to improve the transparency of staff selection procedures. Selection Board members did not always complete their conflict of interest declarations, or did not do so in a timely manner, and there was no evidence of any action taken to address the issues raised by these declarations. The documentation of the Selection Board's proceedings was not always adequate and there is no evidence as to how the method for the short-listing of candidates was established and that the questions for the written tests or interviews were set before the examinations.	**Completed**
2012	The Agency applies differing recognition criteria for fee revenue and associated expenditure. Revenue from application fees is recognised on a straight-line basis over a set time period. Expenditure for the evaluation of such applications by the competent national authorities is however accrued when a specific milestone in service delivery is reached. This is in contradiction with the matching principle.	**Completed**
2012	The Agency has not yet validated its accounting system in the area of intangible fixed assets. Given the considerable investment in the ICT development[1], this is a crucial part of the whole accounting system.	**Completed**

www.parlament.gv.at

Year	Court´s comment	Status of corrective action (Completed / Ongoing / Outstanding / N/A)
2012	In 2011 and 2012, the Council refused salary increases for EU staff. The Commission appealed this decision to the Court of Justice which did not yet rule on the matter. Since the Agency is located in London, the salary increases in question will be paid in GBP whereas the Agency's accounts are prepared in Euros. Given the fluctuations in the exchange rate over the period concerned, the possible back pay to staff would lead to an estimated exchange rate loss for the Agency of 2,9 million euro. The Agency has included this amount in the calculation of its budgetary outturn account, leading to an equivalent understatement of funds to be paid back to the Commission[2].	**N/A**
2012	In 2012, the Agency issued cascading framework contracts for the provision of services[3]. The procurement procedure presented some irregularities affecting the principle of transparency.	**N/A**
2012	In addition to the education allowances provided for in the Staff Regulations[4], 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.	**Ongoing**[5]

www.parlament.gv.at

Year	Court´s comment	Status of corrective action (Completed / Ongoing / Outstanding / N/A)
2012	The Agency's budget implementation rates for the year 2012 were satisfactory for titles I and III. While the rate of committed appropriations carried over was high for title II at 27 %, this primarily relates to the Agency's planned move to new premises in 2014 (4 205 000 euro) and the development of ICT systems (1 596 000 euro). While the latter is of a multiannual nature that can partly justify the carry-overs, the Agency's ICT Unit was significantly reorganised in 2012 and a number of projects planned for 2012 were delayed.	**N/A**

www.parlament.gv.at

1 2012 investments in ICT development amounted to 11 625 000 euro.

2 In so doing, the Agency followed an instruction from the Commission dated December 2012 which however was further clarified in June 2013.

3 By 31 December 2012, total budgetary commitments of 13 475 000 euro had been made for specific contracts under these framework contracts, and payments of 4 690 000 euro had been made.

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

5 A new procedure was prepared in 2013 and will enter into force in 2014.

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, Iceland and 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, 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, with or without request of deferral(s) and/or partial waivers; for modification of a previously agreed paediatric investigation plan; for product-specific waivers and for compliance checks. 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, Iceland and 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** Commission's 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 2013 *(2012)*	**Final Budget** 251,560 *(222,489)* million euro[1]; Union contribution: 13,0 % *(9,6 %)*[2] **Staff as at 31 December 2013** 611 *(590)* in the establishment plan, of which occupied: 583 *(575)* 144 *(160)* other staff (contract staff, seconded national experts, employment agency staff) Total staff: 727 *(735)*, undertaking the following tasks: operational: 590 *(594)*, administrative 137 *(141)*
Products and services in 2013 *(2012)*	**Medicinal Products for Human Use** – Applications for marketing authorisations: 80 *(96)* – Favourable opinions: 80 *(57)* – Average evaluation time: 200 *(188)* days – Opinions after authorisation: 5 447 *(5 137)* – Pharmacovigilance (CAP EEA and non-EEA ADR reports): 679 413 *(522 073)* reports – Periodic safety update reports: 525 *(463)* – Scientific advice finalised: 474 *(420)* – Mutual Recognition Procedures and Decentralised Procedures: started 6 293 *(6 991)*; ended 6 242 *(6 709)* – Applications for paediatric investigation plans: 211 *(178)* relating to 225 *(218)* indications

	Medicinal Products for Veterinary Use – Applications for marketing authorisations: 23 *(13)* – Applications in respect of variants: 315 *(261)* **Inspections** Inspections: 480 *(450)* **Herbal Medicinal Products** Herbal monographs: 9 *(15)* List of herbal substances, preparations and combinations thereof: 0 *(0)* **Orphan Medicinal Products** – Applications: 201 *(197)* – Favourable opinions: 136 *(139)* **SMEs** – Requests for SME status 401 *(684)* – Applications for fee reduction or deferrals 336 *(316)*

[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.

Source: Annex supplied by the Agency.