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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
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Report on the annual accounts of the European Medicines Agency for the financial year 2012

together with the Agency's replies

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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 (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:

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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.

(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 2012, and

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

The management's responsibility

4. In accordance with Articles 33 and 43 of Commission Regulation (EC, Euratom) No 2343/2002[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 transactions:

(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 Director approves the annual accounts of the Agency after its accounting officer has prepared them on the basis of all available

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[3] 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.

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

[5] OJ L 357, 31.12.2002, p. 72.

[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.

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 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

[7] Article 185(2) of Council Regulation (EC, Euratom) No 1605/2002 (OJ L 248, 16.9.2002, p. 1).

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.

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 2012 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 2012 are legal and regular in all material respects.

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

COMMENTS ON THE RELIABILITY OF THE ACCOUNTS

11. 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.

12. The Agency has not yet validated its accounting system in the area of intangible fixed assets. Given the considerable investment in the ICT development[8], this is a crucial part of the whole accounting system.

13. 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[9].

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[8] 2012 investments in ICT development amounted to 11 625 000 euros.

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

COMMENTS ON THE LEGALITY AND REGULARITY OF TRANSACTIONS

14. In 2012, the Agency issued cascading framework contracts for the provision of services[10]. The procurement procedure presented some irregularities affecting the principle of transparency.

15. In addition to the education allowances provided for in the Staff Regulations[11], 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.

COMMENTS ON BUDGETARY MANAGEMENT

16. 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.

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[10] 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.

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

FOLLOW-UP OF PREVIOUS YEAR'S COMMENTS

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

This Report was adopted by Chamber IV, headed by Dr Louis GALEA, Member of the Court of Auditors, in Luxembourg at its meeting of 9 July 2013.

For the Court of Auditors

Vítor Manuel da SILVA CALDEIRA
President

ANNEX I

Follow-up of previous year's comments

Year	Court´s comment	Status of corrective action (Completed / Ongoing / Outstanding / N/A)
2011	The level of carry-over is excessive and at odds with the principle of annuality.	**Completed**
2011	The Agency increased in 2011 the financial envelope of an irregular framework contract for IT services concluded in 2009 for which the Court had qualified its opinion on the legality and regularity of the transactions underlying the Agency's 2009 accounts. The original contract ceiling was 30 million euro. This was irregularly increased in 2011 by 8 million euro and specific contracts were signed for an amount of 8,1 million euro, leading to irregular payments and accrued charges in 2011 amounting to 3,6 million euro. The IT project is ongoing and the Agency has started preparing in 2011 a new framework contract.	**N/A (contract expired)**
2011	There is scope for improving the transparency of procurement procedures.	**Outstanding**
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.	**Ongoing**

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*), consisting of one member and one alternate from each Member State and five co-opted members, advises on any question relating to the evaluation of medicinal products for human use. The **Committee for Medicinal Products for Veterinary Use** (*CVMP*), consisting of one member and one alternate from each Member State, advises on any question relating to the evaluation of veterinary medicinal products. The **Committee for Orphan Medicinal Products** (*COMP*), consisting of one member and one alternate from each Member State, advises on any question relating to the evaluation of orphan medicinal products. The **Committee on Herbal Medicinal Products** (*HMPC*), consisting of one member and one alternate from each Member State and five co-opted members, advises on any question relating to the evaluation of herbal medicinal products. The **Paediatric Committee** (*PDCO*), consisting of one member and one alternate from each Member State, six members and alternates representing healthcare professionals and patients' associations, is responsible for the scientific assessment and agreement of paediatric investigation plans and for the system of waivers and deferrals thereof. The **Committee for Advanced Therapy** (*CAT*), consisting of five members of CHMP and their (five) alternates, one member and one alternate from each Member State, two members and two alternates representing clinicians, two members and two alternates representing patients' associations, is responsible for any question relating to the assessment of advanced therapy medicinal products and ATMP certification and classification. The **Pharmacovigilance Risk Assessment Committee** (*PRAC*), consisting of one member and one alternate from each Member State, six independent scientific experts nominated by the European Commission, one member and an alternate nominated by the European Commission after consultation of the European Parliament to represent healthcare professionals and one member and an alternate nominated by the European Commission after consultation of the European Parliament to represent patients' organisations. The **Management Board** consists of one member and one alternate from each Member State, two representatives of the Commission, two representatives appointed by the European Parliament, 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. **External audit** European Court of Auditors. **Discharge authority** European Parliament, acting on a recommendation from the Council.
Resources made available to the Agency in 2012 *(2011)*	**Final Budget** 222,489[1] *(208,863)* million euro[2]; Union contribution: 9,6 %[3] *(13,4 %[4])* **Staff as at 31 December 2012** 590 *(567)* in the establishment plan, of which occupied: 575 *(552)* 160 *(177)* other staff (contract staff, seconded national experts, employment agency staff) Total staff: 735 *(728)*, undertaking the following tasks: operational: 594 *(584)*, administrative 141 *(144)*
Products and services in 2012 *(2011)*	**Medicinal Products for Human Use** – Applications for marketing authorisations: 96 *(100)* – Favourable opinions: 57 *(87)* – Average evaluation time: 188 *(178)* days – Opinions after authorisation: 5 137 *(4 982)* – Pharmacovigilance (CAP EEA and non-EEA ADR reports): 522 073 *(362 231) reports* – Periodic safety update reports: 463 *(583)* – Scientific advice finalised: 420 *(430)* – Mutual Recognition Procedures and Decentralised Procedures: started 6 991 *(6 401)*; ended 6 709 *(6 715)* – Applications for paediatric investigation plans: 178 *(187)* relating to 218 *(220)* indications **Medicinal Products for Veterinary Use** – Applications for marketing authorisations: 13 *(11)* – Applications in respect of variants: 261 *(287)* **Inspections** Inspections: 450 *(450)* **Herbal Medicinal Products** Herbal monographs: 15 *(20)* List of herbal substances, preparations and combinations thereof: 0 *(0)* **Orphan Medicinal Products** – Applications: 197 *(166)* – Favourable opinions:139 *(111)* **SMEs** – Requests for SME status 684 *(433)* – Applications for fee reduction or deferrals 316 *(350)*

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

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

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

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

Source: Information supplied by the Agency.

THE AGENCY'S REPLY

11: The introduction of the SAP accounting system in 2011 has enabled the Agency to recognise revenue for all fee application types with more precision, on a straight-line basis over a set time period. The significant act with regard to the evaluation of applications by the National Competent Authorities is considered by the Agency to be the delivery of the rapporteur report and review by the competent scientific committee. The accounting policy since 2006 has been to recognise the associated expenditure when that milestone is reached. In light of the Court's observation the Agency will review its accounting policy on recognising fee revenue and associated expenditure to ensure future compliance with the matching principle. The Agency notes that the Court concluded that the effect on the 2012 accounts is not material.

12: The ICT systems providing accounting information for the regulation and control on expenditure on intangible assets have been validated from a technical perspective. The Agency has now made the necessary adjustments to the 2012 provisional accounts and the positive validation of the accounting systems has been completed.

13: The amount was included in the Agency's accounts following an instruction from the Accounting Officer of the EU Commission that all unrealised exchange losses should be included in the budgetary accounts as well as the financial accounts. The Agency expects to need this money in order to cover the salaries payable in GBP to EMA staff when the 2011 and 2012 rappels are adopted. The Agency is aware that DG BUDG considers the "rappel" an unforeseeable expenditure, but judges this position to be untenable because the adaptation of exchange rates and weightings which are part of any "rappel" is not only foreseeable, but legally required and long overdue. For the budgetary accounts the Agency applies the same methodology used to calculate the provision in the financial accounts. The Agency's primary concern is that if these figures are not included in the 2012 budgetary accounts it will find itself returning funds to the Commission when in fact those funds will be needed to pay salary liabilities once the weighting and applicable exchange rates are adapted to real levels.

14: Whilst the Agency does not share the view of the Court that the principle of transparency was infringed in its tender procedure, it has discussed the Court's findings, in particular within its Advisory Committee on Contracts and Procurement, and will make improvements on the issues highlighted by the Court to ensure even greater transparency in the future.

15: It has not been possible to establish a European School for the Agency's staff. Taking account of the spirit of the Staff Regulations, the absence of a European school, the preferred option to use educational institutions providing multilingual education and the local complex geographic situation, the Agency has established an educational contribution benchmarked against and in line with financial support for pupils at the European Schools. This payment is made to the school in respect of school fees only and not to the staff member in the interest of equal treatment of all staff of the European Union.

If such direct payments to schools with mother tongue tuition are now considered irregular, the general question of European School subsidies for EU employees is concerned.

16: The relatively high level of appropriations for title II carried over from year 2012 to 2013 (27 %) was due to the reasons stated. It needs to be noted that the Agency has already substantially reduced its carry over levels as the equivalent carry over in 2011 was 33 % and 2010 36 %. The Agency strives by respecting its operational requirements to further reduce its carry over to a level within tolerable margins of the Financial Regulation.