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

CURIA RATIONUM

CORTE DEI CONTI EUROPEA
EIROPAS REVĪZIJAS PALĀTA
EUROPOS AUDITO RŪMAI

EURÓPAI SZÁMVEVŐSZÉK
IL-QORTI EWROPEA TA' L-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 2008

together with the Agency's replies

12, RUE ALCIDE DE GASPERI
L-1615 LUXEMBOURG

TÉLÉPHONE (+352) 43 98 – 1
TÉLÉFAX (+352) 43 93 42

E-MAIL: euraud@eca.europa.eu
INTERNET: www.eca.europa.eu

CONTENTS

INTRODUCTION

1. The European Medicines Agency (hereinafter "the Agency"), located in London, was created by Council Regulation (EEC) No 2309/93 of 22 July 1993, which was replaced by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004[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].

2. The Agency's 2008 budget amounted to 182,9 million euro compared with 163,1 million euro the previous year.The number of staff employed by the Agency at the end of the year was 587 as compared with 518 in the previous year.

STATEMENT OF ASSURANCE

3. Pursuant to the provisions of Article 248 of the Treaty the Court has audited the annual accounts[3] of the Agency, which comprise the "financial statements"[4] and the "reports on implementation of the budget"[5] for the financial year ended

---

1 OJ L 214, 24.8.1993, p. 18 and OJ L 136, 30.4.2004, p. 1. Pursuant to 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 The ***Table*** summarises the Agency's competences and activities. It is presented for information purposes.

3 These accounts are accompanied by a report on the budgetary and financial management during the year which gives inter alia an account of the rate of implementation of the appropriations with summary information on the transfers of appropriations among the various budget items.

4 The financial statements include the balance sheet and the economic outturn account, the cash-flow table, the statement of changes in capital and the annex to the financial statements which includes the description of the significant accounting policies and other explanatory information.

5 The budget implementation reports comprise the budget outturn account and its annex.

31 December 2008 and the legality and regularity of the transactions underlying those accounts.

4. This Statement of Assurance is addressed to the European Parliament and the Council in accordance with Article 185(2) of Council Regulation (EC, Euratom) No 1605/2002[6].

The Director's responsibility

5. As authorising officer, the Director implements the revenue and expenditure of the budget in accordance with the financial rules of the Agency under his own responsibility and within the limits of authorised appropriations[7]. The Director is responsible for putting in place[8] the organisational structure and the internal management and control systems and procedures relevant for drawing up final accounts[9] that are free from material misstatement, whether due to fraud or error, and for ensuring that the transactions underlying those accounts are legal and regular.

The Court's responsibility

6. The Court's responsibility is to provide, on the basis of its audit, a statement of assurance as to the reliability of the annual accounts of the Agency and the legality and regularity of the transactions underlying them.

---

6 OJ L 248, 16.9.2002, p. 1.

7 Article 33 of Commission Regulation (EC, Euratom) No 2343/2002 of 23 December 2002 (OJ L 357, 31.12.2002, p. 80).

8 Article 38 of Commission Regulation (EC, Euratom) No 2343/2002 of 23 December 2002 (OJ L 357, 31.12.2002, p. 80).

9 The rules concerning the presentation of the accounts and accounting by the Agencies are laid down in chapter 1 of Title VII of Commission Regulation (EC, Euratom) No 2343/2002 of 23 December 2002 (OJ L 357, 31.12.2002, p. 87) as last amended by Commission Regulation (EC, Euratom) No 652/2008 of 9 July 2008 (OJ L 181, 10.7.2008, p. 23) and are integrated as such in the Financial Regulation of the Agency.

7. The Court conducted its audit in accordance with the IFAC and ISSAI[10] International Auditing Standards and Codes of Ethics. Those standards require that the Court complies with ethical requirements and plans and performs the audit to obtain reasonable assurance about whether the accounts are free from material misstatement and whether the underlying transactions are legal and regular.

8. The Court's audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the accounts and about the legality and regularity of the transactions underlying them. The procedures selected depend on its audit judgement including the assessment of the risks of material misstatement of the accounts or of illegal or irregular transactions, whether due to fraud or error. In making those risk assessments internal control relevant to the entity's preparation and presentation of accounts is considered in order to design audit procedures that are appropriate in the circumstances. The Court's audit also includes evaluating the appropriateness of accounting policies used and, the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the accounts.

9. The Court believes that the audit evidence obtained is sufficient and appropriate to provide a basis for the opinions set out below.

Opinion on the reliability of the accounts

10. In the Court's opinion, the Agency's Annual Accounts[11] present fairly, in all material respects, its financial position as of 31 December 2008 and the results

---

[10] International Federation of Accountants (IFAC) and International Standards of Supreme Audit Institutions (ISSAI).

[11] The Final Annual Accounts were drawn up on 30 June 2009 and received by the Court on 6 July 2009. The Final Annual Accounts, consolidated with those of the Commission are published in the Official Journal of the European Union by 15 November of the following year. These can be found on the following website http://eca.europa.eu or www.emea.europa.eu/htms/general/manage/ar.htm.

of its operations and its cash flows for the year then ended, in accordance with the provisions of its Financial Regulation.

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

11. In the Court's opinion, the transactions underlying the annual accounts of the Agency for the financial year ended 31 December 2008 are, in all material respects, legal and regular.

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

COMMENTS ON THE BUDGETARY AND FINANCIAL MANAGEMENT

13. Of the budget appropriations, 36 million euro were carried over and 9,7 million euro were cancelled. As in previous years, the high level of carry-overs for administrative expenditure - 21,4 million euro - was mainly due for IT expenditure for a programme for the regulation of medical products[12]. This situation has existed for a number of years and is at odds with the annuality principle. The Agency should take the appropriate steps to address this shortcoming.

14. The Agency has had a long standing policy to enter into forward foreign exchange contract for the next financial year in order to hedge part (50 %) of its administrative budget against unfavourable fluctuations of the exchange rate for the sterling[13]. As the 2008 closing sterling rate used for drawing up the financial statements was significantly higher than foreseen when the contract was made (in August 2008), the Agency accounted for a negative fair value movement of 8,7 million euro in its capital account. The Agency should consider reassessing its policy in the light of the risks incurred.

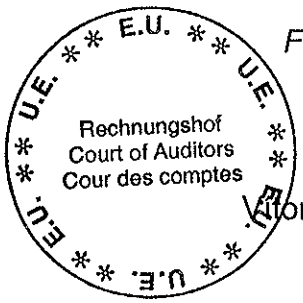
---

[12] In the case of one contract for IT services, 6,8 million euro have been committed at the end of 2008 and almost the entire amount has been carried over to be used in the next year.

[13] See note 17 to the Financial Statements for the financial year 2008.

15. As was the case last year[14], the audit of the tendering procedures showed weaknesses: inadequate evaluation methods for the price criteria[15], insufficient justification of chosen procedures[16] and other procedural weaknesses[17]. The Agency should aim to improve the quality of its public procurement procedures in order to address the issues highlighted above.

This report was adopted by the Court of Auditors in Luxembourg at its meeting of 8 October 2009.



For the Court of Auditors

Vítor Manuel da Silva Caldeira
President

---

14 See paragraph 8 of 2007 Annual Report (OJ C 311, 5.12.2008, p. 28).

15 Four cases, with values of 2 million euro, 1,8 million euro, 0,6 million euro, 0,3 million euro.

16 One case, with value of 6,8 million euro.

17 Five case, with values of 2 million euro, 6,8 million euro, 1,3 million euro, 2,4 million euro, 0,3 million euro.

Table – European Medicines Agency (London)

Areas of Community competence deriving from the Treaty	Competences of the Agency as defined in Regulation (EC) No 726/2004 of the European Parliament and of the Council		Governance	Resources made available to the Agency in 2008 *(Data for 2007)*	Products and Services in 2008 *(Data for 2007)*
A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities. Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases and obviating sources of danger to human health. (...) *(Article 152 of the Treaty)*	**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 Community marketing authorisation procedures. - To coordinate the supervision of medicinal products which have been authorised within the Community (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.	**1 - The Committee for Medicinal Products for Human Use**, consisting of one member and one alternate from each Member State, advises on any question relating to the evaluation of medicinal products for human use. **2 - The Committee for Medicinal Products for Veterinary Use**, consisting of one member and one alternate from each Member State, advises on any question relating to the evaluation of veterinary medicinal products. **3 - The Committee for Orphan Medicinal Products**, consisting of one member and one alternate from each Member State, advises on any question relating to the evaluation of orphan medicinal products. **4 - The Committee on Herbal Medicinal Products**, consisting of one member and one alternate from each Member State, advises on any question relating to the evaluation of herbal medicinal products. **5 - The Paediatric Committee**, consisting of one member and one alternate from each Member State, six members and alternates representing healthcare professionals and patients' associations, responsible for the scientific assessment and agreement of paediatric investigation plans and for the system of waivers and deferrals thereof. **6 - 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. **7 - The Executive Director** is appointed by the Management Board on a proposal from the Commission. **8 - External audit** Court of Auditors, Commission Internal Audit Service. **9 - Discharge authority** Parliament acting on recommendation of the Council.	**Budget** 182.9 million euro *(163,1 million euro)* Community contribution (excluding subsidy for orphan medicines): 21.9 % *(24,3 %)* **Staff numbers at 31 December 2008:** Posts provided for in the establishment plan: 481 *(441)* Posts occupied: 469 *(422)* + 118 *(77)* other staff (contract agents seconded national experts, employment agency staff) **Total staff**: 587 *(518)* Assigned to the following duties: Operational: 483 *(444)* Administrative: 104[18] *(74)*	**Medicinal Products for Human Use** - Applications for marketing authorisations: 103 *(91)* - Favourable opinions: 68 *(58)* - Average evaluation time: 184 days *(171 days)* - Opinions after authorisation: 2 122 *(1 899)* - Pharmacovigilance (CAP EEA and non-EEA ADR reports): 193 587 reports *(150 188 reports)* - Periodic safety update reports: 391 *(313)* - Scientific advice finalised: 263 *(215)* - Procedures for mutual recognition: started 14 522 (12 109); ended positively 12 681 *(10 932)* - Applications for paediatric investigation plans: 271 *(85)* relating to 395 *(202)* indications **Medicinal Products for Veterinary Use** - New applications: 13 *(14)* - Applications in respect of variants: 100 *(100)* - Inspections: 253 *(185)* **Orphan Medicinal Products** - Applications: 119 *(125)* - Favourable opinions : 86 *(97)* **SMEs** - Requests for SME status 242 *(212)* - Applications for fee reduction or deferrals 84 *(81)*

Source: Information supplied by the Agency.

[18] For 2008, administrative staff has been redefined and include the internal audit and legal sectors.

THE AGENCY'S REPLIES

13. The Agency takes note of the Court's observations. It is confirmed that the main reason for carry over in the IT area are a number of multiannual pan-European projects. The Agency will make every effort to respect more closely the annuality principle.

14. The Agency believes that over the long term it is prudent to manage the currency exposure risk. We have taken into account the Court's observation and an internal management group will look at the hedging strategy to follow for 2010 in conjunction with the Agency's bank.

15. The Agency takes note of the observed weaknesses and has taken action to improve the implementation and accompanying controls of procurement and tender procedures.