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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

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Report on the annual accounts of the European Medicines Agency for the financial year 2009

together with the Agency's replies

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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 2009 budget amounted to 194,4 million euro, compared with 182,9 million euro the previous year. The number of staff employed by the Agency at the end of the year was 664, as compared with 587 in the previous year.

STATEMENT OF ASSURANCE

3. Pursuant to the provisions of Article 287(1), second subparagraph of the Treaty on the Functioning of the European Union, the Court has audited the annual accounts[3] of the Agency, which comprise the "financial statements"[4]

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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.

and the "reports on implementation of the budget"[5] for the financial year ended 31 December 2009 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 the 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.

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

6 OJ L 248, 16.9.2002, p. 1.

7 Article 33 of Commission Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 (OJ L 357, 31.12.2002, p. 80).

8 Article 38 of Regulation (EC, Euratom) No 2343/2002.

9 The rules concerning the presentation of the accounts and accounting by the Agencies are laid down in chapter 1 of Title VII of Regulation (EC, Euratom) No 2343/2002 as last amended by 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.

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.

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.

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

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 2009 and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its Financial Regulation.

Basis for qualified opinion on the legality and the regularity of the transactions underlying the accounts

11. In 2009, the Agency concluded a number of procedures for the procurement of large IT framework contracts. The audit showed errors which affected the regularity of 4 operations examined as detailed in paragraphs 12 to 14 below.

12. In the case of a procurement of a large framework contract for IT services[12], the conditions for applying a negotiated procedure following an open procedure where tenders were assessed to be of an unacceptable quality were not satisfied. The audit of the open procedure showed errors such as 1) arithmetical errors in the evaluation of the award criteria, 2) a Member of the Evaluation committee did not properly document the evaluation made which did not ensure that the same approach was followed by all Members, and 3) a lack of evidence that the evaluation method of the selection criteria had been applied consistently which was thus open to interpretation. The Agency did not carry out enough checks to mitigate the risk of errors before launching a negotiated procedure which in turn did not guarantee that best value for money was achieved, due to errors in the implementation of the award criteria.

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[11] The Final Annual Accounts were drawn up on 30 June 2010 and received by the Court on 30 June 2010. 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.

[12] Estimated value: 30 million euro.

13. In another case[13] there was a lack of evidence regarding the method used for the evaluation of the selection criteria which was thus open to interpretation.

14. In a case of negotiated procurement with a single supplier[14] for technical reasons, no formal invitation to tender was issued and no detailed technical specifications were prepared in advance as is required under relevant procurement regulations. Detailed technical specifications should always be prepared detailing the full technical aspects of the agency's needs (full details of services, supplies or products, timelines foreseen, place of execution of services or delivery, etc.). In another similar case[15], the technical specifications did not clearly define all the products to be purchased before the negotiation started. In both cases no evaluation committee was appointed and no evaluation report was prepared.

Qualified opinion on the legality and the regularity of the transactions underlying the accounts

15. In the Court's opinion, except for the matters presented in paragraphs 11 to 14, the transactions underlying the annual accounts of the Agency for the financial year ended 31 December 2009 are, in all material respects, legal and regular.

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

COMMENTS ON THE BUDGETARY AND FINANCIAL MANAGEMENT

17. For Title II – Buildings, equipment and miscellaneous operating expenditure activities, 19,5 million euro or 38 % of the commitments made were carried forward to the budgetary year 2010. According to the accounting

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13 Estimated value: 4 million euro.

14 Estimated value of 5,3 million euro.

15 Estimated value of 4 million euro.

information, approximately 14,8 million euro of the appropriations carried forward corresponded to activities not yet implemented (or in some cases goods not received) at the year-end. This situation indicated delays in the implementation of the activities financed from Title II of the Agency's budget and was not in keeping with the budgetary principle of annuality.

18. As regards own revenue, two recovery orders (226 200 euro and 110 200 euro), out of ten tested, were issued with a very long delay (21 and 5 months respectively), in breach of the Agency's internal rules. This was due to a lack of coordination between the financial and scientific services.

19. As noted by the Court in its 2008 Specific Annual Report[16], the Agency has had a long-standing policy of entering into forward foreign-exchange contracts in order to hedge part (50 %) of its administrative budget against unfavourable fluctuations in the exchange rate for Sterling. In 2009, the total foreign exchange loss recognised in the economic outturn account was 0,9 million euro. The Agency should consider reassessing its treasury policy in the light of the losses and risks incurred.

This Report was adopted by Chamber IV, headed by Mr Igors LUDBORŽS, Member of the Court of Auditors, in Luxembourg at its meeting of 5 October 2010.

For the Court of Auditors

Vítor Manuel da SILVA CALDEIRA
President

[16] OJ C 304, 15.12.2009, p. 29.

Table – European Medicines Agency (London)

Areas of Union competence deriving from the Treaty	Competences of the Agency (Regulation (EC) No 726/2004 of the Parliament and of the Council)		Governance	Resources made available to the Agency in 2009 *(Data for 2008)*	Products and services in 2009 (*Data for 2008*)
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. *(Article 168 of the Treaty on the Functioning of the European Union)*	**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 (pharmaco-vigilance). - 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** (CHMP), consisting of one member and one alternate from each Member State and 5 co-opted members, advises on any question relating to the evaluation of medicinal products for human use. **2 - 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. **3 - 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. **4 - The Committee on Herbal Medicinal Products** (HMPC), consisting of one member and one alternate from each Member State and 5 co-opted members, advises on any question relating to the evaluation of herbal medicinal products. **5 - 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. **6 - 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. **7 - 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. **8 - The Executive Director** is appointed by the Management Board on a proposal from the Commission. **9 – Internal audit** Internal Audit Service of the Commission. **10 - External audit** Court of Auditors. **11 - Discharge authority** Parliament, acting on a recommendation from the Council.	**Budget** 194,389 million euro (*182,895 million euro*); Union contribution: 18,7 % (*18,8 %*) **Staff at 31 December 2009** Posts provided for in the establishment plan: 530 (*481*) Posts occupied: 511 (*469*) 160 (*104*) other staff (contract staff, seconded national experts, employment agency staff) **Total staff**: 664 (*587*) **Allocated to:** Operational: 520 (*483*) Administrative: 144 (*104*)	**Medicinal Products for Human Use** - Applications for marketing authorisations: 96 (*103*) - Favourable opinions: 117 (*68*) - Average evaluation time: 157 days (*184 days*) - Opinions after authorisation: 2 396 (*2 122*) - Pharmaco-vigilance (CAP EEA and non-EEA ADR reports): 252 117 reports (*193 587 reports*) - Periodic safety update reports: 425 (*391*) - Scientific advice finalised: 308 (*263*) - Mutual Recognition Procedures and Decentralised Procedures: started 16 307 (14 522); ended positively 15 335 (*12 681*) - Applications for paediatric investigation plans: 273 (*271*) relating to 364 (*395*) indications **Medicinal Products for Veterinary Use** - Applications for marketing authorisations: 15 (*16*) - Applications in respect of variants: 113 (*100*) - Inspections: 233 (*253*) **Herbal Medicinal Products** Herbal monographs: 17 (*17*) List of herbal substances, preparations and combination thereof: 0 (*5*) **Orphan Medicinal Products** - Applications: 164 (*119*) - Favourable opinions: 113 (*86*) **SMEs** - Requests for SME status 217 (*242*) - Applications for fee reduction or deferrals 80 (*84*)

Source: Information supplied by the Agency.

THE AGENCY'S REPLIES

11. Considering the high number and complexity of tender procedures, notably in the IT area, which lies at the root of the errors noted by the Court and in an effort to organise tender procedures in a more consistent way, the agency will set up a multi-annual procurement plan and will also ensure stronger technical and procedural controls. In EMA's view, the errors affecting the regularity of the procedures in no case led to financial disadvantages.

12. For this highly complex procedure a comprehensive and detailed evaluation guide was used in a draft form by all members of the evaluation committee. This guide was used as a pilot exercise and appears not to have been applied in a strict manner on all occasions. The Agency acknowledges that there was an error in the final marks resulting from the evaluation.

The result of the negotiated procedure was the award of framework contracts in the same order of cascade as the bidders had been ranked in the open procedure. However, both tenders had been substantially improved with regard to quality and the average of prices.

In view of the findings of the Court, the Agency will ensure that the results of procurement procedures are verified before contracts are awarded.

13. As was the case for the procedure mentioned in paragraph 12 above, a comprehensive and detailed evaluation guide was used in draft form by all members of the evaluation committee. This guide was also used as a part of a pilot exercise. Experience with this draft evaluation guide showed that it was too strict leading to unreasonably low marks.

With the benefit of hindsight, given the volume of the contracts concerned, it would have been better to pilot the evaluation guide with a smaller procurement transaction.

The conclusions were based on a consistent and objective assessment of the tenders received by the evaluation committee. The Agency acknowledges however, that the

report of the evaluation committee was unclear regarding the way the selection criteria had been assessed.

Improvement actions have been initiated to avoid a recurrence of such problems.

14. The procurements were necessary for the continuation of services and the maintenance and acquisition of goods because the existing framework contracts were due to expire. There was no alternative to negotiated procedures for technical reasons. The principal objective for negotiation was to bring down the prices for existing goods and services. During the negotiation process the Agency achieved substantial reductions in prices in comparison to the previous framework contracts for some of the products concerned. In view of the findings of the Court, the Agency will ensure that detailed technical specifications are always prepared.

17. Following the Courts' observations on financial year 2006, the Agency had reviewed its financial commitments carried–over especially within Title II. Consequently, for several multi-annual contracts that expired since 2007, the duration was amended with the aim of starting contracts in the 1st quarter of a financial year. The Agency has continued to make significant efforts to reduce its carry-overs. Taking account of the growth in overall budget, in relative terms the carry-over in Title II decreased from 42.6% (2008 to 2009) to 38.1% (2009 to 2010). The Agency will continue reducing the carry-overs of appropriations with a further decline expected for the carry-over from 2010 to 2011.

18. Temporary control measures have been put in place pending the new financial database SAP's ability to automatically create and update fee data from the operational database once validation of applications is completed.

This will immediately flag delays occurring after the scientific operational processes and before the financial initiation of fee recovery.

19. The treasury policy has been revised, adopted and formally approved by the agency's Audit Advisory Committee.