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ΕΥΡΩΠΑΪΚΟ ΕΛΕΓΚΤΙΚΟ ΣΥΝΕΔΡΙΟ
EUROPEAN COURT OF AUDITORS
COUR DES COMPTES EUROPÉENNE
CÚIRT INIÚCHÓIRÍ NA HEORPA

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 2011

together with the Agency's replies

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INTRODUCTION

1. The European Medicines Agency (hereinafter "the Agency" or “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, the Court has audited the annual accounts[3] of the Agency, which comprise the financial statements[4] and the reports on the implementation

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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 The ***Annex*** 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 further information on budget implementation and management.

4 The financial statements 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.

of the budget[5] for the financial year ended 31 December 2011, and the legality and regularity of the transactions underlying those accounts.

The Management's responsibility

4. 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[6]. The Director is responsible for putting in place[7] the organisational structure and the internal management and control systems and procedures relevant for drawing up final accounts[8] 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 Auditor's responsibility

5. The Court's responsibility is to provide, on the basis of its audit, the European Parliament and the Council[9] with 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. The Court conducted its audit in accordance with the IFAC International Standards on Auditing and Codes of Ethics and the INTOSAI International

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

6 Article 33 of Commission Regulation (EC, Euratom) No 2343/2002, (OJ L 357, 31.12.2002, p. 72).

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

8 The rules concerning the presentation of the accounts and accounting by the Agencies are laid down in Chapters 1 and 2 of Title VII of Regulation (EC, Euratom) No 2343/2002 as last amended by Regulation (EC, Euratom) No 652/2008 (OJ L 181, 10.7.2008, p. 23) and are integrated as such in the Financial Regulation of the Agency.

9 Article 185(2) of Council Regulation (EC, Euratom) No 1605/2002.

Standards of Supreme Audit Institutions. These standards require that the Court plans and performs the audit to obtain reasonable assurance as to whether the annual accounts of the Agency are free of material misstatement and the transactions underlying them are legal and regular.

7. An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the accounts and the legality and regularity of the transactions underlying them. The procedures are selected based on the auditor's judgment, including an assessment of the risks of material misstatement of the accounts and of material non-compliance of the underlying transactions with the requirement of the legal framework of the European Union, whether due to fraud or error. In assessing those risks, the auditor considers internal controls relevant to the preparation and fair presentation of the accounts and supervisory and control systems implemented to ensure the legality and regularity of underlying transactions, in order to design audit procedures that are appropriate in the circumstances. An audit also includes evaluating the appropriateness of accounting policies used and reasonableness of accounting estimates made, as well as evaluating the overall presentation of the accounts.

8. The Court considers 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

9. In the Court's opinion, the Agency's Annual Accounts[10] present fairly, in all material respects, its financial position as of 31 December 2011 and the results of its operations and its cash flows for the year then ended, in accordance with

[10] The Final Annual Accounts were drawn up on 29/06/2012 and received by the Court on 02/07/2012. 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. They can be found on the following website http://eca.europa.eu or http://www.ema.europa.eu/.

the provisions of its Financial Regulation and the accounting rules adopted by the Commission's accounting officer[11].

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

10. In the Court's opinion, the transactions underlying the annual accounts of the Agency for the financial year ended 31 December 2011 are legal and regular in all material respects.

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

COMMENTS ON BUDGETARY AND FINANCIAL MANAGEMENT

12. Payment appropriations amounting to 9,6 million euro have been carried over to 2012 for Title II (administrative expenditure), representing 29 % of the Title II budget. Payment appropriations amounting to 10,3 million euro have been carried over to 2012 for Title III (operational expenditure), representing 34 % of the Title III budget[12]. This level of carry-over is excessive and at odds with the principle of annuality.

COMMENTS ON KEY CONTROLS OF THE AGENCY'S SUPERVISORY AND CONTROL SYSTEMS

13. 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

[11] The accounting rules adopted by the Commission's accounting officer are derived from International Public Sector Accounting Standards (IPSAS) issued by the International Federation of Accountants or, in their absence, International Accounting Standards (IAS)/International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board.

[12] The figures presented for Title III exclude the carryover (18,3 million euro) of payment appropriations for the evaluation of medicinal products (71,9 million euro, budget line 3010), for which the carry-over is justified because of the nature of the payments to the national authorities.

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.

14. There is scope for improving the transparency of procurement procedures as regards the justification of the estimated contract volumes and the definition, publication and application of selection criteria.

OTHER COMMENTS

15. 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.

16. As in previous reports, the Court has noted the need to introduce a system of remuneration for services provided by Member State authorities based on their real costs.

17. The Court carried out an audit aimed at evaluating the policies and procedures for the management of conflict of interest situations for four European Agencies, including EMA. The results of the audit are presented in a separate document (Special Report 15/2012).

This Report was adopted by Chamber IV, headed by Dr Louis GALEA, Member of the Court of Auditors, in Luxembourg at its meeting of 5 September 2012.

For the Court of Auditors

Vítor Manuel da SILVA CALDEIRA
President

Annex

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 5 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 5 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 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**, Internal Audit Service of the Commission (*IAS*). **Internal Audit Capability**, Internal Audit Service of the EMA (*IAC*). **External audit**, European Court of Auditors (*ECA*). **Discharge authority**, Parliament, acting on a recommendation from the Council.

Resources made available to the Agency in 2011 *(2010)*	**Final Budget** 208,863 million euro[13] (*208,387*); Union contribution: 13,4 %[14] (*13,6 %*[15]) **Staff as at 31 December 2011** 567 *(567)* foreseen in the establishment plan, of which occupied: 552 *(546)* 177 *(152)* other staff (contract agents, seconded national experts, employment agency staff) Total staff: 728 *(698),* undertaking the following tasks: operational: 584 *(556),* administrative 144 *(142)*
Products and services in 2011 *(2010)*	**Medicinal Products for Human Use** - Applications for marketing authorisations: 100 *(91)* - Favourable opinions: 87 *(51)* - Average evaluation time: 178 days *(167)* - Opinions after authorisation: 4 982 *(3 154)* - Pharmaco-vigilance (CAP EEA and non-EEA ADR reports): 362 231 reports *(302 362)* - Periodic safety update reports: 583 *(559)* - Scientific advice finalised: 430 *(322)* - Mutual Recognition Procedures and Decentralised Procedures: started 6 401 *(21 433);* ended 6 715 *(11 100)* - Applications for paediatric investigation plans: 187 *(326)* relating to 220 *(403)* indications **Medicinal Products for Veterinary Use** - Applications for marketing authorisations: 11 *(18)* - Applications in respect of variants: 287 *(162)* **Inspections** Inspections: 449 *(300)* **Herbal Medicinal Products** Herbal monographs: 20 *(19)* List of herbal substances, preparations and combination thereof: 0 *(3)* **Orphan Medicinal Products** - Applications: 166 *(174)* - Favourable opinions: 111 *(123)* **SMEs** - Requests for SME status 433 *(251)* - Applications for fee reduction or deferrals 350 *(161)*

Source: Information supplied by the Agency.

[13] This is the final budget, not the actual outturn from the budgetary accounts.

[14] 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.

[15] 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.

THE AGENCY'S REPLY

12. Over the last years the Agency has made every effort to reduce its level of carry-over to an acceptable level, i.e. 30% for Title 2 and 3 overall, and has in fact achieved a continuous reduction. As the operations of the Agency are of a multi-annual nature and not linked to the calendar year, a certain level of carry-overs is unavoidable.

13. As it was explained in detail in the Agency's replies to the 2009 discharge observations, the Agency considers that the IT framework contract was not irregular. As a consequence, the extension of the framework contract is considered not irregular as well.

14. The Agency has taken note of the Court's comments and updated its procedures with a view to transparency and documentation.

15. The Agency has taken note of the Court's comments and updated its procedures with a view to transparency and timely documentation.

16. In 2009 a proposal for a new payment system was presented to the Management Board but no agreement was reached. The Management Board will be asked to endorse a new action plan at the meeting to be held in October 2012. Since any new fee system will require a change of the legislation, the European Commission will be approached to integrate the subject issue in its planned review of the Agency's fee regulation.

17. The Agency's replies to the results of this audit will be published together with the Special Report.