TL, APO, FN, GOM, MK, MH, UN, SL, NES, VE, VG, BB,

LUXEMBOURG, LE 29 OCT. 2009
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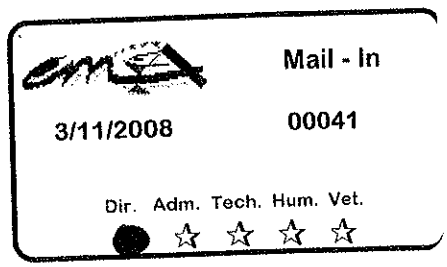
Vítor Caldeira
PRÉSIDENT
COUR DES COMPTES EUROPEENNE



Monsieur le Directeur,

J'ai l'honneur de vous transmettre ci-joint un exemplaire, dans toutes les langues officielles des Communautés européennes, du rapport de la Cour des comptes sur les comptes annuels de l'Agence européenne des médicaments relatifs à l'exercice 2007, ainsi qu'une copie de la lettre sous couvert de laquelle j'ai communiqué ce rapport à M. Pat O'MAHONY.

Veuillez agréer, Monsieur le Directeur, l'expression de ma haute considération.

Vítor CALDEIRA

Monsieur Thomas LÖNNGREN
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Vítor Caldeira
PRÉSIDENT
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Monsieur le Président,

Conformément aux dispositions du règlement (CE, Euratom) n° 1605/2002 du Conseil du 25 juin 2002 portant règlement financier applicable au budget général des Communautés européennes, j'ai l'honneur de vous communiquer ci-joint un exemplaire, dans toutes les langues officielles des Communautés européennes, du rapport de la Cour des comptes sur les comptes annuels de l'Agence européenne des médicaments relatifs à l'exercice 2007.

Ce rapport a été adopté par la Cour en sa réunion du 18 septembre 2008 et est accompagné des réponses de l'Agence. Il fera l'objet d'une publication au Journal officiel de l'Union européenne.

Veuillez agréer, Monsieur le Président, l'expression de ma très haute considération.

Vítor CALDEIRA

Monsieur Pat O'MAHONY
Président du Conseil d'administration
de l'Agence européenne des médicaments

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DEN EUROPÆISKE REVISIONSRET
EUROPÄISCHER RECHNUNGSHOF
EUROOPA KONTROLLIKODA
ΕΥΡΩΠΑΪΚΟ ΕΛΕΓΚΤΙΚΟ ΣΥΝΕΔΡΙΟ
EUROPEAN COURT OF AUDITORS
COUR DES COMPTES EUROPÉENNE
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Report on the annual accounts of the European Medicines Agency for the financial year 2007

together with the Agency's replies

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INTRODUCTION

1. The European Medicines Agency (hereinafter "the Agency") 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. ***Table 1*** summarises the Agency's competences and activities. Key data summarised from the financial statements drawn up by the Agency for the financial year 2007 are presented in ***Tables 2, 3 and 4*** for information purposes.

STATEMENT OF ASSURANCE

3. This Statement is addressed to the European Parliament and the Council in accordance with Article 185(2) of Council Regulation (EC, Euratom) No 1605/2002[2]; it was drawn up following an examination of the Agency's accounts, as required by Article 248 of the Treaty establishing the European Community.

4. The Agency's accounts for the financial year ended 31 December 2007[3] were drawn up by its Executive Director, pursuant to Article 68 of Regulation (EC) No 726/2004, and sent to the Court, which is required to give a Statement

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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 OJ L 248, 16.9.2002, p. 1.

3 These accounts were drawn up on 15 June 2008 and received by the Court on 1 July 2008.

of Assurance on their reliability and on the legality and regularity of the underlying transactions.

5. The Court conducted its audit in accordance with the IFAC and ISSAI[4] International Auditing Standards and Codes of Ethics, insofar as these are applicable in the European Community context. The audit was planned and performed to obtain reasonable assurance that the accounts are reliable and that the underlying transactions are legal and regular.

6. The Court has thus obtained a reasonable basis for the Statement set out below:

Reliability of the accounts

The Agency's accounts for the financial year ended 31 December 2007 are, in all material respects, reliable.

Legality and regularity of the underlying transactions

The transactions underlying the Agency's annual accounts, taken as a whole, are legal and regular.

The observations which follow do not call the Court's Statement into question.

OBSERVATIONS

7. The Agency's final budget for 2007 amounted to 163,1 million euro as compared with 138,7 million euro the previous year. Of the budget appropriations, 32 million euro were carried over and 4 million euro were cancelled. As in 2006, the high level of carry-overs for administrative expenditure, 18,9 million euro, was mainly due to the programme Telematics

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

for the regulation of medical products. The Agency and the other parties involved in this programme must ensure better planning and monitoring of the implementation of the programme. This situation is at odds with the annuality principle. The Agency should consider using the differentiated appropriations system for the Telematics programme which is more suitable for the budgetary management of such programmes.

8. The audit of the tendering procedures showed weaknesses: insufficient justification of the chosen procedures[5] and inadequate evaluation methods for the price criteria[6]. In the case of a joint public procurement procedure with five other Agencies, the volume of the services to be procured had not been adequately identified. This resulted in difficulties in evaluating the cost of the bids as well as the need to review the volumes and values of the services to be procured. The Agency should aim to improve the quality of its public procurement procedures in order to address the issues highlighted above.

9. In its 2006 report[7], the Court observed that the Agency had not performed a comprehensive analysis of the costs incurred by rapporteurs. The Management Board of the Agency has established a Costing Group which at the end of 2007 prepared a report on a generally accepted international costing methods and a proposal for an alternative option for remunerating the rapporteurs. The Court welcomes the steps the Agency has made in order to address the issue of the evaluation of the costs and calls for further progress.

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5 Two cases.

6 Three cases.

7 OJ C 309, 19.12.2007, p. 34.

This report was adopted by the Court of Auditors in Luxembourg at its meeting of 18 September 2008.

For the Court of Auditors

Vítor Manuel da Silva Caldeira
President

Table 1 - 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 2007 *(Data for 2006)*	Products and Services in 2007 *(Data for 2006)*
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 five members with their alternates of the Committee for Medicinal Products for Human Use, 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. **9 - Discharge authority** Parliament acting on recommendation of the Council.	**Final budget for 2007:** 163,1 million euro *(138,7 million euro)* Community contribution (excluding subsidy for orphan medicines): 24,3 % *(21,6 %)* **Staff numbers at 31 December 2007:** 441 *(424)* posts provided for in the establishment plan Posts occupied: 422 *(395)* 95 *(77)* other staff (auxiliary agents, contract agents seconded national experts, employment agency staff) **Total staff**: 518 *(472)* Assigned to the following duties: Operational: 444 *(406)* Administrative: 74 *(66)*	**Medicinal Products for Human Use** - Applications for marketing authorisations: 91 *(79)*; - Favourable opinions: 58 *(51)*; - Average evaluation time: 171 days *(171 days)*; - Opinions after authorisation: 1 899 *(1 380)*; - Pharmacovigilance: 150 188 reports *(94 081 reports)*; - Periodic safety update reports: 313 *(273)*; - Scientific opinions: 215 *(193)*; - Procedures for mutual recognition: 10 932 *(9 241)*; - Applications for paediatric investigation plans: 85 *(0)* relating to 202 *(0)* indications. **Medicinal Products for Veterinary Use** - New applications: 14 *(5)*; - Applications in respect of variants: 100 *(56)*; - Inspections: 185 *(128)*. **Orphan Medicinal Products** - Applications: 125 *(104)*; - Favourable opinions : 97 *(81)*. **SMEs** - Requests for SME status 212 *(145)*; - Applications for fee reduction or deferrals 81.

Source : Information supplied by the Agency.

Table 2 - European Medicines Agency (London) - Implementation of the budget for the financial year 2007

(1 000 euro)

REVENUE			EXPENDITURE									
Source of revenue	Revenue entered in the final budget for the financial year	Revenue collected	Allocation of expenditure	Final budget appropriations					Appropriations carried over from previous year(s)		
				entered	committed	paid	carried over	cancelled	entered	paid	cancelled
Own revenue	113 659	116 799	Title I Staff	51 132	49 871	49 107	764	1 261	767	661	106
Community subsidies	40 548	40 548									
Other subsidies	6 706	5 475	Title II Administration	47 198	44 758	25 863	18 895	2 440	15 061	14 360	701
Other revenue	2 200	2 467	Title III Operating activities	64 783	64 497	52 118	12 379	286	13 585	13 257	328
TOTAL	**163 113**	**165 289**	**TOTAL**	**163 113**	**159 126**	**127 088**	**32 038**	**3 987**	**29 413**	**28 278**	**1 135**

NB: Any discrepancies in totals are due to the effects of rounding.

Source: Data supplied by the Agency. This table summarises the data provided by the Agency in its annual accounts. Revenue collected and payments are estimated on a cash basis.

Table 3 - European Medicines Agency (London) - Economic outturn account for the financial years 2007 and 2006

(1 000 euro)

	2007	2006
OPERATING REVENUE		
Fees and other revenue	120 305	119 039
Community subsidies	41 144	31 503
Total (a)	**161 449**	**150 542**
OPERATING EXPENSES		
Staff expenses	50 165	45 150
Other administrative expenses	33 513	26 607
Operational expenses	67 402	63 437
Total (b)	**151 080**	**135 194**
SURPLUS/(DEFICIT) FROM OPERATING ACTIVITIES (c = a-b)	**10 369**	**15 348**
Financial operations revenue (e)	**-1 188**	**1 433**
SURPLUS/(DEFICIT) FROM NON-OPERATING ACTIVITIES (f = e)	**-1 188**	**1 433**
ECONOMIC RESULT FOR THE YEAR (g = c+f)	**9 181**	**16 781**

Source: Data supplied by the Agency. This table summarises the data provided by the Agency in its annual accounts.

Table 4 - European Medicines Agency (London) - Balance sheet at 31 December 2007 and 2006

(1 000 euro)

	2007	2006
NON-CURRENT ASSETS		
Intangible fixed assets	17 973	14 889
Tangible fixed assets	12 673	6 695
CURRENT ASSETS		
Short-term receivables	32 036	26 045
Cash and cash equivalents	34 318	37 508
Total assets	**97 000**	**85 138**
CURRENT LIABILITIES		
Provisions for risks and charges	2 909	2 699
Accounts payable	41 021	38 550
Total liabilities	**43 930**	**41 249**
Net assets	**53 070**	**43 889**
RESERVES		
Accumulated surplus/deficit	43 889	27 109
Economic result for the year	9 181	16 781
Net capital	**53 070**	**43 889**

Source: Data supplied by the Agency. This table summarises the data provided by the Agency in its annual accounts.

THE AGENCY'S REPLIES

7. The Agency takes note of the Court's observations. Reference is made to the particular difficulties in complying fully with the annuality principle when it comes to the implementation of multi-annual and multinational Telematics programmes, and also, to strictly observe the requirements of sound financial management. The Agency commits itself to make every effort to reduce the level of carry-overs and to consider the proposal of applying differentiated appropriations.

8. The Agency has established a formula for the objective evaluation of price as an award criteria, with effect from 17 March 2008.

In the case of the joint public procurement procedure with five other agencies, the original estimate had to be revalued due to the technological advances that occurred between the definition of the services to be provided and the effective launch of the procurement procedure. The Agency commits itself to make every effort to increase the quality of its public procurement procedures.

9. The Agency notes that the Court welcomes the progress the Agency has made. At its meeting of 12 June 2008 the Management Board endorsed the proposal to implement a pilot phase in order to introduce a new remuneration system for (co)rapporteurs after the pilot phase by the end of 2009.