REPORT

on the annual accounts of the European Agency for the Evaluation of Medicinal Products concerning the 2003 financial year together with the Agency's replies

(2004/C 324/05)

CONTENTS

INTRODUCTION

1. The European Agency for the Evaluation of Medicinal Products (hereinafter referred to as the Agency) was created by Council Regulation (EEC) No 2309/93 of 22 July 1993 ([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. *Table 1* summarises the powers and responsibilities of the Agency on the basis of the information supplied by it.

THE COURT'S OPINION

2. This opinion is addressed to the European Parliament and the Council, pursuant to Article 185(2) of Council Regulation (EC, Euratom) No 1605/2002 ([2]).

3. The Court has examined the annual accounts of the Agency for the financial year ended 31 December 2003. In accordance with Article 57a(1) of Council Regulation (EEC) No 2309/93, the budget was implemented on the responsibility of the Executive Director. This responsibility includes the drawing-up and presentation of the accounts ([3]) in accordance with the internal financial provisions adopted on the basis of Article 57a(11) of the same regulation. The Court is required under Article 248 of the Treaty establishing the European Community to examine these accounts.

4. The Court carried out its audit in accordance with its auditing policies and standards, which have been adapted from generally accepted international auditing standards to reflect the specific nature of the Community context. It examined the accounting documents and applied the procedures it considered necessary in this context.

5. The Court has thus obtained reasonable assurance that the annual accounts for the financial year ended 31 December 2003 are reliable. The Court would nevertheless draw attention to the situation described in paragraph 10. Except for the situations described in paragraphs 7 and 12, the Court has obtained reasonable assurance that the underlying transactions, taken as a whole, are legal and regular.

OBSERVATIONS

6. The implementation of the appropriations for the financial year 2003 and of the appropriations carried over from the previous year is set out in *Table 2*. *Tables 3 and 4* set out, in summary form, the revenue and expenditure account and the balance sheet published by the Agency for the financial year 2003.

7. On 5 June 2003, the Management Board of the Agency, subject to approval by the Commission, adopted a new financial regulation and corresponding implementing rules, which came into effect as of the second half of the financial year 2003 ([4]). In its opinion No 6/2003 of 17 July 2003, the Court had drawn attention to differences between the Agency's own financial regulation and the framework Financial Regulation applicable to the agencies in general. In paragraph 7 of its opinion, the Court emphasised in particular that the Agency's implementing rules on the award of contracts must be in line with the provisions of the general Financial Regulation and the general implementing rules. For example, whereas the general rules provide for a committee for the evaluation of tenders to be set up for any contract involving an amount exceeding 13 800 euro, the Agency sets this threshold at 75 000 euro (*Table 5* sets out the differences noted).

8. The Agency's accounts for 2003 were drawn up on the basis of the accounting principles laid down by its new financial regulation ([5]). The accounting data relating to the financial year 2002 have not been processed again in accordance with the accounting rules used when the accounts for the financial year ended on 31 December 2003 were drawn up.

9. Article 43(1)(e) of the Agency's financial regulation provides that the accounting officer shall validate the systems laid down by the authorising officer to supply or justify accounting information. This validation has not taken place.

10. In 2003 the Agency carried out a physical inventory of fixed assets that was based on the nature of the assets, even though the fixed asset accounts are kept according to the year that the assets are acquired. This situation makes it difficult to reconcile the physical data and the accounting data. Furthermore, some assets appear in neither the inventory nor the fixed asset accounts. Their total value after depreciation was assessed at 4 188 000 euro ([6]) and was included in the balance sheet under the item 'Fixed assets'. The Agency should set up a system for managing the fixed assets that ensures that the inventory data are both exhaustive and consistent with the accounting data.

11. In the application of internal control measures, continuity is not ensured. For example, certain case-files do not contain all the supporting documents required to create a commitment or a payment order.

([1]) OJ L 214, 24.8.1993, p. 18; following the adoption of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 (OJ L 136, 30.4.2004, p. 1) the Agency's new name is the European Medicines Agency.

([2]) OJ L 248, 16.9.2002, p. 1.

([3]) As required under Article 83(3) of the Agency's financial regulation, the final accounts for the financial year 2003 were drawn up on 14 May 2004 and forwarded to the Court of Auditors, which received them on 24 September 2004. A summarised version of these accounts is presented in the tables attached to this report.

([4]) The Commission gave its opinion at the beginning of 2004.

([5]) Article 78 of the Agency's financial regulation.

([6]) The sum relates to software and to alterations to the premises.

12. In certain negotiated procedures the choice of supplier is based on the criterion of 'former experience with the contractor', which is not provided for in the implementing rules [1] for the financial regulation.

13. An examination of the recruitment files has brought to light a significant number of shortcomings in the formalisation and the documentation: reasons are not given to support the choice of candidates invited for interview or check-lists, which are drawn up for the purpose of verifying the admissibility of the candidates, do not include all the selection criteria set out in the vacancy notices.

14. The Agency's 'quality assurance' unit serves as the internal auditor. Two of its audits, carried out in 2002 on the organisation of an electronic documentation system, brought to light a significant increase in costs and time taken caused by insufficient monitoring of the project. A subsequent audit carried out by an external consultant in 2003 confirmed the weaknesses found by the internal auditor. The project undertaken at the end of 2000 ought to have started production at the beginning of 2002 at an estimated cost of 1,2 million euro. The system was still not operational in 2003 and the costs already incurred amounted to 1,7 million euro.

This Report was adopted by the Court of Auditors in Luxembourg at its meeting of 29 and 30 September 2004.

For the Court of Auditors
Juan Manuel FABRA VALLÉS
President

[1] Article 86 of the detailed rules for the implementation of the Agency's financial regulation.

Table 1

European Agency for the Evaluation of Medicinal Products (London)

Areas of Community competence deriving from the Treaty	Competence of the Agency as defined in Council Regulation (EC) No 2309/93 of 22 July 1993		Governance	Resources available to the Agency *(data for 2002)*	Products and services supplied in 2003 *(data for 2002)*
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. *(Extract from 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 or veterinary use — To provide the Member States and the institutions of the 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 the 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 Proprietary Medicinal Products**, consisting of two members from each Member State, advises on any question relating to the evaluation of medicinal products for human use. (2) The **Committee for Veterinary Medicinal Products**, consisting of two members from each Member State, advises on any question relating to the evaluation of veterinary medicinal products. (3) The **Management Board**, consisting of two representatives of each Member State, two representatives of the Commission and two representatives appointed by the European Parliament. The Board adopts the programme of work and the annual report. (4) The **Executive Director** is appointed by the Management Board on a proposal from the Commission. (5) **External audit**: Court of Auditors. (6) **Discharge** is given by the Parliament on a recommendation from the Council.	**Final budget:** 84,2 million EUR (*61,3 million EUR*), of which the Community contribution (excluding subsidy for orphan medicines): 22,9 % (*27,9 %*) **Staff numbers as at 31 December 2003:** 287 (*251*) posts provided for in the establishment plan, Posts occupied: 256 (*227*) + 48 (*37*) other posts (auxiliary contracts, national experts on secondment, local staff, temporary staff) *Total staff:* 304 (*264*) Assigned to the following duties: — operational: 242 (*211*) — administrative: 62 (*53*)	**Medicinal products for human use** Applications for marketing authorisations: 39 (*31*) Favourable opinions: 39 (*24*) Average evaluation time: 190 days (*192 days*) Opinions after authorisation: 941 (*746*) Pharmacovigilance: 45 538 reports (*42 608 reports*) Periodic reliability reports:276 (*223*) Monitoring measures: 1 025 (*738*) Scientific opinions: 65 (*75*) Procedures for mutual recognition: 4 080 (*3 501*) **Veterinary Medicinal Products** New applications: 10 (*3*) Applications in respect of variants: 64 (*33*) Inspection: 76 (*75*)

Source: Information supplied by the Agency.

Table 2

European Agency for the Evaluation of Medicinal Products — Implementation of the budget for the 2003 financial year

(million euro)

Revenue			Expenditure													
				Appropriations in the final budget					Appropriations carried over from the previous financial year			Appropriations available (2003 budget and financial year 2002)				
Origin of revenue	Revenue entered in the final budget for the financial year	Revenue collected	Expenditure allocation	entered	committed	paid	carried over	cancelled	outstanding commitments	paid	cancelled	appropriations	committed	paid	carried over	cancelled
Community subsidies (1)	23,0	22,5	Title I Staff	31,5	29,7	29,2	0,5	1,8	0,4	0,3	0,1	31,9	30,1	29,5	0,5	1,9
Own revenue	59,0	60,1	Title II Administration	19,7	19,2	11,9	7,3	0,5	1,9	1,5	0,4	21,6	21,1	13,4	7,3	0,9
Other revenue	2,2	1,8	Title III Operating expenditure	33,0	32,8	24,5	8,3	0,2	4,5	4,2	0,3	37,5	37,3	28,7	8,3	0,5
Total	84,2	84,4	**Total**	84,2	81,7	65,6	16,1	2,5	6,8	6,0	0,8	91,0	88,5	71,6	16,1	3,3

(1) Includes subsidies received from the European Economic Area.

Source: The Agency's data. This table summarises the data provided by the Agency in its own accounts.

Table 3

European Agency for the Evaluation of Medicinal Products — Revenue and expenditure accounts for the financial years 2003 and 2002

(1 000 euro)

	2003	2002 (1)
Revenue		
Fees relating to marketing authorisations	58 657	38 372
Commission subsidy including subsidies received from the EEA	19 786	14 846
Community subsidy for orphan medicines	2 814	2 407
Contributions for Community programmes	1 208	9
Administrative revenue	2 153	1 688
Sundry revenue	848	54
Total (a)	**85 466**	**57 376**
Expenditure (2)		
Staff expenditure	29 663	26 216
Administrative expenditure	10 905	10 718
Operating expenditure	32 838	21 467
Depreciation	2 364	0
Total (b)	**75 770**	**58 401**
Result (c = a – b)	**9 696**	**– 1 025**
Other factors		
Appropriations carried over from the previous financial year and cancelled (d)	823	1 377
Exchange-rate differences and other adjustments (e)	413	– 352
Balance for the financial year (c + d + e)	**10 932**	**0**

(1) The data for the financial year 2002 have not been reprocessed according to the accounting principles followed for the financial year 2003 (see paragraph 8 of the report).

(2) The portion of the appropriations carried over which is to be regarded as expenditure for the financial year has been evaluated on an overall basis rather than on the basis of examining individual transactions.

Source: The Agency's data. This table summarises the data provided by the Agency in its own accounts.

Table 4

European Agency for the Evaluation of Medicinal Products — Balance sheets as at 31 December 2003 and 31 December 2002 (1)

(1 000 euro)

Assets	2003	2002	Liabilities	2003	2002
Intangible assets	**3 401**	**0**	**Own capital**		
			Budget outturn (a)	4 037	—
Fixed assets			Outturn after adjustments (b)	6 895	—
Plant, machinery and tools	1 635	146	Economic outturn (a + b)	10 932	—
Furniture and vehicle fleet	1 011	991	Outturn carried over from previous financial years (2)	6 872	2 684
Computer equipment	2 548	1 547	*Subtotal*	*17 804*	*2 684*
Subtotal	*5 194*	*2 684*			
			Current liabilities		
Current assets			Amounts owed to Community institutions and bodies	479	444
VAT paid and to be recovered	1 105	571	Payment appropriations to be carried over	11 936	6 811
Amounts receivable from Community institutions and bodies	107	3 744	Sundry accounts payable	127	603
Sundry accounts receivable	1 034	2 854	Advances from customers	8 845	9 293
Sundry receivables	64	0	*Subtotal*	*21 387*	*17 151*
Subtotal	*2 310*	*7 169*			
Available assets	**28 286**	**9 982**			
Total	**39 191**	**19 835**	**Total**	**39 191**	**19 835**

(1) Use of the model proposed by the Commission has resulted in balances being reallocated between the existing headings.

(2) For 2002, the sum corresponds to the total of net fixed assets. For 2003, the sum also includes 4 188 000 euro corresponding to the activation in 2003 of assets acquired in previous years (see paragraph 10 of the report).

Source: The Agency's data. This table summarises the data provided by the Agency in its own accounts.

Table 5

Differences between the general implementing rules and the Agency's implementing rules

Committee for the evaluation of tenders (1)		
	Articles 145 and 146 of the general implementing rules	Article 107 of the Agency's implementing rules
Contract threshold:	13 800 euro	75 000 euro
Rules for negotiated procedures in respect of low-value contracts		
Value of contracts	Article 129 of the general implementing rules	Article 89 of the Agency's implementing rules
less than 200 euro	payment of costs against invoices	provided for in Article 82 but threshold unspecified
less than 1 050 euro: negotiated procedure	award on the basis of a single tender	less than 1 500 euro: award on the basis of a single tender
between 1 050 and 13 800 euro: negotiated procedure with:	at least 3 candidates consulted	between 1 500 and 13 800 euro: at least 3 candidates consulted
between 13 800 and 50 000 euro, restricted procedure but without a CEI (2) with:	at least 5 candidates consulted	at least 3 candidates consulted

(1) The only committee for the evaluation of tenders proposed by the Agency is the Advisory Committee on Procurement and Contracts, which is required to give its opinion on contracts involving amounts exceeding 75 000 euro (Article 107), whereas this threshold is 13 800 euro in the general implementing rules.

(2) CEI: Call for expressions of interest.

Source: Court of Auditors.

THE AGENCY'S REPLIES

7. The Agency has contacted the Commission to finalise the Financial Regulation. The changes made have been in the direction to satisfy the Commission's comments as well as those of the Court of Auditors. In particular the thresholds for contracts and procurement have been aligned in the implementing rules.

8. In accordance with International Public Sector Accounting Standard (IPSA) number 3, the resulting adjustments are reported as an adjustment to the opening capital. Comparative information for the year 2002 has not been restated, as it would not have provided meaningful additional information. As the European institutions and agencies have to present accounts compliant with IPSAS for 2005, the Agency, following the calendar established by the Accounting Officer of the European Commission, will have systems in place which will assure compliance by January 1, 2005 including the presentation of comparative figures for 2004.

9. The observation of the Court is relevant in a sense, however it was not a priority for the EMEA knowing that the current systems, including both procedures and software, existed since 1998 and have provided the necessary and accurate data for the establishment of the financial statements. These systems have not been modified since the application of the new financial regulations.

The systems defined by the authorising officer will be formally validated by the accountant in the course of 2004.

10. In 2003, the Agency capitalised intangible assets (mainly software licenses and certain software development costs) in accordance with the standards issued by the Accounting Standards Committee. In order to establish the inventory of intangible assets and fitting out costs in prior years a detailed analysis of software and fitting out costs for 2000 to 2003 was prepared. During 2004, all assets, tangible and intangible, are being entered in the new asset management system and the accounting is based on the classification by type as set out in the harmonised accounting plan defined by the Commission's Accounting Officer.

11. The Agency has noted the Court's comments. It has taken corrective measures to avoid such situations in the future.

12. The Agency has noted the Court's comments on the criteria of choice of contractors.

13. The Agency follows selection procedures with care. The admissibility of candidates to the selection procedure follows a checklist in each individual case, which covers all the elements stated in the announcement. This is documented on each individual file. In addition to the existing justification for the choice of each candidate for interview, the Agency will implement measures to improve the procedure and avoid the problems mentioned by the Court.

14. In recognition of the serious difficulties being encountered in the implementation of the project, the Agency's management took action, beginning with the commissioning of the external audit in early 2003. The specification has been refined and implementation of the electronic document management system has since been undertaken in the light of that analysis.