

## **P6\_TA(2006)0175**

### **2004 discharge: European Medicines Agency**

#### **1. European Parliament decision on the discharge for the implementation of the budget of the European Medicines Agency for the financial year 2004 (N6-0009/2005 – C6-0166/2005 – 2005/2114(DEC))**

*The European Parliament,*

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2004<sup>1</sup>,
  - having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2004, together with the Agency's replies<sup>2</sup>,
  - having regard to the Council's recommendation of 14 March 2006 (5972/2006 - C6-0093/2006),
  - having regard to the EC Treaty, and in particular Article 276 thereof,
  - having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>3</sup>, and in particular Article 185 thereof,
  - having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>4</sup>, and in particular Article 68 thereof,
  - having regard to Commission Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>5</sup>, and in particular Article 94 thereof,
  - having regard to Rule 71 of and Annex V to its Rules of Procedure,
  - having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on the Environment, Public Health and Food Safety (A6-0101/2006),
1. Grants discharge to the Executive Director of the European Medicines Agency for the implementation of the Agency's budget for the financial year 2004;

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<sup>1</sup> OJ C 269, 28.10.2005, p. 17.

<sup>2</sup> OJ C 332, 28.12.2005, p. 8.

<sup>3</sup> OJ L 248, 16.9.2002, p. 1.

<sup>4</sup> OJ L 136, 30.4.2004, p. 1.

<sup>5</sup> OJ L 357, 31.12.2002, p. 72. Regulation as amended by Regulation (EC, Euratom) No 1261/2005 (OJ L 201, 2.8.2005, p. 3).

2. Sets out its comments in the resolution below;
3. Instructs its President to forward this decision and the resolution that forms an integral part of it to the Executive Director of the European Medicines Agency, the Council, the Commission and the Court of Auditors and to have them published in the Official Journal of the European Union (L series).

## **2. European Parliament decision on the closure of the accounts of the European Medicines Agency for the financial year 2004 (N6-0009/2005 – C6-0166/2005 – 2005/2114(DEC))**

*The European Parliament,*

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2004<sup>1</sup>,
  - having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2004, together with the Agency's replies<sup>2</sup>,
  - having regard to the Council's recommendation of 14 March 2006 (5972/2006 - C6-0093/2006),
  - having regard to the EC Treaty, and in particular Article 276 thereof,
  - having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>3</sup>, and in particular Article 185 thereof,
  - having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>4</sup>, and in particular Article 68 thereof,
  - having regard to Commission Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>5</sup>, and in particular Article 94 thereof,
  - having regard to Rule 71 of and Annex V to its Rules of Procedure,
  - having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on the Environment, Public Health and Food Safety (A6-0101/2006),
1. Notes the following figures for the accounts of the European Medicines Agency for the financial years 2004 and 2003:

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<sup>1</sup> OJ C 269, 28.10.2005, p. 17.

<sup>2</sup> OJ C 332, 28.12.2005, p. 8.

<sup>3</sup> OJ L 248, 16.9.2002, p. 1.

<sup>4</sup> OJ L 136, 30.4.2004, p. 1.

<sup>5</sup> OJ L 357, 31.12.2002, p. 72. Regulation as amended by Regulation (EC, Euratom) No 1261/2005 (OJ L 201, 2.8.2005, p. 3).

## Revenue and expenditure account for the financial years 2004 and 2003 (in EUR 1000)

	2004	2003
<b>Revenue</b>		
Fees relating to marketing authorisations	68 412	58 657
Commission subsidy including subsidies received from the EEA	20 529	19 786
Community subsidy for orphan medicines	4 026	2 814
Contributions for Community programmes	0	1 208
Administrative revenue	1 973	1 703
Sundry revenue	1 473	1 788
<b>Total (a)</b>	<b>96 413</b>	<b>85 956</b>
<b>Expenditure <sup>(1)</sup></b>		
Staff expenditure	34 333	29 663
Administrative expenditure	11 224	10 835
Operating expenditure	38 573	32 838
Depreciation	3 650	2 364
Other expenditure	280	0
<b>Total (b)</b>	<b>88 060</b>	<b>75 700</b>
<b>Surplus from operating activities (c = a - b)</b>	<b>8 353</b>	<b>10 256</b>
<b>Financial operations (e)</b>	<b>1 160</b>	<b>676</b>
<b>Economic result (f = c + e)</b>	<b>9 513</b>	<b>10 932</b>

(1) 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.

2. Approves the closure of the accounts of the European Medicines Agency for the financial year 2004;
3. Instructs its President to forward this decision to the Executive Director of the European Medicines Agency, the Council, the Commission and the Court of Auditors and to have it published in the Official Journal of the European Union (L series).

**3. European Parliament resolution with comments forming an integral part of the decision on the discharge for the implementation of the budget of the European Medicines Agency for the financial year 2004 (N6-0009/2005 – C6-0166/2005 – 2005/2114(DEC))**

*The European Parliament,*

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2004<sup>1</sup>,
  - having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2004, together with the Agency's replies<sup>2</sup>,
  - having regard to the Council's recommendation of 14 March 2006 (5972/2006 - C6-0093/2006),
  - having regard to the EC Treaty, and in particular Article 276 thereof,
  - having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>3</sup>, and in particular Article 185 thereof,
  - having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>4</sup>, and in particular Article 68 thereof,
  - having regard to Commission Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>5</sup>, and in particular Article 94 thereof,
  - having regard to Rule 71 of and Annex V to its Rules of Procedure,
  - having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on the Environment, Public Health and Food Safety (A6-0101/2006),
- A. whereas the Court of Auditors stated that it had obtained reasonable assurance that the annual accounts for the financial year ended 31 December 2004 were reliable and that the underlying transactions, taken as a whole, were legal and regular,
- B. whereas the Court of Auditors states that it has obtained reasonable assurance from all the agencies, excepting the express reservations in respect of the 2004 financial year concerning the European Agency for Reconstruction, the European Centre for the

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<sup>1</sup> OJ C 269, 28.10.2005, p. 17.

<sup>2</sup> OJ C 332, 28.12.2005, p. 8.

<sup>3</sup> OJ L 248, 16.9.2002, p. 1.

<sup>4</sup> OJ L 136, 30.4.2004, p. 1.

<sup>5</sup> OJ L 357, 31.12.2002, p. 72. Regulation as amended by Regulation (EC, Euratom) No 1261/2005 (OJ L 201, 2.8.2005, p. 3).

Development of Vocational Training, the European Training Foundation, the European Monitoring Centre on Racism and Xenophobia and the European Food Safety Authority,

1. Recalls that, under Article 185 of the Financial Regulation, Parliament shall give discharge for the implementation of the budgets of the bodies set up by the Communities and having legal personality which actually receive grants charged to the budget; points out, however, that not all of these bodies are fully, or even partially, funded via grants charged to the budget; emphasises that the discharge decision therefore covers both the budget and the non-budget funding of these bodies; considers it unacceptable that some of the bodies set up by the Union are accountable for the expenditure of income received from sources other than the budget whilst others, which do not receive a subsidy from the budget, are not; affirms the principle that all Community agencies, whether or not they are subsidised, are subject to discharge by Parliament, even when another discharge authority intervenes in accordance with their basic texts; takes the view that there is a need to review all texts that go against this principle;
2. Finds table 1 of the Court of Auditors' report, introduced for the first time during the 2003 discharge exercise, which summarises the Agency's powers and responsibilities, governance, resources, activities and services provided, of great value; notes that the information contained in table 1 is supplied by the Agency; asks the Court of Auditors to verify the contents of table 1;
3. Insists that as well as spending money properly, agencies should also strive to spend money as efficiently and effectively as possible; invites the Court of Auditors to consider the possibility of extending its specific annual reports on the agencies to include an examination of performance and achievement of objectives; in this context and in line with its resolutions on the 2003 discharge, insists that the following aspects be taken into account: that duplication of work among the agencies must be avoided as much as possible and that measures designed to improve transparency and communication with the public must be clarified, along with Community affirmative action measures at all levels of recruitment, training and the assignment of responsibilities;
4. Notes that Community agencies do not always have a good image or good press and that many of them do not deserve such a negative image; points out that EU citizens should be made aware of this, with the appropriate means being used to explain as often as is necessary the *raison d'être* and achievements of the agencies; calls on the Commission to act accordingly, using whatever means it considers necessary;
5. Notes that the enlargement of the European Union in 2004 has affected the structures and operating arrangements of the Community agencies in many ways, and that several of the agencies draw attention to these effects in their activity reports, focusing in particular on the increase in the number of administrators; calls on the Commission to assess the real or supposed problems encountered and to recommend the regulatory changes required;
6. Notes that the Commission has made a commitment to harmonising the way in which activity reports concerning its directorates-general are presented; calls for a similar approach to be taken in respect of the activity reports of the Communities' agencies, which differ significantly in terms of content; calls on the Commission to point out to the Communities' agencies the information and activity indicators that they must provide;

7. Notes the Court of Auditors' finding that contracts concluded with banks have been in force for over five years, in contravention of the Agency's financial regulation implementing rules, which require a new invitation to tender at least every five years; notes the Agency's reply explaining the reasons for the delay in launching a call for tender and setting out the benefits achieved through direct negotiation with the bank and will bear this in mind when considering revisions to the Financial Regulation;
8. Notes that the implementation of both the operating and the administrative budget was lower in 2004 than in 2003; is very pleased with the full implementation of the orphan drugs budget line;
9. Points out that the new pharmaceuticals legislation, which was adopted in 2004, had a considerable impact on the Agency's work and management structures; congratulates the Agency on its successful adaptation to the new regulatory environment;
10. Notes that the implementation by Member States of the Europe-wide pharmacovigilance reporting system (the EudraVigilance database) was slower than expected; is, however, satisfied with the recent announcement by the Executive Director that the situation has substantially improved during 2005;
11. Invites the Agency to improve contacts with consumer protection organisations in order to improve awareness concerning toxic and potentially harmful products in medicinal products; underlines the Agency's duty to act in the public interest;
12. Calls on the Commission to help the agencies follow as closely as possible the work plan agreed for the year ahead, allowing activities to be properly planned and implemented, and particularly to avoid major, last-minute changes to the work load;
13. Asks the Commission to improve synergies between agencies by making cooperation more effective, avoiding duplication of work and addressing shortcomings, in particular as regards common areas such as training, the implementation of Community policies across the board, the use of the latest management systems and solving problems relating to sound management of the budget.