Basic information

2005/2114(DEC) DEC - Discharge procedure	Procedure completed
2004 discharge: European Agency for the Evaluation of Medicinal Products **Subject** 8.40.08 Agencies and bodies of the EU 8.70.03.07 Previous discharges	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	GUIDONI Umberto (GUE/NGL)	20/04/2005

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	HAUG Jutta (PSE)	21/06/2005

Council of the European Union

Council configuration	Meetings	Date
Economic and Financial Affairs ECOFIN	2716	2006-03-14

European Commission

Commission DG	Commissioner
Budget	

Key events

Date	Event	Reference	Summary
15/04/2005	Non-legislative basic document published	N6-0009/2005	Summary
19/01/2006	Committee referral announced in Parliament		
21/03/2006	Vote in committee		Summary
27/03/2006	Committee report tabled for plenary	A6-0101/2006	
26/04/2006	Debate in Parliament		
27/04/2006	Decision by Parliament	T6-0175/2006	Summary
27/04/2006	Results of vote in Parliament		

27/04/2006	End of procedure in Parliament		
06/12/2006	Final act published in Official Journal		

Technical information

Procedure reference	2005/2114(DEC)
Procedure type	DEC - Discharge procedure
Legal basis	Rules of Procedure EP 102
Stage reached in procedure	Procedure completed
Committee dossier	CONT/6/28448

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE367.988	03/02/2006	
Committee opinion	ENVI	PE367.655	23/02/2006	
Amendments tabled in committee		PE370.236	28/02/2006	
Committee report tabled for plenary, single reading		A6-0101/2006	27/03/2006	
Text adopted by Parliament, single reading		T6-0175/2006	27/04/2006	Summary

Council of the EU

Document type	Reference	Date	Summary
Supplementary non-legislative basic document	05972/2006	06/02/2006	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
OS	Non-legislative basic document	N6-0009/2005 OJ C 269 28.10.2005, p. 0017	15/04/2005	Summary
CofA	Court of Auditors: opinion, report	N6-0002/2006 OJ C 332 28.12.2005, p. 0008-0014	05/10/2005	Summary

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Budget 2006/0836
OJ L 340 06.12.2006, p. 0107-0107 Summary

2004 discharge: European Agency for the Evaluation of Medicinal Products

2005/2114(DEC) - 06/02/2006

Having examined the Agency’s revenue and expenditure account and the observations made by the Court of Auditors, the Council recommends the European Parliament to give a discharge to the Director of the Agency in respect of the implementation of the budget for the financial year 2004.

In doing so, the Council confirms that EUR 15 million (93 %) of the EUR 16.1 million in appropriations carried forward from the financial year 2003 to the financial year 2004 have been used. In addition, EUR 22,7 million in appropriations have been carried forward from the financial year

2004 to the financial year 2005 and EUR 3.4 million have been cancelled.

In parallel, the Council makes accompanying comments on the discharge which should be followed up. In particular, it:

- § shares the Court's observation on the Audit Advisory Committee and calls on the Agency, on account of its permanent nature, to provide for its existence and operating procedures in the rules which govern the Agency's internal organisation;
- § shares the Court’s opinion on the need to start a new invitation to tender on services provided by banks.

2004 discharge: European Agency for the Evaluation of Medicinal Products

2005/2114(DEC) - 27/04/2006 - Final act

PURPOSE: to grant discharge to the European Medicines Agency for the financial year 2004.

LEGISLATIVE ACTS: Decisions 2006/836/EC and 2006/837/EC of the European Parliament on the discharge for the implementation of the budget of the European Medicines Agency for the financial year 2004 and closure of accounts for the year in question.

CONTENT: with the present decisions, the European Parliament grants discharge to the Executive Director of the European Medicines Agency for the implementation of the Agency’s budget for the financial year 2004 and approves the closure of the accounts.

This decision is in line with the European Parliament’s resolution adopted on 27 April 2006 and comprises a series of observations that form an integral part of the discharge decision (please refer to the summary of the opinion of 27/04/2006).

2004 discharge: European Agency for the Evaluation of Medicinal Products

2005/2114(DEC) - 27/04/2006 - Text adopted by Parliament, single reading

The European Parliament adopted a resolution drafted by Umberto **GUIDONI** (GUE/NGL, IT) and granted discharge to the Executive Director of the European Medicines Agency for the implementation of the Centre’s budget for the financial year 2004. In its accompanying comments, Parliament noted the Court of Auditors' finding that contracts concluded with banks had 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. It also noted the Agency's reply explaining the reasons for the delay 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.

Parliament also noted that the implementation of both the operating and the administrative budget was lower in 2004 than in 2003, and stated that it was very pleased with the full implementation of the orphan drugs budget line. It pointed out that the new pharmaceuticals legislation, which was adopted in 2004, had a considerable impact on the Agency's work and management structures, and congratulated the Agency on its successful adaptation to the new regulatory environment. The implementation by Member States of the Europe-wide pharmacovigilance reporting system (the EudraVigilance database) was slower than expected, but Parliament was satisfied with the recent announcement by the Executive Director that the situation has substantially improved during 2005.

It invited the Agency to improve contacts with consumer protection organisations in order to improve awareness concerning toxic and potentially harmful products in medicinal products and underlined the Agency's duty to act in the public interest.

Parliament also made a series of general remarks on the agencies. As well as spending money properly, agencies should also strive to spend money as efficiently and effectively as possible. The Court of Auditors was asked to consider the possibility of extending its specific annual reports on the agencies to include an examination of performance and achievement of objectives. The following aspects should be taken into account: duplication of work among the agencies must be avoided as much as possible and 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.

Parliament noted that Community agencies did not always have a good image or good press and that many of them did not deserve such a negative image. EU citizens should be made aware of this, and Parliament called on the Commission to act accordingly, using whatever means it considers necessary.

Furthermore, the enlargement of the European Union in 2004 had affected the structures and operating arrangements of the Community agencies in many ways, and several of the agencies draw attention to these effects in their activity reports, focusing in particular on the increase in the number of administrators. The Commission needed to assess the problems encountered and recommend the regulatory changes required.

The Commission had made a commitment to harmonising the way in which activity reports concerning its directorates-general were presented. Parliament called for a similar approach to be taken in respect of the activity reports of the Communities" agencies, which differed significantly in terms of content. The Commission should point out to the agencies the information and activity indicators that they must provide.

Finally, Parliament asked 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.

2004 discharge: European Agency for the Evaluation of Medicinal Products

2005/2114(DEC) - 15/04/2005 - Non-legislative basic document

PURPOSE : presentation of the final accounts of the European Medicines Agency for the financial year 2004.

CONTENT : this document published in the Official Journal of the EU sets out a detailed account of the implementation of the 2004 budget, including the revenue and expenditure and the balance sheet for the year concerned.

According to this document, the final budget amounted to EUR 99,1 million (in comparison to EUR 84,2 million in 2003) consisting of a 27% Community contribution (excluding subsidy for orphan medicines).

As regards staffing, the Agency, whose headquarters are based in London (UK), set out a total of 314 posts in the establishment plan. 290 posts are currently occupied + 50 other posts (auxiliary contracts, seconded national experts, local staff, employment agency staff) totalling 340 posts (304 in 2003) assigned to operational, administrative and mixed tasks.

Staff expenditure accounted for EUR 34,333 000.

Throughout 2004, the Agency concentrated on coordinating the scientific evaluation of medicinal products which are subject to Community marketing authorisation procedures.

Concerning medicinal products for human use, the Agency:

- replied to 51 applications for marketing authorisations and delivered 34 favourable opinions taking an average evaluation time of 187 days as opposed to 190 days in 2003;

- delivered 926 opinions after authorisation: 926;

- drafted 64 186 pharmacovigilance reports and 253 periodic reliability reports;

- delivered 948 monitoring measures, 77 scientific opinions and 7 081 procedures for mutual recognition.

Concerning veterinary medicinal products, the Agency:

- replied to 8 new applications for marketing authorisations and 40 applications in respect of variants;

- carried out 93 inspections.

Yearly operating expenditure represented EUR 38 573 000. A positive operating result was achieved at EUR 8 353 000 as well as a positive economic outturn of EUR 9 513 000.

The complete version of the final accounts may be found at the following address:

www.emea.eu.int

2004 discharge: European Agency for the Evaluation of Medicinal Products

2005/2114(DEC) - 05/10/2005 - Court of Auditors: opinion, report

This report from the Court of Auditors concerns the results of the audit carried out by the Court on the annual accounts of the European Medicines Agency for the financial year ended 31 December 2004. The Court states that its audit was planned and performed to obtain reasonable assurance that the accounts are reliable and the underlying transactions are legal and regular. The Agency’s accounts for the financial year ended 31 December 2004 are, in all material respects, reliable. 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 opinion into question.

The report shows that the appropriations entered in the final budget amount to EUR 99 089 000 with EUR 96 715 000 committed and EUR 73 964 000 paid. EUR 22 751 000 was carried over to 2005, and EUR 2 374 000 cancelled. The outstanding commitments carried over from the previous financial year were EUR 16 115 000.

The Court observes that the Agency's Management Board has set up an Audit Advisory Committee to advise the Executive Director on matters regarding quality assurance and risk-mitigating strategies. The existence of such a body and its operating procedures, including the recruitment procedure for its members, must be provided for, on account of its permanent nature, in the rules which govern the Agency's internal organisation.

In addition, the contracts concluded with the banks have been in force for over five years even though the detailed rules for the implementation of the Agency's financial regulation lay down that there should be a new invitation to tender at least once every five years.

The Court notes that the Agency's new financial regulation, as finally adopted after receipt of the Commission's opinion, takes account of the observations which the Court made in its previous report. Similarly, the system for managing the Agency's fixed assets has been considerably improved.

The Agency responds point by point to the Court's observations.

The Audit Advisory Committee is a consultative body and has no operational role in the internal organisation of the Agency. On 4 February 2005 the Management Board of the agency adopted the Terms of Reference of the Audit Advisory Committee which include the mission statement of this committee as well as the rules of proceedings.

The Agency goes on to state that it has had to implement a wide-ranging reform of the Financial Regulation and Accounting procedures over the last few years. It was considered prudent not to seek a change in the main bank at the same time due to the integration of our systems with this bank's electronic payment system. Now that the Agency is in the final stage of implementing the new Financial Regulation, a call for tender will be launched in the last quarter of this year. However it should be noted that substantial reductions in bank transfer costs have been achieved through direct negotiations with the bank and automation of payments. Also placements of funds are subject to individual bids from up to three banks based on the market rates on a particular day.

2004 discharge: European Agency for the Evaluation of Medicinal Products

2005/2114(DEC) - 14/03/2006

The Council approved, without discussion, recommendations to the European Parliament on the discharge to be given to the directors of the following Community bodies for execution of the 2004 budget:

- European Agency for Safety and Health at Work
- European Environment Agency
- European Training Foundation
- European Foundation for the Improvement of Living and Working Conditions
- European Maritime Safety Agency
- Eurojust
- European Food Safety Authority
- European Centre for the Development of Vocational Training
- Translation Centre for the Bodies of the European Union
- European Medicines Agency
- European Monitoring Centre on Racism and Xenophobia
- European Monitoring Centre for Drugs and Drugs Addiction
- European Aviation Safety Authority
- European Agency for Reconstruction

(for details of the Council recommendations, please refer to the respective summaries of 6 February 2006).