Procedure file

Basic information

DEC - Discharge procedure	2005/2114(DEC)	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		
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety		21/06/2005
		PSE HAUG Jutta	
Council of the European Union	Council configuration	Meeting	Date
	Economic and Financial Affairs ECOFIN	2716	14/03/2006
European Commission	Commission DG	Commissioner	
	Budget		

Key events

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	Results of vote in Parliament		
27/04/2006	Decision by Parliament	T6-0175/2006	Summary
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 100
Stage reached in procedure	Procedure completed
Committee dossier	CONT/6/28448

Documentation gateway

Non-legislative basic document		N6-0009/2005 OJ C 269 28.10.2005, p. 0017	15/04/2005	OS	Summary
Court of Auditors: opinion, report		N6-0002/2006 OJ C 332 28.12.2005, p. 0008-0014	05/10/2005	CofA	Summary
Committee draft report		PE367.988	03/02/2006	EP	
Supplementary non-legislative basic document		05972/2006	06/02/2006	CSL	Summary
Committee opinion	ENVI	PE367.655	23/02/2006	EP	
Amendments tabled in committee		PE370.236	28/02/2006	EP	
Committee report tabled for plenary, single reading		A6-0101/2006	27/03/2006	EP	
Text adopted by Parliament, single reading		T6-0175/2006	27/04/2006	EP	Summary
Commission response to text adopted in plenary		SP(2006)2095	11/05/2006	EC	

Final act

Budget 2006/836
OJ L 340 06.12.2006, p. 0107-0107 Summary

2004 discharge: European Agency for the Evaluation of Medicinal Products

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

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

The committee adopted the report by Umberto GUIDONI (GUE/NGL, IT) recommending that Parliament should grant discharge for the implementation of the budget of the European Agency for the Evaluation of Medicinal Products for 2004.

In their accompanying comments, MEPs noted that the enlargement of the EU in 2004 had affected the structures and operating arrangements of the Community agencies in many ways. They called on the Commission to "assess the real or supposed problems encountered and to recommend the regulatory changes required".

In addition to calling on the agencies to spend the money available to them as efficiently and effectively as possible, MEPs urged them to avoid duplication as far as possible and to clarify measures for improving transparency and communication with the public. This was particularly important as Community agencies "do not always have a good image or good press" and many of them did not deserve such a negative image. In its other recommendations, the committee called on the Commission to help harmonise the activity reports of the agencies - which differed significantly in terms of content - by informing them of the common indicators that they must provide, and to improve cooperation between the agencies, particularly in such common areas as training, the use of the latest management systems and solving problems relating to sound management of the budget.

Lastly, the committee pointed out that the new pharmaceuticals legislation, adopted in 2004, had had a considerable impact on the Agency's work and management structures, and it congratulated the Agency on its successful adaptation to the new regulatory environment.

2004 discharge: European Agency for the Evaluation of Medicinal Products

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

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.