Basic information

2004/2056(DEC) DEC - Discharge procedure	Procedure completed
2003 discharge: European Agency for the Evaluation of Medicinal products **Subject** 8.70.03.07 Previous discharges	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	AYALA SENDER Inés (PSE) AYALA SENDER Inés (PSE) SCHLYTER Carl (Verts/ALE)	26/07/2004 22/09/2004 22/09/2004

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	HAUG Jutta (PSE)	27/07/2004

Council of the European Union

Council configuration	Meetings	Date
Economic and Financial Affairs ECOFIN	2646	2005-03-08

Key events

Date	Event	Reference	Summary
27/07/2004	Non-legislative basic document published	N6-0212/2004	Summary
10/01/2005	Committee referral announced in Parliament		
16/03/2005	Vote in committee		
16/03/2005	Additional information		Summary
23/03/2005	Committee report tabled for plenary	A6-0074/2005	
12/04/2005	Decision by Parliament	T6-0105/2005	Summary
12/04/2005	Debate in Parliament		
12/04/2005	End of procedure in Parliament		

27/07/2005	Final act published in Official Journal		

Technical information

Procedure reference	2004/2056(DEC)
Procedure type	DEC - Discharge procedure
Legal basis	Rules of Procedure EP 102
Stage reached in procedure	Procedure completed

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee opinion	ENVI	PE353.298	07/02/2005	
Committee report tabled for plenary, single reading		A6-0074/2005	23/03/2005	
Text adopted by Parliament, single reading		T6-0105/2005 OJ C 033 09.02.2006, p. 0029-0251 E	12/04/2005	Summary

Council of the EU

Document type	Reference	Date	Summary
Supplementary non-legislative basic document	06860/2005	08/03/2005	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
OS	Non-legislative basic document	N6-0212/2004	27/07/2004	Summary
CofA	Court of Auditors: opinion, report	C324/2004 OJ C 324 30.12.2004, p. 0001	30/12/2004	Summary

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Budget 2005/0543
OJ L 196 27.07.2005, p. 0093-0093 Summary

2003 discharge: European Agency for the Evaluation of Medicinal products

2004/2056(DEC) - 12/04/2005 - Final act

OBJECTIVE: granting of discharge for implementing the EU's general budget for 2003 – European Medicines Agency.

LEGISLATIVE ACT: Decision 2005/543/EC of the European Parliament concerning the discharge for implementing the general budget of the EU for the 2003 financial year – European Medicines Agency.

CONTENT: With this Decision, the European Parliament grants discharge to the Director of the European Medicines Agency for the implementation of the budget for the 2003 financial year.

This decision is in line with the European Parliament's resolution adopted on 12 April 2005 and comprises a series of observations that form an integral part of the discharge decision (please refer to the summary of the opinion of 12/04/2005).

2003 discharge: European Agency for the Evaluation of Medicinal products

2004/2056(DEC) - 27/07/2004 - Non-legislative basic document

PURPOSE : presentation of the financial statements and the balance sheets for the European Agency for the Evaluation of Medicinal Products for the financial year 2003.

CONTENT : this report presented by the European Agency for the Evaluation of Medicinal Products presents the financial statements and balance sheets of its activities in 2003.

The appropriations entered in the final budget amount to EUR 84.2 million with a Community contribution of 23% (excluding subsidy for orphan medicines).

In terms of the staffing policy, the Agency, whose headquarters are in London (UK), officially provided 287 posts. 256 are occupied with + 48 other posts (auxiliary contracts, national experts on secondment, local and temporary staff). Therefore, there are a total of 304 assigned to operational and administrative duties.

In 2003, the Agency concentrated on the scientific evaluation of medicinal products.

As far as medicinal products for human use are concerned :

- Applications for marketing authorisations: 39;

- Favourable opinions: 39;

- Average evaluation time: 190 days;

- Opinions after authorisation: 941;

- Pharmacovigilance: 45 538 reports;

- Periodic reliability reports: 276;

- Monitoring measures: 1 025;

- Scientific opinions: 65;

- Procedures for mutual recognition: 4 080.

On the issue of Veterinary Medicinal Products:

- New applications: 10;

- Applications in respect of variants: 64;

- Inspection: 76.

2003 discharge: European Agency for the Evaluation of Medicinal products

2004/2056(DEC) - 30/12/2004

This report from the Court of Auditors concerns the results of the audit carried out by the Court on the annual accounts of the the European Agency for the Evaluation of Medicinal Products for the financial year ended 31 December 2003.

The report indicates that the appropriations entered in the final budget for the financial year concerned amount to EUR 84.2 million with EUR 81.7 million committed, EUR 65.6 million paid and EUR 16.1 million carried over to 2004. Only EUR 2.5 million was cancelled.

The Court has obtained reasonable assurance that the annual accounts for the financial year ended 31 December 2003 were reliable and that the underlying transactions, taken as a whole, were legal and regular. The Court nevertheless draws attention to certain management aspects of the Agency, in particular its interpretation its financial regulation which is not always in accordance with the Union's Financial Regulation.

The Court states that 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. In its opinion 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. 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.

The Court also states that it is difficult to reconcile the Agency's physical data and the accounting data. Furthermore, some assets appear in neither the inventory nor the fixed asset accounts. 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. 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.

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.

The report also states that an examination of the recruitment files has brought to light a significant number of shortcomings in the formalization 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.

The Agency's 'quality assurance' unit serves as the internal auditor. Two of its audits, carried out in 2002 on the organization 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.

The Agency responds point by point to the observations made by the Court. Firstly, it mentions that it 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.

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.

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.

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 harmonized accounting plan defined by the Commission's Accounting Officer.

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

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.

2003 discharge: European Agency for the Evaluation of Medicinal products

2004/2056(DEC) - 12/04/2005 - Text adopted by Parliament, single reading

The European Parliament adopted a resolution drafted by co-rapporteurs Inés AYALA SENDER (PES, ES) and Carl SCHLYTER (Greens/EFA, SE) giving discharge to the Executive Director of the European Agency for the Evaluation of Medicinal Productsin respect of the implementation of its budget for the financial year 2003. (Please see the summary of 16/03/05.)

Parliament's resolution is in two parts: the first concerns the discharge itself and the second part deals with an accompanying resolution on the management and implementation of the budget. The accompanying resolution also carries general points addressed to the Commission and the Agencies.

Parliament noted the Agency's efforts in 2004 aimed at strengthening its inventory system and the fact that all its assets are now entered in the new management system in compliance with the Commission's harmonised accounting plan. It stated that the Agency must build on measures already taken in order to respond to the Court of Auditors observation as regards the application of negotiated procedures in procurement.

It also asked the Agency and national authorities to complete work the European-wide pharmacovigilance reporting system (EudraVigilance database), which is still not fully operational.

Whilst Parliament welcomed the Agency's equal opportunities commitment, it regretted the absence of an equality plan. Parliament noted that the EMEA is the only Agency with more women than men in grade A.

Finally, Parliament commended the Agency's commitment to transparency and measures taken to improve its strategy for information and communication to patients and health professionals.

Parliament went on to make some general observations common to all the agencies. The principal points may be summarized as follows:

General points addressed to the Commission and the Agencies: Parliament supported the Commission's efforts to establish a limited number of models, at least for future 'regulatory' agencies. It took the view that the structure of current and future agencies merited in-depth consideration at inter-institutional level. Before the Commission defines the framework conditions for the use of regulatory agencies, an inter-institutional agreement should spell out common guidelines. Parliament invited the Commission to perform by the end of 2005 a cross-cutting analysis of the evaluations carried out on individual Agencies in order to:

- reach conclusions with regard to the coherence of Agency activity with EU policies in general and as regards the synergies existing or to be developed between the agencies and Commission departments and the avoidance of overlapping between them;

- make an assessment of the broader European added value of the Agencies' outputs in their respective area of activity and of the relevance and effectiveness of the Agency model in implementing or contributing to EU policies;

- determine the impact of the Agencies' actions in terms of the proximity and visibility of the EU to its citizens.

In parallel with this exercise, the Commission should present proposals for changes to be made in the existing Agencies' Constituent Acts with a view to optimising its relationship with the Agencies. Before any decision is taken to propose the creation of a new agency, the Commission must undertake a strict evaluation of the added value of the function of this agency, bearing in mind existing structures, the principles of subsidiarity, budgetary austerity and the simplification of procedures.

General points addressed to the Agencies:

Parliament wanted to receive from each of the Agencies, the report summarizing information on the audits carried out by the Internal Auditor, the recommendations made and the action taken on these recommendations in accordance with Regulation 2343/2002/EC. Agencies should also make further efforts to apply correctly the staff regulations and rules applicable to other civil servants with regard to their staff. Parliament made some remarks on the imbalance between men and women in high-grade positions in the agencies, and stated that relevant provisions on equal opportunities must be observed.

In response to the relevant observations of the Court of Auditors, the Agencies must comply fully with the budgetary principles as set out in the Financial Regulation, in particular those of unity and budgetary accuracy.

Parliament went on to encourage the Agencies to strengthen their co-operation, thus opening up opportunities for developing synergies, and avoiding duplication of work. Parliament expected to be informed regularly on this issue.

It called on the Agencies to pay special attention to procedures for the award and management of contracts, and to strengthen their internal control procedures. Parliament suggested the setting-up of specialised units entrusted with the task of advising, on the basis of risk analysis, on how best to prepare contract award procedures.

General points addressed to the European Court of Auditors and the Agencies:

Parliament asked Court of Auditors and the Agencies to strengthen their co-operation in order to enhance the procedures and technical tools to improve the sound management of all the budgetary and finance issues. They should do this in order to establish a methodology that prepares the ground for a positive budget discharge from the start of the process.

2003 discharge: European Agency for the Evaluation of Medicinal products

2004/2056(DEC) - 08/03/2005 - Supplementary non-legislative basic document

Having examined the revenue and expenditure account for the financial year 2003, the balance sheet of revenue and expenditure at 31 December 2003 of the European Agency for the Evaluation of Medicinal Products and the Court of Auditors' report on the annual accounts of the Agency, the Council recommends that the European Parliament give a discharge to the Director of the Agency in respect of the implementation of the budget for the financial year 2003.

To recall, EUR 6.0 million (88%) of the EUR 6.8 million in appropriations carried forward from the financial year 2002 to the financial year 2003 have been used. EUR 16.1 million in appropriations have been carried forward from the financial year 2003 to the financial year 2004 and EUR 3.3 million have been cancelled.

Observations in the Court of Auditors' report in relation to the financial year 2003 call for certain comments by the Council, which are annexed to this Recommendation.

The Council notes that the Court has been able to issue a statement of reasonable assurance on the reliability of the Agency's annual accounts for the financial year 2003. However, it regrets that in respect of the reasonable assurance as to the legality and regularity of the underlying transactions, taken as a whole, the Court has excluded some situations concerning tenders and negotiated procedure for contracts.

The Council shares the Court's concerns on the procurement procedures applied by the Agency: whereas the general rules provide for a committee for the evaluation of tenders to be set up for any contract involving an amount exceeding EUR 13 800, the Agency sets this threshold at EUR 75 000.

The Council urges the Agency to pursue the reinforcement of the implementing rules on the award of contracts in line with the provisions of the general Financial Regulation and its implementing rules. Moreover, in certain negotiated procedures, the choice of supplier was based on the criteria of "former experience with the contractor", which is not provided for in the implementing rules for the financial regulation.

The Council asks the Agency to remedy its shortcomings regarding the criteria of choice of contractor. In this context, it notes that the Agency has aligned its implementing rules with the framework Financial Regulation applicable to Agencies and with the Commission's implementing rules.

The Council notes with satisfaction that the Agency has finally set up a new asset management system enabling the inventory data of all assets, tangible and intangible, to be consistent with the accounting data.