Basic information

2007/2054(DEC) DEC - Discharge procedure	Procedure completed
2006 discharge: European Medicines Agency EMEA **Subject** 8.70.03.07 Previous discharges	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	MARTIN Hans-Peter (NI)	27/03/2007

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	HAUG Jutta (PSE)	09/10/2007

Council of the European Union

Council configuration	Meetings	Date
Economic and Financial Affairs ECOFIN	2847	2008-02-12

European Commission

Commission DG	Commissioner
Budget	KALLAS Siim

Key events

Date	Event	Reference	Summary
30/03/2007	Non-legislative basic document published	SEC(2007)1055	Summary
25/10/2007	Committee referral announced in Parliament		
26/03/2008	Vote in committee		Summary
03/04/2008	Committee report tabled for plenary	A6-0125/2008	
22/04/2008	Decision by Parliament	T6-0152/2008	Summary
22/04/2008	Results of vote in Parliament		
22/04/2008	Debate in Parliament		

22/04/2008	End of procedure in Parliament		
31/03/2009	Final act published in Official Journal		

Technical information

Procedure reference	2007/2054(DEC)
Procedure type	DEC - Discharge procedure
Legal basis	Rules of Procedure EP 102
Stage reached in procedure	Procedure completed
Committee dossier	CONT/6/53871

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE396.696	07/02/2008	
Committee opinion	ENVI	PE400.455	03/03/2008	
Amendments tabled in committee		PE402.809	06/03/2008	
Committee report tabled for plenary, single reading		A6-0125/2008	03/04/2008	
Text adopted by Parliament, single reading		T6-0152/2008	22/04/2008	Summary

Council of the EU

Document type	Reference	Date	Summary
Supplementary non-legislative basic document	05843/2008	29/01/2008	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	SEC(2007)1055	30/03/2007	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
CofA	Court of Auditors: opinion, report	N6-0004/2008 OJ C 309 19.12.2007, p. 0001	15/11/2007	Summary

Additional information

Source	Document	Date

Final act

Budget 2009/0217
OJ L 088 31.03.2009, p. 0175 Summary

2006 discharge: European Medicines Agency EMEA

2007/2054(DEC) - 22/04/2008 - Text adopted by Parliament, single reading

The European Parliament adopted, by 622 votes in favour, 15 against and 38 abstentions, a Decision to grant the Executive Director of the European Medicines Agency discharge in respect of the implementation of its budget for the financial year 2006. The decision to grant discharge also constitutes closure of the accounts of this EU agency.

At the same time, the Parliament adopted by 579 votes in favour, 22 against and 39 abstentions, a Resolution containing the comments which form part of the decision giving discharge. The report had been tabled for plenary by Hans-Peter **MARTIN** (NI, AT) on behalf of the Committee on Budgetary Control.

As is the case for all EU agencies, Parliament's Resolution is divided into two parts: part one contains general comments on EU agencies, while part two focuses on the specific case of the Agency.

1) General comments on the majority of EU agencies: the Parliament notes that the budgets of the 24 agencies and other satellite bodies audited by the Court of Auditors totalled **more than EUR 1 billion** and that the number of agencies is constantly increasing. The number of agencies subject to the discharge procedure evolved from 8 in 2000 to 20 in 2006. It concludes therefore that the auditing/discharge process has become cumbersome and disproportionate compared to the relative size of the agencies and that, in the future, this type of procedure should be simplified and rationalised for decentralised agencies.

On the basis of the financial analysis, the Parliament is of the following opinion:

- **Fundamental considerations**: given the constantly increasing number of agencies, the Parliament requests that, before the creation of a new agency, the Commission provide clear explanations regarding agency type, objectives of the agency, internal governance structure, products, services, clients and stakeholders of the agency, formal relationship with external actors, budget responsibility, financial planning, and personnel and staffing policy. It also requests that each agency be governed by a yearly performance agreement which should contain the main objectives for the coming year and that the performance of the agencies be regularly audited by the Court of Auditors (and extend the financial analysis of expenditure to also cover administrative efficiency and effectiveness). More generally, the Parliament takes the view that, in the case of agencies, which are continually overestimating their respective budget needs, technical abatement should be made on the basis of vacant posts in order to reduce the assigned revenue for the agencies and therefore also lower administrative costs of the EU. It recalls that it is a serious problem that a number of agencies is criticised for not following rules on public procurement, the Financial Regulation, the Staff Regulations etc., and considers that the principal reason for this is that most regulations and the Financial Regulation are designed for bigger institutions rather than for small agencies. Therefore, it is necessary to seek a rapid solution in order to enhance the effectiveness of the legislation by grouping the administrative functions of various agencies together or by establishing implementing rules which are better adapted to the agencies. The Parliament also insists that the Commission, when drafting the Preliminary Draft Budget, take into consideration the results of budget implementation by the individual agencies in former years and revise the budget requested by the particular agency accordingly. If the Commission does not undertake this revision, the Parliament invites **the competent committee to revise, itself, the budget in question to a realistic level**. At the same time, the Parliament recalls that it expects the Commission to present every five years a study on the added value of every existing agency and to not hesitate to close an agency if it is deemed useless by the analysis. Such an assessment is expected as soon as possible given that this type of assessment has yet to be presented. Furthermore, the Parliament insists that recommendations of the Court of Auditors should be promptly implemented and the level of subsidies paid to the agencies should be aligned with their real cash requirements.
- **Presentation of reporting data**: noting that there is no standard approach among the agencies with regard to the presentation of information, the Parliament recalls that it already invited the directors of the agencies to accompany their annual activity report with a declaration of assurance concerning the legality and regularity of operations, similar to the declarations signed by the Directors General of the Commission. It therefore asks the Commission to amend its standing instructions to the agencies and to produce a harmonised model for presenting information, including: i) an annual report intended for a general readership on the body's operations, work and achievements; ii) financial statements and a report on implementation of the agency’s budget; iii) an activity report of the Directors of the agency (as requested by the Parliament since 2005); iv) a declaration of assurance signed by the body's director.
- **General findings by the Court of Auditors**: the Parliament refers to certain recurring findings by the Court, including the disbursement of subsidies paid by the Commission (not sufficiently justified estimates of the agencies' cash requirements), the non implementation of the ABAC accounting system by some agencies or the accrued charges for untaken leave which are accounted for by some agencies. It calls for rapid measures in these areas as well as improvements to the internal audit procedures of the agencies. The Parliament also calls on the agencies to consider an inter-agency disciplinary board, as some individual agencies have difficulty in setting up their own disciplinary boards due to their size.

- **Draft inter-institutional agreement**: the Parliament recalls the Commission's draft Interinstitutional agreement on the operating framework for the European regulatory agencies (see ACI/2005/2035), which was intended to create a framework for the creation, structure, operation, evaluation and control of the European regulatory agencies and awaits its adoption as soon as possible. It particularly welcomes the Commission's commitment to bring forward a Communication on the future of the regulatory agencies during the course of 2008.

2. Specific points concerning the European Medicines Agency: while the Parliament recognises the efforts made by the Agency to accelerate the assessment of medicines that are of critical importance to public health, it criticises the fact that the utilisation rate for commitment appropriations was less than 60% in this Agency. Furthermore, a considerable amount of budget appropriations for 2006 was carried over to 2007 due to the nature of the projects dealt with by the Agency. In addition, the Agency would accumulate a large surplus since it receives a Community subsidy and fees and other revenue paid by undertakings for obtaining and maintaining Community marketing authorisations of medicines (revenue of EUR 119 million and a Community subsidy of EUR 31 million). The total surplus for 2006 therefore amounts to EUR 44 million, which, according to the Agency, is not a budgetary surplus but rather an economic outturn based on the application of accrual accounting principles. The Parliament does not understand why the board is concerned about the agency receiving new tasks that would not be met with adequate financing given that the financial situation of the Agency appears to be booming.

The Parliament welcomes the conclusions of the first audit of the Agency in 2005, with the conclusion that the internal control system in place provides reasonable assurance regarding the achievement of the business objectives set up for the processes audited, with some exceptions.

Lastly, the Parliament is aware that the preparation of the implementation of the Regulation on medicinal products for paediatric use had a considerable impact on the Agency's work in 2006 and welcomes the adoption of the joint Commission/Agency document on priorities for implementation of this Regulation.

2006 discharge: European Medicines Agency EMEA

2007/2054(DEC) - 30/03/2007 - Non-legislative basic document

PURPOSE: presentation of the final accounts of the European Medicines Agency for the financial year 2006.

CONTENT: this document sets out a detailed account of the implementation of the 2006 budget, including the revenue and expenditure and the balance sheet for the year concerned.

According to this document, the final budget amounted to **EUR 138.7 million** (in comparison to EUR 111.8 million in 2005) consisting of a 21.63% Community contribution (excluding subsidy for orphan medicines).

As regards staffing, the Agency, whose head office is based in London (UK), set out a total of 424 posts in the establishment plan. 395 posts are currently occupied + 77 other posts (auxiliary contracts, seconded national experts and employment agency staff) totalling 472 posts assigned to operational and administrative tasks. Staff expenditure in 2006 accounted for EUR 42.941 million (final appropriations paid).

Throughout 2006, the Agency concentrated on coordinating the scientific evaluation of medicinal products.

Concerning medicinal products for human use, the Agency:

- replied to 79 applications for marketing authorisations and delivered 51 favourable opinions taking an average evaluation time of 171 days;
- delivered 1 380 opinions after authorisation;
- drafted 94 081 pharmacovigilance reports (64 186 in 2004) and 273 periodic reliability reports;
- delivered 193 scientific opinions and 9 241 procedures for mutual recognition.

Concerning veterinary medicinal products, the Agency:

- replied to 5 new applications for marketing authorisations and 56 applications in respect of variants;
- carried out 128 inspections.

As regards orphan medicinal products, the Agency replied to 104 applications and gave 81 favourable opinions.

The complete version of the final accounts may be found at the following address: http://www.emea.europa.eu/index/indexg1.htm.

2006 discharge: European Medicines Agency EMEA

2007/2054(DEC) - 22/04/2008 - Final act

PURPOSE: to grant discharge to the European Medicines Agency for the financial year 2006.

LEGISLATIVE ACT: Decision 2009/217/EC of the European Parliament on the discharge for the implementation of the budget of the European Medicines Agency for the financial year 2006.

CONTENT: with the present decision, the European Parliament grants discharge to the Executive Director of the European Medicines Agency for the financial year 2006.

This decision is in line with the European Parliament's resolution adopted on 22 April 2008 and comprises a series of observations that form an integral part of the discharge decision (please refer to the summary of the opinion of 22/04/2008).

2006 discharge: European Medicines Agency EMEA

2007/2054(DEC) - 15/11/2007

PURPOSE: presentation of the report by the Court of Auditors on the 2006 annual accounts of the European Medicines Agency.

CONTENT: the report indicates that the appropriations entered in the Agency's budget for the financial year in question are **EUR 138.676 million**, EUR 136.147 million were committed and EUR 106.733 million paid. Of this overall amount, EUR 29.414 million was carried over to 2007 and EUR 2.529 million was cancelled.

The Court notes that the annual accounts are reliable in all material respects and that the underlying transactions of the Agency's accounts, taken as a whole, are legal and regular.

Analysis of the accounts by the Court: in the Court's opinion, as regards the implementation of the budget for administrative expenditure (Title II of the budget), the utilisation rate for commitment appropriations was less than 60%. More than 40% of the commitments, in particular in the area of Information Technology, were carried over to the financial year 2007. Thus, the budgetary principle of **annuality** was not strictly observed.

The Court also indicates that, in accordance with the Fee Regulation, "Any review of the fees shall be based on an evaluation of the Agency's costs and on the basis of the related costs of the services provided for by the Member States. Those costs shall be calculated in accordance with generally accepted international costing methods". However, according to the Court, in 2006 the Agency's customers were billed an amount which was divided in two parts: one part covering the Agency's costs, and the other being repaid to the Member States' rapporteurs to cover their own expenses. As the Member States' rapporteurs never provided full evidence or documentation of their real costs, this situation was in breach of the Fee Regulation, according to the Court.

Moreover, the Court emphasises that the Agency has not been in a position to make a comprehensive analysis of the costs incurred by Member States' rapporteurs in order to obtain an objective and documented basis on which to adapt the payments it makes to them and, consequently, the fees charged to its customers.

The Agency's replies: the Agency recalls that the total automatic carryover to 2007 under Title II amounted to EUR 15 million, of which EUR 8 million was for Information Technology (Chapter 21). The Agency indicates that it is in the process of developing and implementing a multi-annual programme of EU Telematics for the regulation of medicinal products. It also indicates that its governance process and the nature of its projects make it difficult to strictly observe the principle of annuality, especially as many governance actions are outside of its control. However, it indicates that every effort is being made to lower the level of automatic carryovers in the future.

Concerning the costs incurred by Member States' rapporteurs, the Agency indicates that it has, together with the national competent authorities, made great effort to assess the costs incurred by rapporteurs. At its December 2006 meeting, the Management Board of the Agency took the decision to revise the scale of fees system and decided to establish a costing group in order to prepare and agree on generally accepted costing methods, referred to in Article 12 of the Fee Regulation. Finally, the Agency indicates that representatives from all national competent authorities will be invited to participate in this work.

2006 discharge: European Medicines Agency EMEA

2007/2054(DEC) - 29/01/2008

Based on the observations contained in the revenue and expenditure account and the balance sheet of the European Medicines Agency for the financial year 2006, as well as on the Court of Auditor's report and the Agency's replies to the Court's observations, the Council recommends that the Parliament grant the Director of the Agency discharge in respect of the implementation of the budget for the financial year 2006.

In doing so, the Council confirms that EUR 16.7 million (89%) of the appropriations carried over from 2005 to 2006 (EUR 18.8 million) was used, that the appropriations carried over from 2006 to 2007 amount to EUR 29.4 million and that a total of EUR 2.5 million was cancelled.

Recalling that the Court of Auditors was able to obtain reasonable assurance that the Agency's annual accounts were, in all material aspects, reliable, the Council believes that there is a certain number of observations that must be taken into consideration when providing the discharge on the implementation of the 2006 budget, particularly regarding the following points:

- **Carry-overs:** the Council notes with concern the remaining high rates of carry-overs, particularly for administrative expenditure (Title II), and calls on the Agency to rectify this situation and to comply in the short term with the principle of annuality;
- **Fees:** the Council notes the Court's observation concerning the lack of an objective and documented basis on which to review the fees owed to the Agency, in line with article 12 of the Fee Regulation. In this context, the Council encourages the Agency to continue its efforts, in cooperation with the relevant national authorities, to make a comprehensive analysis of the costs incurred by Member States' rapporteurs.