Basic information

2008/2262(DEC) DEC - Discharge procedure	Procedure completed
2007 discharge: European Medicines Agency EMEA **Subject** 8.70.03.07 Previous discharges	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	FJELLNER Christofer (PPE-DE)	26/03/2008

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	OLAJOS Péter (PPE-DE)	29/01/2008

Council of the European Union

Council configuration	Meetings	Date
Economic and Financial Affairs ECOFIN	2922	2009-02-10

European Commission

Commission DG	Commissioner
Budget	KALLAS Siim

Key events

Date	Event	Reference	Summary
23/07/2008	Non-legislative basic document published	SEC(2008)2359	Summary
20/11/2008	Committee referral announced in Parliament		
16/03/2009	Vote in committee		Summary
20/03/2009	Committee report tabled for plenary	A6-0162/2009	
21/04/2009	Debate in Parliament		
23/04/2009	Decision by Parliament	T6-0266/2009	Summary
23/04/2009	Results of vote in Parliament		

23/04/2009	End of procedure in Parliament		
26/09/2009	Final act published in Official Journal		

Technical information

Procedure reference	2008/2262(DEC)
Procedure type	DEC - Discharge procedure
Legal basis	Rules of Procedure EP 102
Stage reached in procedure	Procedure completed
Committee dossier	CONT/6/67273

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE416.343	29/01/2009	
Committee opinion	ENVI	PE416.685	12/02/2009	
Committee report tabled for plenary, single reading		A6-0162/2009	20/03/2009	
Text adopted by Parliament, single reading		T6-0266/2009	23/04/2009	Summary

Council of the EU

Document type	Reference	Date	Summary
Document attached to the procedure	05588/2009	23/01/2009	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	SEC(2008)2359	23/07/2008	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
CofA	Court of Auditors: opinion, report	N6-0004/2009 OJ C 311 05.12.2008, p. 0001	05/12/2008	Summary

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Budget 2009/0645
OJ L 255 26.09.2009, p. 0117 Summary

2007 discharge: European Medicines Agency EMEA

2008/2262(DEC) - 23/01/2009

Based on the observations contained in the revenue and expenditure account and the balance sheet of the European Medicines Agency (EMEA) for the financial year 2007, 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 2007.

In doing so, the Council confirms that EUR 28.3 million (96.1%) of the appropriations carried over from 2006 to 2007 (EUR 29.4 million) were used, that the appropriations carried over from 2007 to 2008 amount to EUR 32 million and that a total of EUR 4 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 granting discharge in respect of the implementation of the 2007 budget, particularly regarding the following points:

- **Carry-over rates**: the Council notes with concern the persistently high carry-over rates, in particular for administrative expenditure, and urges the Agency to follow the Court's recommendations and to make every effort to comply fully with the provisions of the Financial Regulation, in particular those regarding the annuality principle;
- **Procurement**: the Council notes the Court's findings on weaknesses in the tendering procedures and calls on the Agency to continue its efforts to improve the quality of its public procurement procedures.

2007 discharge: European Medicines Agency EMEA

2008/2262(DEC) - 05/12/2008

PURPOSE: to present the report by the Court of Auditors on the 2007 annual accounts of the European Medicines Agency (EMEA).

CONTENT: the Court of Auditor's report includes a detailed section on the Agency's expenditure and an analysis of the expenditure, as well as the Agency's replies.

- **Analysis of the accounts by the Court**: in its report, the Court makes a number of observations, particularly with regard to carry-overs and cancellations of budget appropriations (which, in 2007, amounted to EUR 32 million and EUR 4 million respectively). As in 2006, the high level of carry-overs for administrative expenditure (EUR 189 million) was mainly due to the programme Telematics for the regulation of medical products. The Court calls on the Agency and the other parties involved in this programme to ensure better planning and monitoring of the implementation of the programme. The Agency should consider using the differentiated appropriations system for the Telematics programme which is more suitable for the budgetary management of such programmes. The Court also notes weaknesses in the tendering procedures. There were difficulties in evaluating the cost of the bids and there was a need to review the volumes and values of the services to be procured. The Court calls on the Agency to improve the quality of its public procurement procedures;
- **The Agency's replies**: the Agency takes note of the Court's observations in terms of difficulties in complying fully with the annuality principle when it comes to the implementation of Telematics programmes and in terms of financial management. It notes that it commits itself to make every effort to reduce the level of carry-overs and to consider the proposal of applying differentiated appropriations. It also notes that it has established a formula for the objective evaluation of price as an award criterion.

2007 discharge: European Medicines Agency EMEA

2008/2262(DEC) - 23/04/2009 - Final act

PURPOSE: to grant discharge to the European Medicines Agency for the financial year 2007.

LEGISLATIVE ACT: Decision 2009/645/EC of the European Parliament on the discharge for the implementation of the budget of the European Medicines Agency for the financial year 2007.

CONTENT: with the present decision, the European Parliament grants discharge to the Executive Director of the European Medicines Agency for the financial year 2007.

This decision is in line with the European Parliament's resolution adopted on 23 April 2009 and comprises a series of observations that form an integral part of the discharge decision (please refer to the summary of the opinion of 23/04/2009). The decision to grant discharge is also an approval of the closure of the accounts of this EU agency.

2007 discharge: European Medicines Agency EMEA

2008/2262(DEC) - 23/07/2008 - Non-legislative basic document

PURPOSE: to present the final accounts of the European Medicines Agency for the financial year 2007.

CONTENT: this document sets out a detailed account of the implementation of the European Medicines Agency's budget for the financial year 2007. It notes that the final budget amounts to EUR 163.1 million in 2007 (compared to EUR 138.7 million in 2006), representing a 24.3% Community subsidy (excluding subsidy for orphan medicines).

As regards the staffing policy, the Agency, whose head office is in London (United Kingdom), officially set out 441 posts in its establishment plan. 422 of these posts are currently occupied with 95 other posts (auxiliary agents, contract agents seconded national experts, employment agency staff) totalling 518 posts assigned to operational and administrative tasks.

Throughout 2007, the Agency concentrated on coordinating the scientific evaluation of medicinal products.

Concerning medicinal products for human use, the Agency:

- replied to 91 applications for marketing authorisations and delivered 58 favourable opinions taking an average evaluation time of 171 days;
- delivered 1 899 opinions after authorisation;
- drafted 150 188 pharmacovigilance reports and 313 periodic safety update reports;
- delivered 215 scientific opinions and 10 932 procedures for mutual recognition;
- made 85 applications for paediatric investigation plans relating to 202 indications (new task).

Concerning veterinary medicinal products, the Agency:

- replied to 14 new applications for marketing authorisations and 100 applications in respect of variants;
- carried out 185 inspections.

Concerning orphan medicinal products, the Agency replied to 125 applications and gave 97 favourable opinions.

Concerning SMEs, the Agency:

- replied to 212 requests for SME status;
- replied to 81 applications for fee reduction or deferrals.

The complete version of the final accounts may be found at the following address: www.emea.europa.eu

2007 discharge: European Medicines Agency EMEA

2008/2262(DEC) - 23/04/2009 - Text adopted by Parliament, single reading

The European Parliament adopted by 582 votes to 13, with 40 abstentions, a decision concerning the discharge to be granted to the Executive Director of the European Medicines Agency in respect of the implementation of its budget for the financial year 2007. The decision to grant discharge is also an approval of the closure of the accounts of this EU agency.

In parallel, the European Parliament adopted a resolution with observations which are an integral part of the decision to grant discharge.

Parliament notes that the Agency's budget is financed both from the EU Budget and mainly by fees paid by pharmaceutical industry applicants for obtaining or maintaining a Community marketing authorisation. It encourages the Agency to continue its action in the Orphan Medicines field, while discouraging the decrease in the Orphan Medicines contribution which resulted in a 26.25% reduction in revenue in 2007 compared to 2006.

On the issue of weaknesses in **budgetary management concerning the Telematics programme**, Parliament calls on the Agency to implement the ECA's recommendation to use differentiated appropriations for the Telematics programme promptly and calls on the Agency to report on the action taken in its annual activity report for 2008.

In relation to **procurement procedures**, Parliament notes the Court's observations and the Agency's replies and call on the Agency to address the weaknesses identified as soon as possible.

On the issue of **fees**, Parliament notes that the ECA, in its 2006 annual report, found that the Agency's practice was in breach of its fee regulation for the following reasons: the Agency's customers were billed an amount which was divided into two parts, the Agency's costs and an amount which was repaid to the Member States' rapporteurs to cover their own costs; and the Member States' rapporteurs however never provided full evidence of their actual costs. It calls on the Agency to resolve this issue and report on the follow-up action taken in its annual activity report for 2008.

Lastly, noting that the Agency's annual accounts for the financial year 2007 are reliable, and the underlying transactions are legal and regular, the Parliament approves the closure of its accounts and refers, for other observations accompanying its decision on discharge, to its resolution on financial management and control of EU agencies - see 2008/2207(INI) - adopted in parallel.