

Procedure file

Basic information		
DEC - Discharge procedure	2008/2262(DEC)	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		26/03/2008
		PPE-DE FJELLNER Christofer	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety		29/01/2008
		PPE-DE OLAJOS Péter	
Council of the European Union	Council configuration	Meeting	Date
	Economic and Financial Affairs ECOFIN	2922	10/02/2009
European Commission	Commission DG	Commissioner	
	Budget	KALLAS Siim	

Key events			
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	Results of vote in Parliament		
23/04/2009	Decision by Parliament	T6-0266/2009	Summary
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 100
Stage reached in procedure	Procedure completed
Committee dossier	CONT/6/67273

Documentation gateway

Non-legislative basic document		SEC(2008)2359	23/07/2008	EC	Summary
Court of Auditors: opinion, report		N6-0004/2009 OJ C 311 05.12.2008, p. 0001	05/12/2008	CofA	Summary
Document attached to the procedure		05588/2009	23/01/2009	CSL	Summary
Committee draft report		PE416.343	29/01/2009	EP	
Committee opinion	ENVI	PE416.685	12/02/2009	EP	
Committee report tabled for plenary, single reading		A6-0162/2009	20/03/2009	EP	
Text adopted by Parliament, single reading		T6-0266/2009	23/04/2009	EP	Summary

Final act

[Budget 2009/645](#)
[OJ L 255 26.09.2009, p. 0117](#) Summary

2007 discharge: European Medicines Agency EMEA

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

The Committee on Budgetary Control adopted the report drawn up by Christofer FJELLNER (EPP-ED, SE) on discharge to be granted to the European Medicines Agency, calling on the European Parliament to grant the Executive Director of the Agency discharge in respect of the implementation of its budget for the financial year 2007.

Noting that the Agency's annual accounts for the financial year 2007 are reliable, and the underlying transactions are legal and regular, MEPs approve the closure of the Agency's accounts.

However, they make a number of recommendations as part of the decision on discharge. In addition to the general recommendations appearing in the draft resolution on financial management and control of EU agencies (see [2008/2207\(INI\)](#)), MEPs make the following observations:

- 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;
- the Agency as a source of important scientific advice, science-based recommendations, best practice for medicines evaluation, which contributes towards the harmonisation of regulatory standards at international level.

MEPs encourage 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, MEPs call on the Agency to implement the ECA's recommendation to use differentiated appropriations for the Telematics programme promptly and call on the Agency to report on the action taken in its annual activity report for 2008.

In relation to procurement procedures, MEPs note 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, MEPs note that the ECA, in its 2006 annual report, found that the Agency's practice was in breach of its fee regulation. The ECA, in its 2007 annual report, followed up on these findings, stating that the Agency's Management Board set up a costing group which made a proposal for an alternative option for remunerating the rapporteurs at the end of 2007. In this context, MEPs insist that the Agency make further progress to resolve this issue and report on the follow-up action taken in its annual activity report for 2008.

2007 discharge: European Medicines Agency EMEA

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.

2007 discharge: European Medicines Agency EMEA

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.

