Basic information

2009/2118(DEC) DEC - Discharge procedure	Procedure completed
2008 discharge: European Medicines Agency EMEA **Subject** 8.70.03.07 Previous discharges	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	MATHIEU HOUILLON Véronique (PPE)	01/10/2009
	Shadow rapporteur STAVRAKAKIS Georgios (S&D) GERBRANDY Gerben-Jan (ALDE) STAES Bart (Verts/ALE)	

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	HAUG Jutta (S&D)	06/10/2009

Council of the European Union

Council configuration	Meetings	Date
Economic and Financial Affairs ECOFIN	2994	2010-02-16

European Commission

Commission DG	Commissioner
Budget	ŠEMETA Algirdas

Key events

Date	Event	Reference	Summary
23/07/2009	Non-legislative basic document published	SEC(2009)1089	Summary
07/10/2009	Committee referral announced in Parliament		

23/03/2010	Vote in committee		Summary
26/03/2010	Committee report tabled for plenary	A7-0078/2010	
21/04/2010	Debate in Parliament		
05/05/2010	Decision by Parliament	T7-0108/2010	Summary
05/05/2010	Results of vote in Parliament		
05/05/2010	End of procedure in Parliament		
25/09/2010	Final act published in Official Journal		

Technical information

Procedure reference	2009/2118(DEC)
Procedure type	DEC - Discharge procedure
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	CONT/7/01104

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE430.483	03/02/2010	
Committee opinion	ENVI	PE431.177	23/02/2010	
Amendments tabled in committee		PE439.368	03/03/2010	
Committee report tabled for plenary, single reading		A7-0078/2010	26/03/2010	
Text adopted by Parliament, single reading		T7-0108/2010	05/05/2010	Summary

Council of the EU

Document type	Reference	Date	Summary
Document attached to the procedure	05827/2010	01/02/2010	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	SEC(2009)1089	23/07/2009	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary

CofA	Court of Auditors: opinion, report	N7-0012/2010 OJ C 304 15.12.2009, p. 0001	08/10/2009	Summary
CofA	Document attached to the procedure	N7-0036/2009 OJ C 269 10.11.2009, p. 0001	10/11/2009	

Additional information		
Source	**Document**	**Date**
European Commission	EUR-Lex	

Final act	
Decision 2010/0528 OJ L 252 25.09.2010, p. 0164	Summary

2008 discharge: European Medicines Agency EMEA

2009/2118(DEC) - 05/05/2010 - Text adopted by Parliament, single reading

The European Parliament adopted by 553 votes to 30, with 57 abstentions, a decision on 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 2008. The decision to grant discharge is also an approval of the closure of the accounts of this EU agency. Furthermore, Parliament adopted a resolution with observations which are an integral part of the decision to grant discharge to this Agency.

The main points are as follows:

- **carry over of appropriations:** Parliament is concerned that the Court of Auditors has pointed out that the budget appropriations carried over and cancelled have amounted respectively to EUR 36 million (19.7% of the budget). It points out, as noted in previous financial years, that the high level of carry-overs for administrative expenditure was mainly due to IT expenditure. It is, consequently, concerned as this situation has existed for a number of years and is at odds with the annuality principle;
- **procurement procedures:** Parliament calls on the Agency to improve the quality of its procurement procedures so as to put an end to the shortcomings identified by the Court of Auditors. It takes note of the Agency's longstanding policy of entering into a forward foreign exchange contract in order to hedge part of its administrative budget against unfavourable fluctuations in the exchange rate of sterling. Parliament expects the Agency to manage such transactions prudently and recommends that a working group be set up to observe and closely monitor the hedging strategy;
- **revenue from fees:** Parliament points out that the fees charged for evaluation services are the main source of the Agency's revenue, accounting for 70.2% of its total revenue in 2008. It notes that the Agency reported EUR 2 046 000 in income from interest in 2008. It concludes from the financial statements and from the level of the interest payments that the Agency has a permanently extremely high level of cash holdings (on 31 December 2008, the Agency's cash holdings amounted to EUR 41.887 million). It asks the Commission to examine what scope there is for helping to ensure that the cash holdings are managed entirely on a needs-orientated basis and what changes of approach are necessary in order to keep the Agency's cash holdings permanently as low as possible;
- internal audit: lastly, Parliament asks the Agency to implement the recommendations from the Internal Audit Service (IAS) in particular as regards the conflicts of interest.

Noting that the Agency's annual accounts for the financial year 2008 are reliable, and the underlying transactions are legal and regular, Parliament approves the closure of its accounts and refers to the general recommendations that appear in the draft resolution on financial management and control of EU agencies (see 2010/2007(INI) adopted in parallel).

2008 discharge: European Medicines Agency EMEA

2009/2118(DEC) - 08/10/2009

PURPOSE: to present the report by the Court of Auditors on the 2008 annual accounts of the European Medicines Agency (EMEA).

CONTENT: in the Court's opinion, the Agency's Annual Accounts present fairly, in all material respects, its financial position as of 31 December 2008 and the results of its operations and its cash flows for the year then ended. The transactions underlying the annual accounts of the Agency for the financial year ended are, in all material respects, legal and regular.

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.

- **The Court's analysis of the accounts**: in its report, the Court makes a number of observations, particularly with regard to the budgetary and financial management. It states that of the budget appropriations, EUR 36 million were carried over and EUR 9.7 million were cancelled. As in previous years, the high level of carry-overs for administrative expenditure – EUR 21.4 million - was mainly due for IT expenditure for a programme for the regulation of medical products. This situation has existed for a number of years and is at odds with the annuality principle. The Agency should take the appropriate steps to address this shortcoming. The Agency has had a long standing policy to enter into forward foreign exchange contract for the next financial year in order to hedge part (50 %) of its administrative budget against unfavourable fluctuations of the exchange rate for the sterling. As the 2008 closing sterling rate used for drawing up the financial statements was significantly higher than foreseen when the contract was made (in August 2008), the Agency accounted for a negative fair value movement of EUR 8.7 million in its capital account. The Agency should consider reassessing its policy in the light of the risks incurred. Lastly, the Court states that, as was the case last year, the audit of the tendering procedures showed weaknesses: inadequate evaluation methods for the price criteria, insufficient justification of chosen procedures and other procedural weaknesses. The Agency should aim 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 and it will make every effort to respect more closely the this principle. The Agency believes that over the long term it is prudent to manage the currency exposure risk. It has taken into account the Court’s observation and an internal management group will look at the hedging strategy to follow for 2010 in conjunction with the Agency’s bank. The Agency takes note of the observed weaknesses and has taken action to improve the implementation and accompanying controls of procurement and tender procedures.

2008 discharge: European Medicines Agency EMEA

2009/2118(DEC) - 01/02/2010

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 2008, 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 2008.

The Council welcomes the Court's opinion that, on the one hand, the Agency's annual accounts present fairly, in all material aspects, the financial position as at 31 December 2008 and the results of operations and cash-flows for the year then ended, in accordance with the provisions of the Agency's Financial Regulation, and that, on the other hand, the underlying transactions for the financial year ended on 31 December 2008 are, in all material respects, legal and regular.

However, the Council considers that observations made in the Court of Auditor’s report call for a certain number of observations to be taken into account when granting discharge, particularly on the following points:

- **carry-over rates**: the Council reiterates that the persistently high carry-over rates, in particular for administrative expenditure, necessitate improvements. It 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;
- **tendering procedures**: 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.

2008 discharge: European Medicines Agency EMEA

2009/2118(DEC) - 05/05/2010 - Final act

PURPOSE: to grant discharge to the European Medicines Agency for the financial year 2008.

LEGISLATIVE ACT: Decision 2010/528/EU of the European Parliament on the discharge for the implementation of the budget of the European Medicines Agency for the financial year 2008.

CONTENT: with the present decision, the European Parliament grants discharge to the Executive Director of the European Medicines Agency for the financial year 2008.

This decision is in line with the European Parliament’s resolution adopted on 5 May 2010 and comprises a series of observations that form an integral part of the discharge decision (please refer to the summary of the opinion of 5 May 2010).

A parallel Decision, adopted on the same day, approves the closure of the accounts of this EU agency.

2008 discharge: European Medicines Agency EMEA

2009/2118(DEC) - 23/07/2009 - Non-legislative basic document

PURPOSE: to present the final accounts of the European Medicines Agency for the financial year 2008.

CONTENT: this document sets out a detailed account of the implementation of the European Medicines Agency's budget for the financial year 2008. It notes that the final budget amounts to EUR 182.9 million in 2008 (compared to EUR 163.1 million in 2007), representing a 21.9% 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 481 posts in its establishment plan. 469 of these posts are currently occupied with 118 other posts (auxiliary agents, contract agents seconded national experts, employment agency staff) totalling 587 posts assigned to operational and administrative tasks.

Throughout 2008, the Agency concentrated on coordinating the scientific evaluation of medicinal products.

Medicinal Products for Human Use

- replied to 103 applications for marketing authorisations and delivered 68 favourable opinions. The average evaluation time dedicated was 184 days
- delivered 2 122 opinions after authorisation
- drafted 193 587 Pharmacovigilance reports and 391 periodic safety update reports
- delivered 263 scientific advice finalised: 263 and 14 522 procedures for mutual recognition
- made 271 applications for paediatric investigation plans and relating to 395 indication(new task).

Medicinal Products for Veterinary Use

- replied to 13 new applications and 100 applications in respect of variants
- carried out 253 inspections.

Orphan Medicinal Products

- made 119 applications and gave 86 favourable opinions.

SMEs

- replied to 242 requests for SME status
- replied to 84 applications for fee reduction or deferrals.

The complete version of the final accounts may be found at the following address: http://www.emea.europa.eu/htms/general/manage/ar.htm