



# Procedure file

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

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	<b>CONT</b> Budgetary Control		01/10/2009
		PPE <a href="#">MATHIEU HOUILLON</a> <a href="#">Véronique</a>	
		Shadow rapporteur	
		S&D <a href="#">STAVRAKAKIS Georgios</a>	
		ALDE <a href="#">GERBRANDY</a> <a href="#">Gerben-Jan</a>	
		Verts/ALE <a href="#">STAES Bart</a>	
	Committee for opinion	Rapporteur for opinion	Appointed
	<b>ENVI</b> Environment, Public Health and Food Safety		06/10/2009
		S&D <a href="#">HAUG Jutta</a>	
Council of the European Union	Council configuration	Meeting	Date
	<a href="#">Economic and Financial Affairs ECOFIN</a>	<a href="#">2994</a>	16/02/2010
European Commission	Commission DG	Commissioner	
	<a href="#">Budget</a>	ŠEMETA Algirdas	

Key events			
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	<a href="#">A7-0078/2010</a>	
21/04/2010	Debate in Parliament		
05/05/2010	Results of vote in Parliament		
05/05/2010	Decision by Parliament	<a href="#">T7-0108/2010</a>	Summary

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 159
Stage reached in procedure	Procedure completed
Committee dossier	CONT/7/01104

## Documentation gateway

Non-legislative basic document		SEC(2009)1089	23/07/2009	EC	Summary
Court of Auditors: opinion, report		N7-0012/2010 <a href="#">OJ C 304 15.12.2009, p. 0001</a>	08/10/2009	CofA	Summary
Document attached to the procedure		N7-0036/2009 <a href="#">OJ C 269 10.11.2009, p. 0001</a>	10/11/2009	CofA	
Document attached to the procedure		<a href="#">05827/2010</a>	01/02/2010	CSL	Summary
Committee draft report		<a href="#">PE430.483</a>	03/02/2010	EP	
Committee opinion	ENVI	<a href="#">PE431.177</a>	23/02/2010	EP	
Amendments tabled in committee		<a href="#">PE439.368</a>	03/03/2010	EP	
Committee report tabled for plenary, single reading		<a href="#">A7-0078/2010</a>	26/03/2010	EP	
Text adopted by Parliament, single reading		<a href="#">T7-0108/2010</a>	05/05/2010	EP	Summary

## Final act

[Decision 2010/528](#)  
[OJ L 252 25.09.2010, p. 0164](#) Summary

## 2008 discharge: European Medicines Agency EMEA

**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>

## 2008 discharge: European Medicines Agency EMEA

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The Committee on Budgetary Control adopted the report by Véronique MATHIEU (EPP, FR) 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 the Agency's budget for the financial year 2008.

Noting that the Agency's annual accounts for the financial year 2008 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 that need to be taken into account when the discharge is granted, in addition to the general recommendations that appear in the draft resolution on financial management and control of EU agencies (see [2010/2007\(INI\)](#)):

- carry over of appropriations: Members are 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). They point out, as noted in previous financial years, that the high level of carry-overs for administrative expenditure was mainly due to IT expenditure. They are consequently concerned as this situation has existed for a number of years and is at odds with the annuality principle;
- procurement procedures: Members called 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. They take 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. MEPs expect the Agency to manage such transactions prudently and recommend that a working group be set up to observe and closely monitor the hedging strategy;
- revenue from fees: Members point 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. They note that the Agency reported EUR 2 046 000 in income from interest in 2008. They conclude 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). They ask 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, Members ask the Agency to implement the recommendations from the Internal Audit Service (IAS) in particular as regards the conflicts of interest.

## 2008 discharge: European Medicines Agency EMEA

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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

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**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.