Basic information

2012/2190(DEC) DEC - Discharge procedure	Procedure completed
2011 discharge: European Medicines Agency (EMA) **Subject** 8.70.03.07 Previous discharges	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	GERBRANDY Gerben-Jan (ALDE)	29/02/2012
	Shadow rapporteur SARVAMAA Petri (PPE) AYALA SENDER Inés (S&D) STAES Bart (Verts/ALE) BRADBOURN Philip (ECR) SØNDERGAARD Søren Bo (GUE/NGL) ANDREASEN Marta (EFD) EHRENHAUSER Martin (NI)	

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	HAUG Jutta (S&D)	20/09/2012

European Commission

Commission DG	Commissioner
Budget	ŠEMETA Algirdas

Key events

Date	Event	Reference	Summary
25/07/2012	Non-legislative basic document published	COM(2012)0436	Summary
13/09/2012	Committee referral announced in Parliament		

19/03/2013	Vote in committee		
22/03/2013	Committee report tabled for plenary	A7-0098/2013	Summary
16/04/2013	Debate in Parliament		
17/04/2013	Decision by Parliament	T7-0150/2013	Summary
17/04/2013	Results of vote in Parliament		
17/04/2013	End of procedure in Parliament		
16/11/2013	Final act published in Official Journal		

Technical information

Procedure reference	2012/2190(DEC)
Procedure type	DEC - Discharge procedure
Stage reached in procedure	Procedure completed
Committee dossier	CONT/7/10520

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE497.831	23/01/2013	
Committee opinion	ENVI	PE500.745	28/01/2013	
Amendments tabled in committee		PE497.879	27/02/2013	
Committee report tabled for plenary, single reading		A7-0098/2013	22/03/2013	Summary
Text adopted by Parliament, single reading		T7-0150/2013	17/04/2013	Summary

Council of the EU

Document type	Reference	Date	Summary
Document attached to the procedure	05753/2013	01/02/2013	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2012)0436	25/07/2012	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
CofA	Court of Auditors: opinion, report	N7-0022/2013 OJ C 388 15.12.2012, p. 0116	05/09/2012	Summary

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

Final act	
Decision 2013/0584 OJ L 308 16.11.2013, p. 0254	Summary

2011 discharge: European Medicines Agency (EMA)

2012/2190(DEC) - 05/09/2012 - Court of Auditors: opinion, report

PURPOSE: presentation of the EU Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2011, together with the Agency's reply.

CONTENT: in accordance with the tasks conferred on the Court of Auditors by the Treaty on the Functioning of the European Union, the Court presents to the European Parliament and to the Council, in the context of the discharge procedure, a Statement of Assurance as to the reliability of the annual accounts of each institution, body or agency of the EU, and the legality and regularity of the transactions underlying them, on the basis of an independent external audit.

This audit concerned, amongst others, the annual accounts of the European Medicines Agency (EMA).

In the Court's opinion, the **Agency's Annual Accounts fairly present, in all material respects, its financial position as of 31 December 2011** and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its Financial Regulation.

The Court also considers that the **transactions underlying the annual accounts** of the Agency for the financial year ended 31 December 2011 are, in all material respects, **legal and regular**.

The report confirms that the Agency's 2011 budget amounted to EUR 208.863 million and that the number of staff employed by the Agency at the end of the year was 728.

The report also makes a series of observations on the budgetary and financial management of the Agency, accompanied by the latter's response. The main observations may be summarised as follows:

Court's comments:

- carry-overs: the Court notes again that the level of carry- over is excessive and at odds with the principle of annuality;
- public procurement: the Agency increased in 2011 the financial envelope of an irregular framework contract for IT services concluded in 2009 for which the Court had qualified its opinion on the legality and regularity of the transactions underlying the Agency's 2009 accounts. According to the Court, there is scope for improving the transparency of procurement procedures as regards the justification of the estimated contract volumes and the definition, publication and application of selection criteria;
- recruitment: the Court identified a need to improve the transparency of staff selection procedures.

Agency's replies:

- the Agency states that since 2008 it has made every effort to reduce its level of carry-over to an acceptable level. It has in fact achieved a continuous reduction. As the operations of the Agency are of a multi-annual nature and not linked to the calendar year, a certain level of carry-overs is unavoidable;
- the Agency considers that the IT framework contract was not irregular. As a consequence, the extension of the framework contract is considered not irregular as well;
- the Agency has taken note of the Court's comments and updated its procedures with a view to transparency and timely documentation.

Lastly, the Court of Auditors' report contains a summary of the **Agency's activities in 2011**. This is focused on the following:

- applications for marketing authorisations for 100 medicines for human use ;
- pharmacovigilance activities;
- mutual recognition procedures and decentralised procedures: started 6 401; (6 715 ended positively);

- scientific advice;
- applications for paediatric investigation plans: 187 relating to 220 indications;
- applications for marketing authorisations for 11 medicinal products for veterinary use;
- 449 inspections;
- herbal medicinal products;
- 166 applications for orphan medicinal products (111 favourable opinions);
- requests for SME status: 433 requests and 350 applications for fee reduction or deferrals.

2011 discharge: European Medicines Agency (EMA)

2012/2190(DEC) - 01/02/2013

Having examined the revenue and expenditure accounts for the financial year 2011 and the balance sheet at 31 December 2011 of the European Medicines Agency, as well as the Court of Auditors' report on the annual accounts of the Agency for the financial year 2011, accompanied by the Agency's replies to the Court's observations, the Council recommends the European Parliament to give a discharge to the Executive Director of the Agency in respect of the implementation of the budget for the financial year 2011.

The observations in the Court of Auditors' report in relation to the financial year 2011 call for some comments by the Council, which may be summarised as follows:

- the Council welcomes the Court's opinion that, in all material respects, the Agency's annual accounts present fairly its financial position as at 31 December 2011 and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of the Agency's Financial Regulation, and that the underlying transactions for that financial year are legal and regular;
- the Council, nevertheless, urges the Agency to improve its financial programming and its monitoring of the budget implementation in order to reduce the amounts carried over to the next financial year, in line with the budgetary principle of annuality;
- it notes the Court's findings in relation to the Agency's decision to increase the financial envelope of a framework contract where the Court had found irregularities, and which had given
- rise to the Court's qualified opinion in 2009. It notes that the Agency started preparing in 2011 a new framework contract. Moreover, the Council **calls on the Agency to take actions to remedy the weaknesses found by the Court in the transparency of its procurement procedures**;
- the Council regrets the shortcomings detected by the Court in the transparency of the recruitment procedures, including the irregularities found regarding the conflict of interest declarations of the Selection Board members, and expects this to be fully remedied by the Agency.

2011 discharge: European Medicines Agency (EMA)

2012/2190(DEC) - 22/03/2013 - Committee report tabled for plenary, single reading

The Committee on Budgetary Control adopted the report by Gerben-Jan GERBRANDY (ADLE, NL) on discharge to be granted to the Executive Director of the European Medicines Agency (EMA) in respect of the implementation of the Agency's budget for the financial year 2011.

Noting that the Court of Auditors stated that it has obtained reasonable assurances that the annual accounts of the Agency for the financial year 2011 are reliable and that the underlying transactions are legal and regular, Members 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 performance, financial management and control of EU agencies:

- **Financing, budget and financial management**: Members recall that the Agency's budget for 2011 was EUR 208 863 000, which represents a nominal increase over the financial year 2010. They recall that the total Union contributions amounted to EUR 39 765 191.39 for 2011, which represents an 8.65% increase compared to the previous year and that the rest was financed by **fees paid by the pharmaceutical industry** when applying for, obtaining or maintaining Union marketing authorisations. Members state that a large amount of the Agency's revenue is estimated to have derived from the fee revenue, which continues to increase year on year. Members are concerned as regards the need to introduce a system of remuneration for services provided by Member States’ authorities, based on their real costs.
- **Implementation rate of appropriations**: Members observe that in terms of committed and paid appropriations, the Agency's execution rate stands at 95.21% and 81.97% respectively. They call on the Agency to continue its efforts to improve its execution rate of payment. They are concerned that once again, the Court of Auditors reported that payment appropriations for Title II ("Administrative expenditure") have been carried over to 2012, representing 29% of the budget which is excessive and at odds with the principle of annuality.
- **Conflicts of interest**: noting the problems as regards the conflict of interest in the light of the previous discharge procedure, Members welcome the efforts made but state that the Agency did not adequately manage conflict of interest situations. They welcome the Agency's commitment to undertake in the first half of 2013 a review of the implementation of its revised policy on the handling of conflicts of interests and that an *ex ante* and *ex post* check on the handling of conflicts of interests is currently being developed for implementation in the second quarter of 2013. The Agency is called upon to keep the discharge authority informed on their respective outcomes.

Lastly, Members made a series of observations concerning the recruitment and procurement procedures and controls carried out by this Community Agency.

2011 discharge: European Medicines Agency (EMA)

2012/2190(DEC) - 17/04/2013 - Text adopted by Parliament, single reading

The European Parliament adopted a decision on discharge to be granted to the Executive Director of the European Medicines Agency (EMA) in respect of the implementation of the Agency's budget for the financial year 2011. The vote on the decision to grant discharge covers the closure of the accounts (in accordance with Annex VI, Article 5(1) of the European Parliament's Rules of Procedure).

Noting that the Court of Auditors stated that it has obtained reasonable assurances that the annual accounts of the Agency for the financial year 2011 are reliable and that the underlying transactions are legal and regular, Parliament adopted a resolution containing 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 performance, financial management and control of EU agencies:

- **Financing, budget and financial management**: Parliament recalls that the Agency's budget for 2011 was EUR 208 863 000, which represents a nominal increase over the financial year 2010. It recalls that the total Union contributions amounted to EUR 39 765 191.39 for 2011, which represents an 8.65% increase compared to the previous year and that the rest was financed by **fees paid by the pharmaceutical industry** when applying for, obtaining or maintaining Union marketing authorisations. Members state that a large amount of the Agency's revenue is estimated to have derived from the fee revenue, which continues to increase year on year. Members are concerned as regards the need to introduce a system of remuneration for services provided by Member States' authorities, based on their real costs.
- **Implementation rate of appropriations**: Parliament observes that in terms of committed and paid appropriations, the Agency's execution rate stands at 95.21% and 81.97% respectively. It calls on the Agency to continue its efforts to improve its execution rate of payment. It is concerned that once again, the Court of Auditors reported that payment appropriations for Title II ("Administrative expenditure") have been carried over to 2012, representing 29% of the budget which is excessive and at odds with the principle of annuality.
- **Recruitment procedures**: Parliament states the lack of transparency in the staff selection procedures. It states that there was no evidence of any action taken to address the issues.
- **Conflicts of interest**: noting the problems as regards the conflict of interest in the light of the previous discharge procedure, Parliament welcomes the efforts made but state that the Agency did not adequately manage conflict of interest situations. It welcomes the Agency's commitment to undertake in the first half of 2013 a review of the implementation of its revised policy on the handling of conflicts of interests and that an *ex ante* and *ex post* check on the handling of conflicts of interests is currently being developed for implementation in the second quarter of 2013. The Agency is called upon to keep the discharge authority informed on their respective outcomes.

Lastly, Parliament made a series of observations concerning the procurement procedures and controls carried out by this Community Agency.

2011 discharge: European Medicines Agency (EMA)

2012/2190(DEC) - 17/04/2013 - Final act

PURPOSE: to grant discharge to the European Medicines Agency (EMA) for the financial year 2011.

NON-LEGISLATIVE ACT: Decision 2013/584/EU of the European Parliament on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2011.

CONTENT: with this Decision and in accordance with Article 319 of the Treaty on the Functioning of the European Union (TFEU), the European Parliament gives discharge to the Executive Director of the European Medicines Agency for the implementation of the Agency's budget for 2011.

The Decision is consistent with the European Parliament's resolution adopted on 17 April 2013 and includes a series of observations that form an integral part of the discharge decision (refer to the summary of the opinion of 17 April 2013).

Decision 2013/585/EU, adopted on the same day, approves the closure of the accounts for this Community agency for 2011.

2011 discharge: European Medicines Agency (EMA)

2012/2190(DEC) - 25/07/2012 - Non-legislative basic document

PURPOSE: presentation by the Commission of the consolidated annual accounts of the European Union for the financial year 2011, as part of the 2011 discharge procedure.

Analysis of the accounts of the **European Medicines Agency (EMEA)**.

CONTENT: this Commission document sets out the consolidated annual accounts of the European Union for the financial year 2011 as prepared on the basis of the information presented by the institutions, organisations and bodies of the EU, in accordance with Article 129 (2) of the Financial Regulation applicable to the EU's General Budget, including the European Medicines Agency (EMEA).

In 2011, the tasks and budget of this agency were as follows:

- **description of the Agency's tasks**: the European Medicines Agency, which is located in London, was created by Council Regulation (EEC) No 2309/93, which was replaced by Regulation (EC) No 726/2004 of the European Parliament and of the Council and its role is the coordination of the scientific resources made available by the national authorities in order to ensure the evaluation and supervision of medicinal products for human or veterinary use;

- **the Agency's budget for the 2011 financial year**: the Agency's budget for 2011, as presented in the Commission document on the consolidated annual accounts of the European Union, gives the following figures:

- forecasted income budget: EUR 209 million;
- entitlements established: EUR 220 million;
- amounts received: EUR 199 million;
- outstanding: EUR 21 million.

The complete version of the Agency's final accounts may be found at the following address: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2012/07/WC500129887.pdf