Procedure file

Basic information

DEC - Discharge procedure	2014/2102(DEC)	Procedure completed
2013 discharge: European Medicines Agency (EMA) Subject 8.70.03.03 2013 discharge		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	CONT Budgetary Control		09/10/2014
		ECR CZARNECKI Ryszard	
		Shadow rapporteur	
		epp ZDECHOVSKÝ Tomáš	
		S&D VAUGHAN Derek	
		ALI Nedzhmi	
		JÁVOR Benedek	
		EFD VALLI Marco	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety		05/11/2014
		epp LA VIA Giovanni	
European Commission	Commission DG	Commissioner	
	Budget	GEORGIEVA Kristalina	

Key events

30/07/2014	Non-legislative basic document published	COM(2014)0510	Summary
20/10/2014	Committee referral announced in Parliament		
23/03/2015	Vote in committee		
30/03/2015	Committee report tabled for plenary	A8-0075/2015	Summary

28/04/2015	Debate in Parliament		
29/04/2015	Results of vote in Parliament		
29/04/2015	Decision by Parliament	T8-0147/2015	Summary
29/04/2015	End of procedure in Parliament		
30/09/2015	Final act published in Official Journal		

Technical information

Procedure reference	2014/2102(DEC)
Procedure type	DEC - Discharge procedure
Stage reached in procedure	Procedure completed
Committee dossier	CONT/8/01623

Documentation gateway

Court of Auditors: opinion, report		N8-0087/2014 OJ C 442 10.12.2014, p. 0193	01/07/2014	CofA	Summary
Non-legislative basic document		COM(2014)0510	30/07/2014	EC	Summary
Committee draft report		PE539.704	29/01/2015	EP	
Document attached to the procedure		05304/2015	30/01/2015	CSL	Summary
Committee opinion	ENVI	PE541.523	02/02/2015	EP	
Amendments tabled in committee		PE539.758	06/03/2015	EP	
Committee report tabled for plenary, single reading		A8-0075/2015	30/03/2015	EP	Summary
Text adopted by Parliament, single reading		T8-0147/2015	29/04/2015	EP	Summary

Final act

Budget 2015/1663
OJ L 255 30.09.2015, p. 0263 Summary

2013 discharge: European Medicines Agency (EMA)

PURPOSE: presentation of the EU Court of Auditors report on the annual accounts of the European Medicines Agency for the financial year 2013, together with the Agencys 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).

Statement of assurance: pursuant to the provisions of Article 287 of the Treaty on the Functioning of the European Union (TFEU), the Court has audited:

- the annual accounts of the Agency, which comprise the financial statements and the reports on the implementation of the budget for the financial year ended 31 December 2013;
- the legality and regularity of the transactions underlying those accounts.

Opinion on the reliability of the accounts: in the Courts opinion, the Agencys annual accounts present fairly, in all material respects, its financial position as at 31 December 2013 and the results of its operations and its cash flows for the year then ended, in accordance with the

provisions of its Financial Regulation and the accounting rules adopted by the Commissions accounting officer.

Opinion on the legality and regularity of the transactions underlying the accounts: in the Courts opinion, the transactions underlying the annual accounts for the year ended 31 December 2013 are legal and regular in all material respects.

The Courts report makes no observations on the budgetary and financial management of the Agency.

Lastly, the Court of Auditors report contains a summary of the Agencys activities in 2013. This is focused on the following:

Budget: EUR 251.56 million of which the Union subsidy is 13%.

Activities:

- applications for marketing authorisations for 80 medicines for human use ;
- applications for marketing authorisations for 23 medicinal products for veterinary use;
- pharmacovigilance activities;
- mutual recognition procedures and decentralised procedures: started 6991; (ended 6709);
- 480 inspections;
- herbal medicinal product studies;
- 201 applications for orphan medicinal products (139 favourable opinions);
- requests for SME status: 401 requests and 336 applications for fee reduction or deferrals.

2013 discharge: European Medicines Agency (EMA)

PURPOSE: presentation by the Commission of the consolidated annual accounts of the European Union for the financial year 2013, as part of the 2013 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 2013 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).

The document contains the figures on which the discharge procedure is based.

Discharge procedure of the EU agencies: the EU Budget finances a wide range of policies and programmes throughout the EU. In accordance with the priorities set by the European Parliament and the Council in the multi-annual financial framework (MFF), the European Commission carries out specific programmes, activities and projects in the field with the technical support of some specialised agencies.

The consolidated annual accounts of the EU provide information on the activities of the institutions, agencies and other bodies of the EU from a budgetary and accrual accounting perspective.

The consolidated reports on the implementation of the general budget of the EU include the budget implementation of all Institutions. Agencies do not have a separate budget inside the EU budget; and they are partially financed by a Commission budget subsidy.

Each agency is subject to its own discharge procedure.

EMEA: in 2013, 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 on the basis of a centralised procedure;
- the Agency's budget for the 2013 financial year: the Agencys budget for 2013, as presented in the Commission document on the consolidated annual accounts of the European Union, gives the following figures:

  § Commitment appropriations:

  - committed : EUR 252 million;

  - paid : EUR 243 million;

  - carried over : 0.

  § Payment appropriations:

  - committed : EUR 292 million;

  - paid : EUR 249 million;

  - carried over : EUR 33 million.

See also the final accounts of the EMA.

2013 discharge: European Medicines Agency (EMA)

The Committee on Budgetary Control adopted the report by Ryszard CZARNECKI (ECR, PL) on discharge in respect of the implementation of the budget of the European Medicines Agency (EMA) for the financial year 2013.

The committee recommended that the European Parliament grant the Executive Director of the Agency discharge in respect of the

implementation of the Agencys budget for the financial year 2013.

Noting that the Court of Auditors stated that it has obtained reasonable assurances that the annual accounts of the Agency for the financial year 2013 are reliable, and that the underlying transactions are legal and regular, Members called on the Parliament to approve the closure of the Agencys accounts. They made, however, a number of recommendations that needed 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.

- Centres financial statements: Members noted that the final budget of the Centre for the financial year 2013 was EUR 251.56, representing an increase of 13.07 % compared to 2012. The overall contribution of the Union to the Centre's budget for 2013 amounted to EUR 40 937 951.
- Commitments and carry-overs: Members noted that budget monitoring efforts during the financial year 2013 resulted in a relatively low budget implementation rate of 96.76 % and that the payment appropriations execution rate was 83.49%. They noted the Agency's compliance with the principle of annuality and the timely execution of its budget.

Members also made a series of observations on transfers, procurement and recruitment procedures, internal controls and internal audits and the prevention and management of conflicts of interest.

They acknowledged from the Agency that the transparency criteria for partner, patient, healthcare and consumer organisations had been revised during 2014 in order to increase the transparency of funding. They noted the adoption of the document with detailed criteria regarding the evaluation of financial information from patients, consumers and healthcare professionals organisations. This document was used to assess the organizations eligibility to participate in the dialogue with the Agency.

The committee regretted that the policies on proactive publication of clinical trial data recently adopted by the Agency went against the transparency provisions of Regulation (EU) No 536/2014 by allowing companies to redact data based on potential jeopardy of commercial interests. It called on the Agency to report to the discharge Authority on this issue.

2013 discharge: European Medicines Agency (EMA)

PURPOSE: to grant discharge to the European Medicines Agency (EMA) for the financial year 2013.

NON-LEGISLATIVE ACT: Decision (EU) 2015/1663 of the European Parliament on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2013.

CONTENT: with this Decision, the European Parliament gives discharge to the Executive Director of the European Medicines Agency for the implementation of the Agencys budget for 2013.

The Decision is consistent with the European Parliaments resolution adopted on 29 April 2015 and includes a series of observations that form an integral part of the discharge decision (refer to the summary of the opinion of 29 April 2015).

Amongst the main observations made, Parliament called on the Agency to ensure complete transparency as regards to the origins of its budget and to shed light on the recruitment procedures.

2013 discharge: European Medicines Agency (EMA)

The European Parliament adopted by 556 votes to 110, with 26 abstentions, a decision to grant discharge to the Executive Director of the European Medicines Agency (EMA) for the financial year 2013. The vote on the discharge decision approved the closure of the accounts (in accordance with Annex VI, Article 5(1) of the Rules of Procedure of the European Parliament.

Noting that the Court of Auditors stated that it has obtained reasonable assurances that the annual accounts of the Authority for the financial year 2013 are reliable, and that the underlying transactions are legal and regular, Parliament adopted by 570 votes to 81, with 29 abstentions, a resolution containing a number of recommendations that form an integral part of the discharge decision and as well as the general recommendations that appear in the resolution on performance, financial management and control of EU agencies:

- Centres financial statements: Parliament noted that the final budget of the Centre for the financial year 2013 was EUR 251.56 million, representing an increase of 13.07% compared to 2012. The overall contribution of the Union to the Centre's budget for 2013 amounted to EUR 40 937 951.
- Commitments and carry-overs: Parliament noted that budget monitoring efforts during the financial year 2013 resulted in a relatively low budget implementation rate of 96.76% and that the payment appropriations execution rate was 83.49%. It noted the Agency's compliance with the principle of annuality and the timely execution of its budget.

Parliament also made a series of observations on transfers, procurement and recruitment procedures, internal controls and internal audits and the prevention and management of conflicts of interest. It acknowledged from the Agency that the transparency criteria for partner, patient, healthcare and consumer organisations had been revised during 2014 in order to increase the transparency of funding.

Transparency and data confidentiality: Parliament regrets that the policies on proactive publication of clinical trial data recently adopted by the Agency go against the transparency provisions of Regulation (EU) No 536/2014 of the European Parliament and the Council1 (the Clinical Trials Regulation) by allowing companies to redact data based on potential jeopardy of commercial interests. It notes with regret that the Agency's understanding of what constitutes commercial confidential information (CCI) is far too broad and includes companies to redact key data about the trial design, methods. It called on the Agency to properly implement the provisions of the Clinical Trials Regulation especially with regard to clinical trial data not to be considered CCI.

Parliament also called on the Agency to publish on its website detailed reports of the scientific advice provided by the Agency to pharmaceutical companies during the drug development and pre-registration process at the time of trial authorisation and in any case not later than 12 months after the end of the trial.

Lastly, it noted that advice provided by regulators to companies on drug development and pre-registration plans cannot be considered CCI since there is an overriding public interest in disclosure.