Basic information

2015/2171(DEC) DEC - Discharge procedure	Procedure completed
2014 discharge: European Medicines Agency (EMA) **Subject** 8.70.03.04 2014 discharge	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	VAUGHAN Derek (S&D)	19/08/2015
	Shadow rapporteur DEUTSCH Tamás (PPE) VISTISEN Anders (ECR) ALI Nedzhmi (ALDE) DE JONG Dennis (GUE/NGL) JÁVOR Benedek (Verts/ALE) VALLI Marco (EFDD) KAPPEL Barbara (ENF)	

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	LA VIA Giovanni (PPE)	01/10/2015

European Commission

Commission DG	Commissioner
Budget	GEORGIEVA Kristalina

Key events

Date	Event	Reference	Summary
23/07/2015	Non-legislative basic document published	COM(2015)0377	Summary
05/10/2015	Committee referral announced in Parliament		

04/04/2016	Vote in committee		
08/04/2016	Committee report tabled for plenary	A8-0114/2016	Summary
27/04/2016	Debate in Parliament		
28/04/2016	Decision by Parliament	T8-0176/2016	Summary
28/04/2016	Results of vote in Parliament		
28/04/2016	End of procedure in Parliament		
14/09/2016	Final act published in Official Journal		

Technical information

Procedure reference	2015/2171(DEC)
Procedure type	DEC - Discharge procedure
Stage reached in procedure	Procedure completed
Committee dossier	CONT/8/04180

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee opinion	ENVI	PE571.772	22/01/2016	
Committee draft report		PE569.754	26/01/2016	
Amendments tabled in committee		PE576.947	04/03/2016	
Committee report tabled for plenary, single reading		A8-0114/2016	08/04/2016	Summary
Text adopted by Parliament, single reading		T8-0176/2016	28/04/2016	Summary

Council of the EU

Document type	Reference	Date	Summary
Supplementary non-legislative basic document	05584/2016	27/01/2016	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2015)0377	23/07/2015	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
CofA	Court of Auditors: opinion, report	N8-0137/2015 OJ C 409 09.12.2015, p. 0197	08/09/2015	Summary

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

Final act	
Budget 2016/1534 OJ L 246 14.09.2016, p. 0281	Summary

2014 discharge: European Medicines Agency (EMA)

2015/2171(DEC) - 08/09/2015 - 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 2014, 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).

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 2014, and
- the legality and regularity of the transactions underlying those accounts.

Opinion on the reliability of the accounts: in the Court's opinion, the Agency's annual accounts present fairly, in all material respects, its financial position as at 31 December 2014 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 Commission's accounting officer.

Opinion on the legality and regularity of the transactions underlying the accounts: in the Court's opinion, the transactions underlying the annual accounts for the year ended 31 December 2014 are legal and regular in all material respects.

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:

The Court's observations:

- **legality and regularity of transactions**: the Court noted that due dates for the collections fees from applicants and the Agency's related payments to National Competent Authorities were not respected;
- **public procurement**: the Court noted that in 2014, the Agency concluded a EUR 15 million framework contract (covering the years 2014 to 2017) for high-level management consultancy services. The objectives and activities to be carried out were not sufficiently specific to justify the procurement decision or the volume of the contract.

The Agency's response:

- **legality and regularity of transactions**: the Agency stated that during 2013-14, the Agency has redesigned and streamlined its main operational processes including financial authorisations and fee collections. The further planned automation of the latter was delayed because of the Agency's reorganisation in 2014. To ensure compliance with the Agency's fee regulation concerning due dates, this automation is now planned to be implemented by the end of 2015;
- **public procurement**: the Agency rejected the Court's position and stated that it had clearly assessed the needs to justify a call for tender.

Lastly, the Court of Auditors' report contains a summary of the **Agency's activities in 2014**. This is focused on the following:

Budget: EUR 282.47 of which the Union contribution amounts to 8.2 %.

Activities:

- applications for marketing authorisations for 100 medicines for human use;
- applications for marketing authorisations for 12 medicinal products for veterinary use;
- 506 inspections;
- herbal medicinal product studies;
- 329 applications for orphan medicinal products;
- requests for SME status: 499 requests and 333 applications for fee reduction or deferrals.

2014 discharge: European Medicines Agency (EMA)

2015/2171(DEC) - 08/04/2016 - Committee report tabled for plenary, single reading

The Committee on Budgetary Control adopted the report by Derek VAUGHAN (S&D, UK) on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2014.

The parliamentary committee calls 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 2014.

Noting that the Court of Auditors issued a statement of assurance as to the reliability of the accounts and the legality and regularity of the underlying transactions for the financial year 2014, Members call on Parliament to approve the closure of the Agency's 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:

- **Agency's financial statements:** Members note the final budget of the European Medicines Agency for the financial year 2014 was EUR 282 474 000, representing an increase of 12.29 % compared to 2013. 12.53 % of the Agency's budget derives from the Union budget.

- **Legality and regularity of transactions:** Members note that the Agency's Fee Regulation provides due dates for the collection of fees from applicants and the Agency's related payments to national competent authorities. They note that these due dates were not respected for most of the transactions audited by the Court. They call on the Agency to report to the discharge authority on measures implemented to remedy this issue

Members also made a series of observations regarding commitments and carryovers, procedures for contract awards, recruitment, internal control and audit.

Members note the Agency revised its policy on handling of **declarations of interests** of scientific committee members and experts. It defined what are direct and indirect interests and ordered all experts to declare all direct and indirect interests in their annual declaration of interests. They note, moreover, that **restrictions are applied to experts declaring direct or indirect interests which depend on the activity in which they are involved**, maintaining the policy distinction between those interests in line with the relevant legislation.

Lastly, Members recall that the Pharmacovigilance Fee Regulation was published in the Official Journal of the European Union on 27 June 2014 and has applied to procedures starting from 26 August 2014, although annual fees to support information technology systems and literature monitoring activities will not be levied until 2015. They stress that that Regulation now allows the Agency to collect fees from marketing authorisation holders to finance these pharmacovigilance activities conducted at Union level in respect of medicinal products for human use. They point out that the income is used to **remunerate national competent authorities for the scientific assessment** carried out by the rapporteurs of the Agency's Pharmacovigilance Risk Assessment Committee and contributes to the pharmacovigilance costs of the Agency.

2014 discharge: European Medicines Agency (EMA)

2015/2171(DEC) - 23/07/2015 - Non-legislative basic document

PURPOSE: presentation by the Commission of the consolidated annual accounts of the European Union for the financial year 2014, as part of the 2014 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 2014 as prepared on the basis of the information presented by the institutions, organisations and bodies of the EU, in accordance with Article 148 (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.

On this basis, the Financial Controller of the European Commission ensures the certification of the consolidated accounts as declared by the institutions, agencies and bodies of the European Union.

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.

This document sets out how the Agencies spent and implemented their budget in 2014. Each agency is subject to its own discharge procedure.

EMEA: in 2014, 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 (UK), 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 2014 financial year**: the Agency's budget for 2014, as presented in the Commission document on the consolidated annual accounts of the European Union, gives the following figures:

Commitment appropriations:

- **committed** : EUR 282 million;

- **paid** : EUR 266 million;

- **carried over** : 0.

Payment appropriations:

- **committed** : EUR 316 million;

- **paid** : EUR 251 million;

- **carried over** : EUR 47 million.

See also the final accounts of the EMA.

2014 discharge: European Medicines Agency (EMA)

2015/2171(DEC) - 28/04/2016 - Text adopted by Parliament, single reading

The European Parliament decided to grant discharge to the Executive Director of the European Medicines Agency (EMA) in respect of the implementation of its budget for the financial year 2014. The vote on the decision on discharge covers the closure of the accounts (in accordance with Annex V, Article 5 (1)(a) to Parliament's Rules of Procedure.

Noting that the Court of Auditors has stated that it has obtained reasonable assurances that the Agency's annual accounts for the financial year 2014 are reliable and that the underlying transactions are legal and regular, Parliament adopted by 516 votes to 113 with 10 abstentions, a resolution containing a series of recommendations, which form an integral part of the decision on discharge and which add to the general recommendations set out in the resolution on performance, financial management and control of EU agencies:

- **Agency's financial statements**: Parliament noted the final budget of the European Medicines Agency for the financial year 2014 was EUR 282 474 000, representing an increase of 12.29 % compared to 2013. 12.53 % of the Agency's budget derives from the Union budget.
- **Legality and regularity of transactions**: Parliament noted that the Agency's Fee Regulation provides due dates for the collection of fees from applicants and the Agency's related payments to national competent authorities. It noted that these due dates were not respected for most of the transactions audited by the Court. It called on the Agency to report to the discharge authority on measures implemented to remedy this issue.
- Parliament also made a series of observations regarding commitments and carryovers, procedures for contract awards, recruitment, internal control and audit.
- **Conflicts of interest**: Parliament acknowledged that the Agency has defined what are direct and indirect interests and ordered all experts to declare all direct and indirect interests in their annual declaration of interests. Moreover, it noted that **restrictions are applied to experts declaring direct or indirect interests** which depend on the activity in which they are involved, maintaining the policy distinction between those interests in line with the relevant legislation.

Lastly, Parliament recalled that the Pharmacovigilance Fee Regulation was published in the Official Journal of the European Union on 27 June 2014 and has applied to procedures starting from 26 August 2014, although annual fees to support information technology systems and literature monitoring activities will not be levied until 2015. It stressed that that Regulation now allows the Agency to collect fees from marketing authorisation holders to finance these pharmacovigilance activities conducted at Union level in respect of medicinal products for human use. It pointed out that the income is

used to **remunerate national competent authorities for the scientific assessment** carried out by the rapporteurs of the Agency's Pharmacovigilance Risk Assessment Committee and contributes to the pharmacovigilance costs of the Agency.

2014 discharge: European Medicines Agency (EMA)

2015/2171(DEC) - 27/01/2016 - Supplementary non-legislative basic document

Having examined the revenue and expenditure accounts for the financial year 2014 and the balance sheet as at 31 December 2014 of the European Medicines Agency (EMA), as well as the Court of Auditors' report on the annual accounts of the Agency for the financial year 2014, accompanied by the Agency's replies to the Court's observations, the Council recommended 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 2014.

The Council welcomed the Court's opinion that, in all material respects, the Agency's annual accounts present fairly its financial position as at 31 December 2014 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 2014 are legal and regular in all material respects.

Nevertheless, the Council has made some observations which may be summarised as follows:

- **fees**: the Council noted the Court's observation that the Agency did not ensure that the due dates for the collection of fees and the related payments to the National Competent Authorities were respected. It encouraged the Agency to pursue its efforts to comply with the Agency's own fee regulation;
- **management control**: the Council welcomed the Agency's corrective measures, but regretted the deficiencies found by the Court in the Agency's management control. It urged the Agency to thoroughly evaluate the effectiveness of the measures taken;
- **procurement procedures**: lastly, the Council encouraged the Agency to further improve its procurement procedures in order to ensure their effectiveness.

2014 discharge: European Medicines Agency (EMA)

2015/2171(DEC) - 28/04/2016 - Final act

PURPOSE: to grant discharge to the European Medicines Agency (EMA) for the financial year 2014.

NON-LEGISLATIVE ACT: Decision (EU) 2016/1534 of the European Parliament on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2014.

CONTENT: with this Decision, the European Parliament gives discharge to the Executive Director of the European Medicines Agency for the implementation of the Agency's budget for 2014.

The Decision is consistent with the European Parliament's resolution adopted on 28 April 2016 and includes a series of observations that form an integral part of the discharge decision (refer to the summary of the opinion of 28 April 2016).

Amongst Parliament's main observations in the resolution accompanying the discharge decision, it broached the **difficulties on the legality and regularity of transactions**. It noted that the Agency's Fee Regulation provides due dates for the collection of fees from applicants and the Agency's related payments to national competent authorities. These due dates were not respected for most of the transactions audited by the Court. It called on the Agency to take all measures necessary to remedy this issue.