Basic information

2016/2169(DEC) DEC - Discharge procedure	Procedure completed
2015 discharge: European Medicines Agency (EMA) **Subject** 8.70.03.05 2015 discharge	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	AYALA SENDER Inés (S&D)	05/08/2016
	Shadow rapporteur ZDECHOVSKÝ Tomáš (PPE) FITTO Raffaele (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)	31/08/2016

European Commission

Commission DG	Commissioner
Budget	GEORGIEVA Kristalina

Key events

Date	Event	Reference	Summary
11/07/2016	Non-legislative basic document published	COM(2016)0475	Summary

04/10/2016	Committee referral announced in Parliament		
22/03/2017	Vote in committee		
28/03/2017	Committee report tabled for plenary	A8-0084/2017	Summary
26/04/2017	Debate in Parliament		
27/04/2017	Decision by Parliament	T8-0172/2017	Summary
27/04/2017	Results of vote in Parliament		
27/04/2017	End of procedure in Parliament		
29/09/2017	Final act published in Official Journal		

Technical information

Procedure reference	2016/2169(DEC)
Procedure type	DEC - Discharge procedure
Stage reached in procedure	Procedure completed
Committee dossier	CONT/8/07467

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE593.883	03/02/2017	
Committee opinion	ENVI	PE592.296	15/02/2017	
Amendments tabled in committee		PE599.891	06/03/2017	
Committee report tabled for plenary, single reading		A8-0084/2017	28/03/2017	Summary
Text adopted by Parliament, single reading		T8-0172/2017	27/04/2017	Summary

Council of the EU

Document type	Reference	Date	Summary
Supplementary non-legislative basic document	05873/2017	07/02/2017	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2016)0475	11/07/2016	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary

CofA	Court of Auditors: opinion, report	N8-0124/2016 OJ C 449 01.12.2016, p. 0123	13/09/2016	Summary

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

Final act	
Budget 2017/1681 OJ L 252 29.09.2017, p. 0250	Summary

2015 discharge: European Medicines Agency (EMA)

2016/2169(DEC) - 13/09/2016 - 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 2015, 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 brief, the Agency operates through a network and coordinates 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.

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 2015, 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 2015 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 2015 are legal and regular in all material respects.

The report did not make any particular comments apart from stating that the elements taken into consideration in the report do not take account of the **referendum results of 23 June 2016** on the UK vote to leave the EU (and the consequences this may have on the Agency whose headquarters is located in London) as the Court had presented its report before this date.

Lastly, the Court of Auditors' report contains a summary of the **Agency's key figures in 2015**:

- **Budget**: EUR 304 million.
- **Staff**: 775 including officials, temporary and contract staff and seconded national experts.

2015 discharge: European Medicines Agency (EMA)

2016/2169(DEC) - 07/02/2017 - Supplementary non-legislative basic document

Having examined the revenue and expenditure accounts for the financial year 2015 and the balance sheet as at 31 December 2015 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 2015, 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 2015.

The Council welcomed the Court's opinion that the Agency's annual accounts present fairly its financial position as at 31 December 2015 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 2015 are legal and regular in all material respects.

Nevertheless, it made one observation:

- **fees**: the Council encouraged the Agency to continue implementing the Court's recommendations from last year as regards the respect of due dates for the collection of fees and the related payments to national competent authorities.

2015 discharge: European Medicines Agency (EMA)

2016/2169(DEC) - 28/03/2017 - Committee report tabled for plenary, single reading

The Committee on Budgetary Control adopted the report by Inés AYALA SENDER (S&D, ES) on discharge in respect of the implementation of the budget of the European Medicines Agency (EMA) for the financial year 2015.

The committee called 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 2015.

Noting that the Court of Auditors stated that it had obtained reasonable assurance that the annual accounts of the Agency for the financial year 2015 were reliable and that the underlying transactions were legal and regular, Members called 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 2015 was EUR 308 097 000 representing an increase of 9.07 % compared to 2014.
- **Prevention and management of conflicts of interests and transparency**: Members acknowledged that the revised policy on the handling of declarations of interests of scientific committees' members and experts entered into force in 2015. They reminded the Agency that Directive 2003/63/EC states that medicines can only be considered for Union marketing authorisation if they have been tested in accordance with ethical guidelines. They also reminded it of its commitment to perform extra checks on clinical trials carried out outside the European Union before granting a drug market authorisation. The Agency is asked to report to the discharge authority every year on actions taken to ensure drugs for the Union market were tested ethically.

Members also made a series of observations regarding the budgetary and financial management, commitments and carry-overs, transfers, procurement and recruitment procedures, the prevention and management of conflicts of interests and internal audits and controls.

Impact of Brexit: on 23 June 2016, the citizens of the United Kingdom voted to leave the European Union. Members noted that following the outcome of the UK referendum on 23 June 2016, the Agency established a dedicated task force to focus on **relocation** preparedness, operational and financial preparedness, HR-related matters and communication (internal and external) aspects. They observed that the work currently ongoing is focussed on the impact of a loss of EMA staff in the event of relocation and loss of external expertise due to the potential unavailability of UK expertise in the scientific committees and other EMA fora. An impact assessment including remedial solutions should be available by the end of the first quarter of 2017.

Lastly, Members noted with concern that the Agency's rental contract until 2039 does not include an **early termination clause to release the Agency** from the liabilities of rent and associated costs, and that the payable rent for the remaining period from 2017 to 2039 is estimated at EUR 347.6 million. They asked the Agency to report to the discharge authority on any developments on this matter.

2015 discharge: European Medicines Agency (EMA)

2016/2169(DEC) - 27/04/2017 - 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 the budget of Agency for the financial year 2015.

The vote on the decision on discharge covers the closure of the accounts (in accordance with Annex IV, 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 2015 are reliable and that the underlying transactions are legal and regular, Parliament adopted by 510 votes to 101 with 13 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.

These recommendations may be summarised as follows:

- **Agency's financial statements**: Parliament noted the final budget of the European Medicines Agency for the financial year 2015 was EUR 308 097 000 representing an increase of 9.07 % compared to 2014.

- **Prevention and management of conflicts of interests and transparency**: It acknowledged that the revised policy on the handling of declarations of interests of scientific committees' members and experts entered into force in 2015. Parliament also made a series of observations regarding the budgetary and financial management, commitments and carry-overs, transfers, procurement and recruitment procedures, the prevention and management of conflicts of interests and internal audits and controls.

Communication: Parliament noted that in 2015, the **Agency recommended 93 medicines for marketing authorisation** and that those include 39 new active substances. It stressed that those substances have previously never been authorised in a medicine in the Union and are not related to the chemical structure of any other authorised substance.

Parliament reminded the Agency that Directive 2003/63/EC states that medicines can only be considered for Union marketing authorisation if they have been tested in accordance with ethical guidelines, and reminded the Agency of its commitment to perform extra checks on clinical trials carried out outside the European Union before granting a drug market authorisation. Therefore, due to the special vulnerabilities of those tests, Parliament asked the Agency to report to the discharge authority every year on actions taken to ensure drugs for the Union market were **tested ethically in lower and middle income countries**, in accordance with the law.

It underlined that the Agency should continue promoting dialogue with stakeholders and citizens and incorporate it as part of the priorities and activities to be implemented.

Adaptive pathways: Parliament noted that the Agency launched a pilot project on "adaptive pathways" in March 2014 aiming to accelerate market authorisations for specific medicines using the so-called post-marketing authorisation. It is concerned that the pilot project raises numerous public health concerns and undermines the core mission of the Agency, namely to ensure safety of medicines. It asked the Agency to report to the discharge authority on the project and the measures it has taken to ensure that this acceleration of the procedure does not undermine its core mission.

Impact of Brexit: Parliament stated that on 23 June 2016, the citizens of the United Kingdom voted to leave the European Union. It noted that following the outcome of the UK referendum on 23 June 2016, the Agency established a dedicated task force to focus on **relocation** preparedness, operational and financial preparedness, HR-related matters and communication (internal and external) aspects. It observed that the work currently ongoing is focussed on the impact of a loss of EMA staff in the event of relocation and loss of external expertise due to the potential unavailability of UK expertise in the scientific committees and other EMA fora. An impact assessment including remedial solutions should be available by the end of the first quarter of 2017.

Lastly, Parliament noted with concern that the Agency's rental contract until 2039 does **not include an early termination clause to release the Agency** from the liabilities of rent and associated costs, and that the payable rent for the remaining period from 2017 to 2039 is estimated at EUR 347.6 million. It asked the Agency to report to the discharge authority on any developments on this matter.

2015 discharge: European Medicines Agency (EMA)

2016/2169(DEC) - 11/07/2016 - Non-legislative basic document

PURPOSE: presentation by the Commission of the consolidated annual accounts of the European Union for the financial year 2015, as part of the 2015 discharge procedure.

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

CONTENT: the organisational governance of the EU consists of institutions, agencies and other EU bodies whose expenditure is included in the general budget of the Union.

The EU's operational expenditure of these institutions takes different forms, depending on how the money is paid out and managed.

From 2014 onwards, the Commission classifies its expenditure as follows:

- **Direct management**: the budget is implemented directly by the Commission services.
- **Indirect management**: the Commission confers tasks of implementation of the budget to bodies of EU law or national law, **such as the EU agencies**.

- **Shared management**: under this method of budget implementation tasks are delegated to Member States. About 80 % of the expenditure falls under this management mode covering such areas as agricultural spending and structural actions.

This Commission document concerns the EU's consolidated accounts for the year 2015 and details how spending by the EU institutions and bodies was carried out. The consolidated annual accounts of the EU provide financial information on the activities of the institutions, agencies and other bodies of the EU from an accrual accounting and budgetary perspective.

It is the responsibility of the Commission's Accounting Officer to prepare the EU's consolidated annual accounts and ensure that they present fairly, in all material aspects, the financial position, the result of the operations and the cashflows of the EU institutions and bodies, including the European Medicines Agency (EMA), with a view to granting discharge.

Discharge procedure: the final step of a budget lifecycle is the discharge of the budget for a given financial year. It represents the political aspect of the external control of budget implementation and is the decision by which the European Parliament, acting on a Council recommendation, "releases" the Commission (and other EU bodies) from its responsibility for management of a given budget by marking the end of that budget's existence. The European Parliament is the discharge authority within the EU.

The discharge procedure may produce three outcomes: (i) the granting; (ii) postponement or; (iii) the refusal of the discharge.

The final discharge report including specific recommendations to the Commission for action is adopted in plenary by the European Parliament and are subject to an annual follow up report in which the Commission outlines the concrete actions it has taken to implement the recommendations made.

Each agency is subject to its own discharge procedure, including the European Medicines Agency (EMA).

The European Medicines Agency: the 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.

As regards Agency's accounts, these are presented in detail in the document on the consolidated annual accounts of the European Union for 2015:

Commitment appropriations:

- **committed**: EUR 308 million;
- **paid**: EUR 290 million;
- **carried-over**: EUR 6 million.

Payment appropriations:

- **committed**: EUR 349 million;
- **paid**: EUR 291 million;
- **carried-over**: EUR 43 million.

For further details on expenditure, please refer to the final accounts of the EMA.

2015 discharge: European Medicines Agency (EMA)

2016/2169(DEC) - 27/04/2017 - Final act

PURPOSE: to grant discharge to the European Medicines Agency (EMA) for the financial year 2015.

NON-LEGISLATIVE ACT: Decision (EU) 2017/1681 of the European Parliament on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2015.

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 2015.

The Decision is consistent with the European Parliament's resolution adopted on 27 April 2017 and includes a series of observations that form an integral part of the discharge decision (refer to the summary of the opinion of 27 April 2017).

Amongst Parliament's main observations in the resolution accompanying the discharge decision, it noted that 2015 marked the 20th anniversary of the Agency and the 50th anniversary of pharmaceutical legislation in the Union. Parliament observed that following the outcome of the UK referendum on 23 June 2016, the Agency established a dedicated task force to focus on relocation preparedness, operational and financial preparedness, HR-related matters and communication (internal and external) aspects.

While welcoming the information provided by the Agency to the discharge authority on its current contractual commitments and liabilities linked to its physical presence in the UK, Parliament noted with concern that the Agency's rental contract until 2039 **does not include an early termination clause** to release the Agency from the liabilities of rent and associated costs, and that the payable rent for the remaining period from 2017 to 2039 is estimated at EUR 347.6 million. The Agency is asked to report to the discharge authority on any developments on this matter.

The resolution also highlighted that although there had been **delays** in the collection of fees as noted by the discharge authority, these had **no impact** on the Agency's and Member States' ability to perform their public health tasks, including pharmacovigilance activities.

Parliament acknowledged from the Agency that the revised policy on the handling of declarations of interests of scientific committees' members and experts entered into force in 2015. The revised policy on handling of declared interests of members of staff of the Agency and candidates before recruitment was finalised in October 2016.

Moreover, an anti-fraud office was established as part of its anti-fraud strategy.

Lastly, Parliament encouraged the Agency to further raise awareness of its conflict-of-interest policy among its staff, alongside ongoing awareness-raising activities and the inclusion of integrity and transparency as obligatory items to be discussed during recruitment procedures and performance reviews.