Basic information

2018/2185(DEC) DEC - Discharge procedure	Procedure completed
2017 discharge: European Medicines Agency (EMA) **Subject** 8.70.03.02 2017 discharge	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	SARVAMAA Petri (PPE)	26/07/2018
	Shadow rapporteur KADENBACH Karin (S&D) CZARNECKI Ryszard (ECR) ALI Nedzhmi (ALDE) DE JONG Dennis (GUE/NGL) STAES Bart (Verts/ALE) KAPPEL Barbara (ENF)	

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	VĂLEAN Adina (PPE)	30/08/2018

European Commission

Commission DG	Commissioner
Budget	OETTINGER Günther

Key events

Date	Event	Reference	Summary
28/06/2018	Non-legislative basic document published	COM(2018)0521	Summary
11/09/2018	Committee referral announced in Parliament		
20/02/2019	Vote in committee		

01/03/2019	Committee report tabled for plenary	A8-0135/2019	Summary
26/03/2019	Decision by Parliament	T8-0271/2019	Summary
26/03/2019	Results of vote in Parliament		
26/03/2019	Debate in Parliament		
26/03/2019	End of procedure in Parliament		
27/09/2019	Final act published in Official Journal		

Technical information

Procedure reference	2018/2185(DEC)
Procedure type	DEC - Discharge procedure
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	CONT/8/14287

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE626.799	17/12/2018	
Committee opinion	ENVI	PE627.701	23/01/2019	
Amendments tabled in committee		PE634.505	31/01/2019	
Committee report tabled for plenary, single reading		A8-0135/2019	01/03/2019	Summary
Text adopted by Parliament, single reading		T8-0271/2019	26/03/2019	Summary

Council of the EU

Document type	Reference	Date	Summary
Supplementary non-legislative basic document	05825/2019	31/01/2019	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2018)0521	28/06/2018	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
CofA	Court of Auditors: opinion, report	N8-0012/2019 OJ C 434 30.11.2018, p. 0001	18/09/2018	Summary

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

Final act
Budget 2019/1485 OJ L 249 27.09.2019, p. 0233

2017 discharge: European Medicines Agency (EMA)

2018/2185(DEC) - 26/03/2019 - Text adopted by Parliament, single reading

The European Parliament decided to grant discharge to the Executive Director of the European Medicines Agency (EMA) for the financial year 2017 and to approve the closure of the accounts for the financial year in question.

Noting that the Court of Auditors has stated that it has obtained reasonable assurances that the Agency's annual accounts for the financial year 2017 are reliable and that the underlying transactions are legal and regular, Parliament adopted by 492 votes to 121 with 24 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 draft resolution on performance, financial management and control of EU agencies:

Agency's financial statements

The European Medicines Agency's final budget for the financial year 2017 was EUR 331 266 000, representing an increase of 7.41 % compared to 2016. The Agency is a fee-funded agency, with 86 % of its 2017 revenue stemming from fees paid by the pharmaceutical industry for services provided, and 12 % stemming from the Union budget.

Budget and financial management

The budget monitoring efforts during the financial year 2017 resulted in a budget implementation rate of 92.92 %, representing a decrease of 3.38 % compared to 2016. Payment appropriations execution rate was 76.62 %, representing a decrease of 5.73 % compared to 2016. Parliament regretted that the cancellations of carry-overs from 2016 to 2017 amounted to EUR 4 350 908, representing 10.11 % of the total amount carried-over, showing a notable increase of 5.65 % in comparison to 2016. It called on the Agency to report to the discharge authority on the measures taken to ensure complete use of the appropriations carried-over, in order to avoid substantial resources being de-committed.

Members also made a series of observations regarding performance, staff, procurement and internal controls.

In particular, they noted that:

- the Agency implemented a new and improved version of the EudraVigilance system, an information system used to report suspected side effects of medicines;

- a number of the Agency's activities were delayed or postponed due to Brexit or external circumstances;

- the Agency recommended 110 new medicines for marketing authorisation (92 for human use and 18 for veterinary use), and that those included 42 new active substances (35 for human use and 7 for veterinary use);

- on 31 December 2017, the establishment plan was 97.82 % executed, with 583 temporary agents appointed out of 596 temporary agents authorised under the Union budget;

- the staff expenses increased by EUR 10 million. The Agency is asked to report comprehensively on this expenditure and urged not to replace permanent staff by more expensive contract agents;

- the Agency received 25 reports on cases of whistleblowing from an external source, 15 cases were closed and 10 cases are still ongoing;

- the Court issued an emphasis of matter paragraph in relation to the two London-based agencies, concerning the United Kingdom's decision to withdraw from the European Union; notes that the seat of the Agency will move to Amsterdam at the beginning of 2019 and that the Agency's accounts include provisions for related costs amounting to EUR 18 600 000. Parliament regretted that the lease agreement for the London based premises sets

a rental period until 2039 with no exit clause. Efforts should be made to minimise the financial, administrative and operational impact of the unfavourable lease agreement.

2017 discharge: European Medicines Agency (EMA)

2018/2185(DEC) - 31/01/2019 - Supplementary non-legislative basic document

Having examined the revenue and expenditure accounts for the financial year 2017 and the balance sheet as at 31 December 2017 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 2017, 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 2017.

The Council welcomed the Court's opinion that the Agency's annual accounts present fairly its financial position as at 31 December 2017 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 2017 are legal and regular in all material respects.

Nevertheless, the following observations were made:

- ***financial programming***: the Council encouraged the Agency to continue improving its financial programming and monitoring of the budget implementation, taking into account the decision on the future location of the Agency;

- ***accounting***: deficiencies were found by the Court in the Agency's accounting environment. The Council called on the Agency to take appropriate actions mainly to ensure the accounting officer's independence, as well as to remedy any unjustified delays in the re-validation of its accounting system;

- ***action plan***: the Council welcomed the efforts made by the Agency to implement an action plan established with a view to address the Court's recommendations from previous years to remedy the weaknesses found by the Court in the Agency's information, communication and technology management control. The Council encourages the Agency to promptly assess the measures taken;

- ***staff***: the Council regretted the Court's finding about the critical dependence of the Agency on the extensive use of external consultants, as well as about an inadequate control over project development and implementation. While welcoming the implementation of some measures, it encouraged the Agency to continue improving the development of a structured and systematic policy governing the use of consultants.

2017 discharge: European Medicines Agency (EMA)

2018/2185(DEC) - 28/06/2018 - Non-legislative basic document

PURPOSE: presentation by the Commission of the consolidated annual accounts of the European Union for the financial year 2017, as part of the 2017 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.

This Commission document concerns the **EU's consolidated accounts for the year 2017** 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 cash flows of the EU institutions and bodies with a view to granting discharge.

Discharge procedure: **the final step of a budget lifecycle is the discharge**. It is the decision by which the European Parliament '**releases**' the Commission from its responsibility for management of a given budget by marking the end of that budget's existence. It is granted by the European Parliament on the recommendation of the Council.

The decision is based in particular on the European Court of Auditors reports, in particular its annual report, in which the Court provides a Statement of Assurance (DAS) on the legality and regularity of transactions (payments and commitments).

The procedure results in the granting, postponement or refusal of 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.

All EU institutions and other agencies, bodies and joint undertakings are subject to their own discharge procedures.

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.

The year 2017 was a challenging year for EMA. The impact of the UK's decision to withdraw from the European Union left its mark. As well as continuing with its day-to-day work and successfully delivering most of its work plan, the Agency worked with the national competent authorities to prepare the network for the impact of the UK's withdrawal.

The Agency received the long-awaited decision on its new home. On 20 November 2017, the General Affairs Council (Art. 50) decided on **Amsterdam as EMA's new location**. The decision ended a long period of uncertainty and allowed the Agency to begin more concrete decision-making on how to ensure a successful move and retain majority of the existing staff.

As regards Agency's accounts, these are presented in detail in the document on the consolidated annual accounts of the European Union for 2017:

Commitment appropriations:

- available: EUR 331 million;
- made: EUR 302 million.

Payment appropriations:

- available: EUR 347 million;
- made: EUR 292 million.

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

2017 discharge: European Medicines Agency (EMA)

2018/2185(DEC) - 01/03/2019 - Committee report tabled for plenary, single reading

The Committee on Budgetary Control adopted the report by Petri SARVAMAA (EPP, FI) on discharge in respect of the implementation of the budget of the European Medicines Agency (EMA) for the financial year 2017.

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 2017.

Noting that the Court of Auditors stated that it had obtained reasonable assurance that the annual accounts of the Agency for the financial year 2017 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

The European Medicines Agency's final budget for the financial year 2017 was EUR 331 266 000, representing an increase of 7.41 % compared to 2016. The Agency is a fee-funded agency, with 86 % of its 2017 revenue stemming from fees paid by the pharmaceutical industry for services provided, and 12 % stemming from the Union budget.

Budget and financial management

The budget monitoring efforts during the financial year 2017 resulted in a budget implementation rate of 92.92 %, representing a decrease of 3.38 % compared to 2016. Payment appropriations execution rate was 76.62 %, representing a decrease of 5.73 % compared to 2016.

Members regretted that the cancellations of carry-overs from 2016 to 2017 amounted to EUR 4 350 908, representing 10.11 % of the total amount carried-over, showing a notable increase of 5.65 % in comparison to 2016. They called on the Agency to report to the discharge authority on the measures taken to ensure complete use of the appropriations carried-over, in order to avoid substantial resources being de-committed.

Members also made a series of observations regarding performance, staff, procurement and internal controls.

In particular, they noted that:

- the Agency implemented a new and improved version of the EudraVigilance system, an information system used to report suspected side effects of medicines;

- a number of the Agency's activities were delayed or postponed due to Brexit or external circumstances;

- the Agency recommended 110 new medicines for marketing authorisation (92 for human use and 18 for veterinary use), and that those included 42 new active substances (35 for human use and 7 for veterinary use);

- on 31 December 2017, the establishment plan was 97.82 % executed, with 583 temporary agents appointed out of 596 temporary agents authorised under the Union budget;

- the staff expenses increased by EUR 10 million. The Agency is asked to report comprehensively on this expenditure and urged not to replace permanent staff by more expensive contract agents;

- that in 2017 the Agency received 25 reports on cases of whistleblowing from an external source, 15 cases were closed in 2017 and 10 cases are still ongoing;

- the Court issued an emphasis of matter paragraph in relation to the two London-based agencies, concerning the United Kingdom's decision to withdraw from the European Union; notes that the seat of the Agency will move to Amsterdam at the beginning of 2019 and that the Agency's accounts include provisions for related costs amounting to EUR 18 600 000. Members regretted that the lease agreement for the London based premises sets a rental period until 2039 with no exit clause. Efforts should be made to minimise the financial, administrative and operational impact of the unfavourable lease agreement.

2017 discharge: European Medicines Agency (EMA)

2018/2185(DEC) - 18/09/2018

PURPOSE: presentation of the EU Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2017, together with the Agency's reply.

CONTENT: the Court of Auditors carried out the audit on 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 and reliability of the accounts

The Court considered that:

- the Agency's annual accounts present fairly, in all material respects, its financial position as at 31 December 2017 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;

- the transactions underlying the annual accounts for the year ended 31 December 2017 are legal and regular in all material respects.

Emphasis of matter

Without calling into question its opinion, the Court draws attention to the fact that the United Kingdom (UK) notified the European Council on 29 March 2017 of its decision to withdraw from the European Union. An agreement setting out the arrangements for its withdrawal is currently being negotiated. The accounts and related notes of the Agency, which is located in London, were prepared using the information available at the date of signature (1 June 2018).

On 20 November 2017, the General Affairs Council of the European Union agreed to move the seat of the Agency to Amsterdam, The Netherlands. The removal to temporary premises is planned for the beginning of 2019 and the Agency's accounts include provisions for related costs amounting to EUR 18.6 million.

Moreover, the lease agreement for the Agency's current premises in London sets a rental period until 2039 with no exit clause. The notes to the accounts disclose an amount of EUR 489 million remaining rent until 2039, of which a maximum amount of EUR 465 million corresponding to the lease period after the Agency's planned move to Amsterdam is disclosed as a contingent liability.

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

Financial management

Agencies should introduce a single solution for the electronic exchange and storage of information with third parties participating in public procurement procedures (e-procurement). As the same requirement exists for all EU Institutions, the Commission is developing a comprehensive IT solution covering all phases of public procurement procedures. The Commission launched tools for electronic invoicing (e-invoicing), for the electronic publication of documents related to contract notices (e-tendering) and for the electronic submission of tenders (e-submission). By the end of 2017, the Agency had introduced e-tendering for certain procedures, but not e-invoicing and e-submission.

On the management of consulting services, the Court noted the excessive use of consulting firms for external expertise. Control over project development and implementation was also inadequate and that projects were considerably delayed and costs were escalating.

Several measures were taken to improve the situation. The Agency is moving to the use of fixed price rather than time and means based consulting contracts, allowing for a better cost management.

The Agency's reply

Financial management

The Agency stated that by the end of 2017 the Agency had introduced e-tendering for all procedures above the directive threshold and email tender procedures for procedures below the directive threshold. The Agency has not introduced e-invoicing and e-submission, but in September 2017 the Agency signed a Memorandum of Understand with the European Commission for access to and the use of e-submission and is awaiting a date from the European Commission for the same.

Lastly, the Court of Auditors' report contains a summary of the Agency's key figures in 2017:

Budget

EUR 331 million.

Staff

766 including officials, temporary and contract staff and seconded national experts.