Basic information

2017/2154(DEC) DEC - Discharge procedure	Procedure completed
2016 discharge: European Medicines Agency (EMA) **Subject** 8.70.03.06 2016 discharge	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	STAES Bart (Verts/ALE)	14/09/2017
	Shadow rapporteur SARVAMAA Petri (PPE) LIBERADZKI Bogusław (S&D) MACOVEI Monica (ECR) ALI Nedzhmi (ALDE) DE JONG Dennis (GUE/NGL) VALLI Marco (EFDD) KAPPEL Barbara (ENF)	

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	VĂLEAN Adina (PPE)	31/08/2017

European Commission

Commission DG	Commissioner
Budget	OETTINGER Günther

Key events

Date	Event	Reference	Summary
26/06/2017	Non-legislative basic document published	COM(2017)0365	Summary
13/09/2017	Committee referral announced in Parliament		

20/03/2018	Vote in committee		
26/03/2018	Committee report tabled for plenary	A8-0103/2018	Summary
18/04/2018	Decision by Parliament	T8-0150/2018	Summary
18/04/2018	Results of vote in Parliament		
18/04/2018	Debate in Parliament		
18/04/2018	End of procedure in Parliament		
03/10/2018	Final act published in Official Journal		

Technical information

Procedure reference	2017/2154(DEC)
Procedure type	DEC - Discharge procedure
Stage reached in procedure	Procedure completed
Committee dossier	CONT/8/10788

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee opinion	ENVI	PE612.232	25/01/2018	
Committee draft report		PE613.458	30/01/2018	
Amendments tabled in committee		PE618.255	02/03/2018	
Committee report tabled for plenary, single reading		A8-0103/2018	26/03/2018	Summary
Text adopted by Parliament, single reading		T8-0150/2018	18/04/2018	Summary

Council of the EU

Document type	Reference	Date	Summary
Supplementary non-legislative basic document	05941/2018	09/02/2018	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2017)0365	26/06/2017	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
CofA	Court of Auditors: opinion, report	N8-0028/2018 OJ C 417 06.12.2017, p. 0142	19/09/2017	Summary

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

Final act	
Budget 2018/1388 OJ L 248 03.10.2018, p. 0258	Summary

2016 discharge: European Medicines Agency (EMA)

2017/2154(DEC) - 26/03/2018 - Committee report tabled for plenary, single reading

The Committee on Budgetary Control adopted the report by Bart STAES (Greens/EFA, BE) on discharge in respect of the implementation of the budget of the European Medicines Agency (EMA) for the financial year 2016.

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 2016.

Noting that the Court of Auditors stated that it had obtained reasonable assurance that the annual accounts of the Agency for the financial year 2016 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 2016 was EUR 308 422 000, representing an increase of 0.1 % compared to 2015. As a reminder, the Agency is a fee-funded agency, with 89.34% of its 2016 revenue stemming from fees paid by the pharmaceutical industry, for services provided, 5.49% stemming from the Union budget to fund various public health and harmonisation activities, and 5.01% stemming from external assigned revenue.
- **Reliability of the accounts**: according to the Court's report, since the introduction of a new IT accounting system in 2011, reporting on commitment workflow and consumption has not been sufficiently transparent. Members noted with regret that, although the matter was repeatedly raised with the Agency, no corrective action has been taken. They called on the Agency to implement corrective actions as soon as possible in 2018.
- **Legality and regularity of transactions**: irregularities concerned corporate rate agreements for the provision of accommodation for experts with 25 hotels in London without using a competitive procurement procedure. For six hotels, payments made in 2016 were above the Financial Regulation's threshold for which an open or restricted competitive procurement procedure is required. The six corporate rate agreements and the related 2016 payments, amounting to some EUR 2.1 million are therefore irregular.
- **Budget and financial management**: budget monitoring efforts during the financial year 2016 resulted in a budget implementation rate of 96.30 %, representing an increase of 2.25 % compared with the previous year. It was highlighted that Agency was **not allowed to create a 'Brexit' contingency reserve**.
- **Prevention and management of conflicts of interests and transparency** and democracy: the report noted that the revised policy on the handling of competing interests of the Management Board members came into effect on 1 May 2016 and was further revised in October 2016. The implementation of the revised policy now includes an *ex ante* evaluation which is performed to compare the details contained in each new declaration, with those of the previous declaration, and with the CV of each board member provided.

Impact of Brexit: Members stressed that the Agency will be facing an additional workload and additional budgetary needs throughout the 2018-2020 relocation and transition period, as a consequence of the decision of the United Kingdom (UK) to withdraw from the Union. The Commission is called on to provide adequate staff and budgetary resources in preparation for its relocation in 2019. They proposed in addition that the Agency be authorised to maintain a budgetary reserve generated from revenue fees to respond to unforeseen costs and unfavourable exchange rate fluctuations that may be incurred in 2018 and beyond. They also stressed the need for the accelerated building approval so as to avoid any delays in the start of the construction of the new Agency's premises in Amsterdam. The Agency has disclosed in its financial statements an estimated EUR 448 million in rent for the remaining rental period between 2017 and 2039 as a contingent liability, as the **rental contract does not include any exit clause**.

2016 discharge: European Medicines Agency (EMA)

2017/2154(DEC) - 03/10/2018 - Final act

PURPOSE: to grant discharge to the European Medicines Agency (EMA) for the financial year 2016.

NON-LEGISLATIVE ACT: Decision (EU) 2018/1388 of the European Parliament on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2016.

CONTENT: the European Parliament decided to **grant discharge** to the Executive Director of the European Medicines Agency for the implementation of the Agency's budget for 2016.

This decision is accompanied by a resolution of the European Parliament containing the observations which form an integral part of the discharge decision in respect of the implementation of the general budget of the European Union for the financial year 2016 (*please refer to the summary dated 18.4.2018*).

In this resolution, Parliament noted in particular that the Agency will be facing an additional workload and additional budgetary needs throughout the 2018-2020 relocation and transition period, as a consequence of the decision of the United Kingdom (UK) to withdraw from the Union. It called on the Commission to make available adequate staff and budgetary resources during this period to ensure that the Agency can both continue to carry out its tasks effectively and launch all required activities in preparation for its relocation in 2019. It proposed in addition that the Agency, limited by legislation and in line with the principle of sound financial management, be authorised to **maintain a budgetary reserve** generated from revenue fees to respond to unforeseen costs and unfavourable exchange rate fluctuations that may be incurred in 2018 and beyond.

Lastly, Parliament stressed the need for the accelerated building approval procedure so as to avoid any delays in the start of the construction of the new Agency's premises in **Amsterdam**.

2016 discharge: European Medicines Agency (EMA)

2017/2154(DEC) - 26/06/2017 - Non-legislative basic document

PURPOSE: presentation by the Commission of the consolidated annual accounts of the European Union for the financial year 2016, as part of the 2016 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 2016 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 2016:

Commitment appropriations:

- available: EUR 314 million;
- made: EUR 301 million.

Payment appropriations:

- available: EUR 347 million;

- made: EUR 294 million.

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

2016 discharge: European Medicines Agency (EMA)

2017/2154(DEC) - 18/04/2018 - Text adopted by Parliament, single reading

The European Parliament decided to **grant discharge** to the Director of the European Medicines Agency (EMA) in regard to the implementation of the agency's budget for the 2016 financial year 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 2016 are reliable and that the underlying transactions are **legal and regular**, Parliament adopted by 534 votes to 45 with 18 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:

Follow-up to the 2014 discharge: Members noted with concern that some of the Court's comments from the 2014 discharge are still not marked as "completed", in particular the evaluation of the weaknesses in **management control**, **the dissemination of appropriate pharmacovigilance information to the Member States** and to the general public. They called on the agency to complete the corrective actions as soon as possible in 2018 and to report to the discharge authority on their implementation.

- **Agency's financial statements:** the European Medicines Agency's final budget for the financial year 2016 was EUR 308 422 000, representing an increase of 0.1 % compared to 2015. As a reminder, the agency is a fee-funded agency, with 89.34% of its 2016 revenue stemming from fees paid by the pharmaceutical industry, for services provided, 5.49% stemming from the Union budget to fund various public health and harmonisation activities, and 5.01% stemming from external assigned revenue.
- **Reliability of the accounts:** according to the Court's report, since the introduction of a new IT accounting system in 2011, reporting on commitment workflow and consumption has not been sufficiently transparent. Members noted with regret that, although the matter was repeatedly raised with the Agency, no corrective action has been taken. They called on the Agency to implement corrective actions as soon as possible in 2018.
- **Legality and regularity of transactions:** irregularities concerned **corporate rate agreements** for the provision of accommodation for experts with 25 hotels in London without using a competitive procurement procedure. For six hotels, payments made in 2016 were above the Financial Regulation's threshold for which an open or restricted competitive procurement procedure is required. The six corporate rate agreements and the related 2016 payments, amounting to some EUR 2.1 million are therefore irregular.
- **Budget and financial management:** budget monitoring efforts during the financial year 2016 resulted in a **budget implementation rate of 96.30 %**, representing an increase of 2.25 % compared with the previous year. It was highlighted that agency was not allowed to create a 'Brexit' contingency reserve.
- **Human resources policy:** Members regretted that the **gender balance** had not been met, since the ratio is 69 % female to 31 % male. They stressed that the **staff cuts** imposed in recent years have meant a reduction in staff working on tasks that are actually funded by applicants' fees and not by the Union budget. Members observed with satisfaction that the agency put in place a health and safety group for consultation with staff. It also has a policy in place for protecting the dignity of the person and preventing any form of psychological or sexual harassment.
- **Prevention and management of conflicts of interests, transparency and democracy:** Parliament noted that the revised policy on the **handling of competing interests** of the Management Board members came into effect on 1 May 2016 and was further revised in October 2016. The implementation of the revised policy now includes an *ex ante* evaluation which is performed to compare the details contained in each new declaration, with those of the previous declaration, and with the CV of each board member provided. The agency's **Code of Conduct** extends the requirements for impartiality and the submission of annual declarations of interests to all members of staff of the agency. Members emphasised the need to establish an independent body with sufficient budgetary resources to support **whistleblowers** wishing to disclose information on possible irregularities negatively impacting on the Union's financial interests, while ensuring their confidentiality is protected.

Impact of Brexit: Members stressed that the agency will be facing an additional workload and additional budgetary needs throughout the 2018-2020 relocation and transition period, as a consequence of the decision of the United Kingdom (UK) to withdraw from the Union. They called on the Commission to provide **adequate staff and budgetary resources** in preparation for its relocation in 2019.

Parliament also proposed that the agency be authorised to maintain a budgetary reserve generated from revenue fees to respond to unforeseen costs and unfavourable exchange rate fluctuations that may be incurred in 2018 and beyond. They also stressed the need for the accelerated building approval so as to avoid any delays in the start of the construction of the new agency premises in Amsterdam. The agency has disclosed in its financial statements an estimated EUR 448 million in rent for the remaining rental period between 2017 and 2039 as a contingent liability, as the rental contract does not include any exit clause.

2016 discharge: European Medicines Agency (EMA)

2017/2154(DEC) - 19/09/2017 - 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 2016, 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 2016, 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 2016 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 2016 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 will be negotiated. The provisional accounts and related notes of the Agency, which is located in London, were prepared using the limited information available at the date of signature (28 February 2017).

In view of upcoming decisions on the future location of the Agency, it has disclosed in its Financial Statements an estimated EUR 448 million rent for the remaining rental period between 2017 and 2039 as a contingent liability, as the rental contract does not include any exit clause. Moreover, contingent liabilities in relation to other costs associated with a removal such as, for example the relocation of staff together with their families, actions to mitigate a potential loss of internal and UK-based external expertise, and consequent risk to business continuity, are yet to be determined. Furthermore, the Agency's 2016 budget was financed 95 % by fees from pharmaceutical companies and 5 % from European Union funds. A future decrease of the Agency's revenue resulting from the UK's decision to leave the EU is possible.

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

The Court's observations:

- **legality of the transactions**: the Court noted that the Agency concluded Corporate Rate Agreements for the provision of accommodation for experts with 25 hotels in London without using a competitive procurement procedure. For six hotels, payments made in 2016 were above the Financial Regulation's threshold for which an open or restricted competitive procurement procedure is required. The six Corporate Rate Agreements and the related 2016 payments, amounting to some EUR 2.1 million, are therefore irregular.

The Agency's replies:

- **legality of the transactions**: the Agency noted the finding of the Court and, as discussed with the auditors, will identify and implement a solution for hotel bookings during 2017-2018. The Agency wants to highlight that the procedure subject to ECA's comment was put in place in order to minimise the administrative and financial burden of the Agency's delegates, simplify the organisation and guarantee an efficient running of their meetings. The rules regarding delegate reimbursements apply hotel cost ceilings approved by the Management Board and are in line with the European Commission. A procurement to address this matter is being prepared.

Lastly, the Court of Auditors' report contains a summary of the **Agency's key figures in 2016**:

Budget: EUR 305 million.

Staff: 768 including officials, temporary and contract staff and seconded national experts.

2016 discharge: European Medicines Agency (EMA)

2017/2154(DEC) - 09/02/2018 - Supplementary non-legislative basic document

Having examined the revenue and expenditure accounts for the financial year 2016 and the balance sheet as at 31 December 2016 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 2016, 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 2016.

The Council welcomed the Court's opinion that the Agency's annual accounts present fairly its financial position as at 31 December 2016 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 2016 are legal and regular in all material respects.

Nevertheless, the following observations were made:

- **IT issues**: although efforts made by the Agency, the Council urged the Agency to continue implementing the Court's recommendations from previous years as regards the evaluation of the effectiveness of the measures taken to remedy the weaknesses found by the Court in the Agency's information, communication and technology management control. The Council encouraged the Agency to pursue efforts to address the weaknesses detected by the Court regarding its IT accounting systems;
- **procurement**: the Council regretted the deficiencies found by the Court in some of the Agency's procurement procedures and called on the Agency to take appropriate actions in order to ensure the effectiveness of the process.
- **controls**: the Council, whilst acknowledging the Agency's own assessment of its control standards, regretted the Court's finding that the Agency is not yet fully complying with certain Internal Control Standards and invited the Agency to take the appropriate measures to bring its controls in compliance with these standards.