Procedure file

Basic information

DEC - Discharge procedure	2019/2073(DEC)	Procedure completed
2018 discharge: European Medicines Agency (EMA) Subject 8.70.03.08 2018 discharge		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	CONT Budgetary Control		01/10/2019
		ECR CZARNECKI Ryszard	
		Shadow rapporteur	
		epp NOVAKOV Andrey	
		S&D WOLTERS Lara	
		renew europe. CSEH Katalin	
		KUHS Joachim	
		EICKHOUT Bas	
		OMARJEE Younous	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety		04/09/2019
		renew europe. CANFIN Pascal	
European Commission	Commission DG	Commissioner	
	Budget	OETTINGER Günther	

Key events

27/06/2019	Non-legislative basic document published	COM(2019)0316	
18/09/2019	Committee referral announced in Parliament, 1st reading/single reading		
19/02/2020	Vote in committee, 1st reading/single reading		
04/03/2020	Committee report tabled for plenary, single reading	A9-0076/2020	
13/05/2020	Decision by Parliament, 1st reading/single reading	T9-0119/2020	Summary
13/05/2020	End of procedure in Parliament		

11/12/2020	Final act published in Official Journal		

Technical information

Procedure reference	2019/2073(DEC)
Procedure type	DEC - Discharge procedure
Stage reached in procedure	Procedure completed
Committee dossier	CONT/9/00853

Documentation gateway

Non-legislative basic document		COM(2019)0316	27/06/2019	EC	
Committee draft report		PE639.917	05/12/2019	EP	
Committee opinion	ENVI	PE641.162	22/01/2020	EP	
Amendments tabled in committee		PE644.998	31/01/2020	EP	
Supplementary non-legislative basic document		05761/2020	06/02/2020	CSL	
Committee report tabled for plenary, single reading		A9-0076/2020	04/03/2020	EP	
Text adopted by Parliament, single reading		T9-0119/2020	13/05/2020	EP	Summary

Final act

Budget 2020/1981
OJ L 417 11.12.2020, p. 0460

2019/2073(DEC) - 13/05/2020 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 2018 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 Agencys annual accounts for the financial year 2018 are reliable and that the underlying transactions are legal and regular, Parliament adopted by 607 votes to 79 with 7 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:

Agencys financial statements

The European Medicines Agencys final budget for the financial year 2018 was EUR 337 761 000, representing an increase of 1.96 % compared to 2017. The Agency is a fee-funded agency, with 90 % of its 2018 revenue stemming from fees paid by the pharmaceutical industry for services provided, and 10 % stemming from the Union budget.

Budget and financial management

Budget monitoring efforts during the financial year 2018 resulted in a budget implementation rate of 89.14 %, representing a decrease of 1.91 % compared to 2017. The payment appropriations execution rate was 73.64 %, representing a decrease of 2.98 % compared to 2017. The Agency is called on to improve its budget implementation and payment appropriations execution rate.

Other observations

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

In particular, they noted that:

- that EudraVigilance, an information system used to report suspected side effects of medicines, and other telematics projects had to be postponed or reduced due to the United Kingdoms decision to withdraw from the European Union. The Agency acknowledged that the Agency reassures that the projects and activities under the Brexit preparedness business continuity plan were carried out in a way which did not affect the functioning of the safety monitoring system for medicines in the Union and allowed all parties involved (industry, the Agency and national competent authorities) to continue complying with their legal obligations under the Union pharmaceutical legislation;

- in 2018, the Agency recommended 94 new medicines for marketing authorisation (84 for human use and 10 for veterinary use), and that

those included 46 new active substances (42 for human use and 4 for veterinary use). It recommended the immediate suspension of the sale of and recall of a medicine for multiple sclerosis due to it causing serious and sometimes fatal immune reactions, and the suspension of the sale of several antibiotics;

- delays were observed in the development of the EU clinical trials portal and database;

- the Agencys data centre was successfully moved to Hamburg in 2018;

- on 31 December 2018, the establishment plan was 98.31 % executed, with 581 temporary agents appointed out of 591 temporary agents authorised under the Union budget;

- the Agency received 21 reports on cases of whistleblowing from an external source raising the problem of maladministration at the Agency, 5 of which were closed in 2017 and 17 cases are still ongoing;

- as regards Brexit, the Agency worked closely with the Commission and the network to ensure an orderly redistribution of the work so far carried out by the United Kingdom. A successful move to Amsterdam was made, however, significant resources and new tasks had to be redistributed following the relocation to Amsterdam, with the consequent loss of short term contract staff combined with a reduction of 10 % of the Agencys establishment plan imposed since 2014 and an increased workload. Outstanding legal and financial issues are highlighted notably as regards the cancellation of the lease agreement of the London premises.