Basic information

2021/2132(DEC) DEC - Discharge procedure	Procedure completed
2020 discharge: European Medicines Agency (EMA) **Subject** 8.70.03.10 2020 discharge	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	ZDECHOVSKÝ Tomáš (EPP)	28/07/2021
	Shadow rapporteur CHINNICI Caterina (S&D) CSEH Katalin (Renew) EICKHOUT Bas (Greens/EFA) CZARNECKI Ryszard (ECR) KUHS Joachim (ID) OMARJEE Younous (The Left)	

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	CANFIN Pascal (Renew)	29/09/2021

European Commission

Commission DG	Commissioner
Budget	HAHN Johannes

Key events

Date	Event	Reference	Summary
30/06/2021	Non-legislative basic document published	COM(2021)0381	
14/09/2021	Committee referral announced in Parliament		

31/03/2022	Vote in committee		
07/04/2022	Committee report tabled for plenary	A9-0103/2022	
04/05/2022	Decision by Parliament	T9-0161/2022	Summary
04/05/2022	Debate in Parliament		
05/10/2022	Final act published in Official Journal		

Technical information

Procedure reference	2021/2132(DEC)
Procedure type	DEC - Discharge procedure
Stage reached in procedure	Procedure completed
Committee dossier	CONT/9/06735

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee opinion	ENVI	PE699.211	17/01/2022	
Committee draft report		PE698.974	19/01/2022	
Amendments tabled in committee		PE704.733	02/03/2022	
Committee report tabled for plenary, single reading		A9-0103/2022	07/04/2022	
Text adopted by Parliament, single reading		T9-0161/2022	04/05/2022	Summary

Council of the EU

Document type	Reference	Date	Summary
Supplementary non-legislative basic document	06003/2022	16/02/2022	

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2021)0381	30/06/2021	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
CofA	Court of Auditors: opinion, report	N9-0044/2022 OJ C 439 29.10.2021, p. 0003	29/10/2021	

Final act

Budget 2022/1764
OJ L 258 05.10.2022, p. 0303

2020 discharge: European Medicines Agency (EMA)

2021/2132(DEC) - 04/05/2022 - 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 2020 and to approve the closure of the accounts for that year.

Noting that the Court of Auditors has stated that it has obtained reasonable assurance that the Agency's annual accounts for the financial year 2020 are reliable and that the underlying transactions are legal and regular, Parliament adopted, by 559 votes to 55 with 27 abstentions, a resolution containing a series of recommendations which form an integral part of the discharge decision and which complement the general recommendations set out in the resolution on the performance, financial management and control of EU agencies.

Agency's financial statements

The Agency's final budget for the year 2019 was EUR 369 749 000, which represents an increase of 6.63% compared to 2019. In 2020, 84% of the Agency's revenue came from fees paid by the pharmaceutical industry for services provided.

Budgetary and financial management

Budget monitoring efforts during 2020 resulted in a budget implementation rate of 98.83 %, representing an increase of 0.27 % compared to 2019. The payment appropriations execution rate was 78.47 %, representing a decrease of 4.58 % compared to 2019.

Parliament noted the Agency's decision to waive all fees for scientific advice applications from developers of potential COVID-19 therapeutics or vaccines, as of 13 March 2020, and welcomed the waiving of all fees for provision of scientific advice to academic researchers developing orphan medicines from 19 June 2020. It considered that other instances of waiving fees subject to specific criteria set out by the Agency, in particular regarding

small and medium-sized enterprises (SMEs), should follow;

Other observations

Parliament also made a series of observations concerning performance, staff, conflicts of interest, internal controls and Covid-19.

In particular, it noted that:

- the Agency played an important role in the preparation of the Union's response to the Covid-19 pandemic and effectively analysed and quickly approved vaccines against Covid-19 in the Member States;

- the Agency recommended 97 new human medicines for marketing authorisation, including 39 new active substances, and 20 new veterinary medicines, including 13 new active substances;

- there is a need to strengthen the capabilities of the Agency so as to improve its resilience and effectiveness during periods of emergency;

- the EMA is revising its set of indicators and metrics with the objective of further reducing complexity, increasing transparency and extending the efficacy of monitoring its activities;

- the Covid-19 pandemic has highlighted the need for the EU to reach the highest possible level of self-sufficiency in the development and production of medicines;

- on 31 December 2020, the establishment plan was 100% implemented, with 596 temporary agents appointed out of 596 temporary agents authorised under the Union budget (compared to 591 authorised posts in 2019);

- the Agency should closely monitor the workload burden allocated to staff, especially under exceptional peak periods related to Covid-19;

- additional resources should be allocated to the Agency to cover the increasing workload and to improve its competence in the fight against medicine shortages;

- the pandemic dominated the Agency's activities in 2020 which resulted in substantial resources being allocated to respond to the public health crisis. Consequently, the scope of the Agency's 2020 work programme had to be reduced, with important public health activities either delayed or suspended;

- no internal whistleblowing case was reported, however, 25 reports of external whistleblowing cases were received;

- the Agency’s should continue efforts to increase the level of transparency of its decision making and further steps should be taken in order to enhance the transparency of the Agency’s activities following consistent concerns about the lack of transparency about vaccine contracts with pharmaceutical companies, even though it is the Commission who is party in those contracts;

- the Agency’s defensive cybersecurity capabilities were enhanced following a cyberattack in December 2020;

- the Agency developed and implemented a communication plan for 2020 that aimed to broaden the reach of its communication activities, especially those related to the unprecedented situation of the COVID-19 pandemic.