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.