2019 discharge: European Medicines Agency (EMA)

2020/2157(DEC) - 28/04/2021 - Text adopted by Parliament, single reading

The European Parliament decided by 580 votes to 79, with 39 abstentions, to **grant discharge** to the Executive Director of the European Medicines Agency (EMA) for the financial year 2019 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 2019 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 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 346 762 000, which represents an increase of 2.66% compared to 2018. In 2019, 85.70% of the Agency's revenue came from fees paid by the pharmaceutical industry for services provided.

Budgetary and financial management

Members noted with satisfaction the budget monitoring efforts during 2019 which resulted in a budget execution rate of 98.56%, which is an increase of 9.42% compared to 2018. The implementation rate of payment appropriations was 83.05%, which represents an increase of 9.41% compared to 2018.

Other observations

Members also made a series of observations concerning performance, staff, procurement, conflicts of interest and internal controls.

In particular, they noted that:

- the Agency uses a number of key performance indicators, including a set of operational, management and governance, communication and stakeholder indicators, to measure the implementation of its work programme and stakeholder satisfaction, as well as to assess the added value of its activities;

- the Agency cooperates with other agencies on joint scientific contributions and exchanges scientific data. It continues to have working arrangements with the European Centre for Disease Prevention and Control, the European Food Safety Authority, the European Chemicals Agency and the European Monitoring Centre for Drugs and Drug Addiction;

- the Agency plays an important role in the protection and promotion of public and animal health through the evaluation and monitoring of medicinal products for human and veterinary use. In 2019, it recommended 81 new medicinal products for marketing authorisation (66 for human use and 15 for veterinary use), including 35 new active substances (30 for human use and 5 for veterinary use);

- on 31 December 2019, the establishment plan was 98.65 % implemented, with 583 temporary agents appointed out of 591 temporary agents authorised under the Union budget (compared to 591 posts authorised in 2018). The lack of gender balance in the Agency's senior management is a matter of concern, as is the large size of the Management Board;

- the Agency's procurement and planning procedures, including the use of temporary and external staff, need to be improved;

- no internal whistleblowing cases were reported, but 20 external whistleblowing cases were identified. 4 cases were closed, of which 13 were opened in 2019 and 11 in previous years, and 7 cases are still ongoing. No cases of conflict of interest were reported by the Agency;

- following the move to Amsterdam on 30 March 2019, the Agency entered into an agreement with its landlord to sublet its former office premises to a sub-tenant on terms consistent with the terms of the head lease. The sub-lease agreement runs until the expiry of the Agency's lease in 2039. As the Agency remains bound by the lease agreement, it could be held liable for the entire amount remaining payable under the rental contract if the subtenant fails to meet its obligations.

Parliament welcomed the Agency's efforts to strengthen its transparency policy regarding COVID-19 medicines and vaccines. It urged the Agency to publish data from clinical trials before marketing authorisation and failing that, in a timely manner.