

2018 discharge: European Medicines Agency (EMA)

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 Agency's 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:

Agency's financial statements

The European Medicines Agency's 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 Kingdom's 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 Agency's 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 Agency's 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.