2017 discharge: European Medicines Agency (EMA)

2018/2185(DEC) - 01/03/2019 - Committee report tabled for plenary, single reading

The Committee on Budgetary Control adopted the report by Petri SARVAMAA (EPP, FI) on discharge in respect of the implementation of the budget of the European Medicines Agency (EMA) for the financial year 2017.

The committee called on the European Parliament to grant the Executive Director of the Agency discharge in respect of the implementation of the agency's budget for the financial year 2017.

Noting that the Court of Auditors stated that it had obtained reasonable assurance that the annual accounts of the Agency for the financial year 2017 were reliable and that the underlying transactions were legal and regular, Members called on Parliament to approve the closure of the Agency's accounts.

They made, however, a number of recommendations that needed to be taken into account when the discharge is granted, in addition to the general recommendations that appear in the draft 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 2017 was EUR 331 266 000, representing an increase of 7.41 % compared to 2016. The Agency is a fee-funded agency, with 86 % of its 2017 revenue stemming from fees paid by the pharmaceutical industry for services provided, and 12 % stemming from the Union budget.

Budget and financial management

The budget monitoring efforts during the financial year 2017 resulted in a budget implementation rate of 92.92 %, representing a decrease of 3.38 % compared to 2016. Payment appropriations execution rate was 76.62 %, representing a decrease of 5.73 % compared to 2016.

Members regretted that the cancellations of carry-overs from 2016 to 2017 amounted to EUR 4 350 908, representing 10.11 % of the total amount carried-over, showing a notable increase of 5.65 % in comparison to 2016. They called on the Agency to report to the discharge authority on the measures taken to ensure complete use of the appropriations carried-over, in order to avoid substantial resources being de-committed.

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

In particular, they noted that:

- the Agency implemented a new and improved version of the EudraVigilance system, an information system used to report suspected side effects of medicines;

- a number of the Agency's activities were delayed or postponed due to Brexit or external circumstances;

- the Agency recommended 110 new medicines for marketing authorisation (92 for human use and 18 for veterinary use), and that those included 42 new active substances (35 for human use and 7 for veterinary use);

- on 31 December 2017, the establishment plan was 97.82 % executed, with 583 temporary agents appointed out of 596 temporary agents authorised under the Union budget;

- the staff expenses increased by EUR 10 million. The Agency is asked to report comprehensively on this expenditure and urged not to replace permanent staff by more expensive contract agents;

- that in 2017 the Agency received 25 reports on cases of whistleblowing from an external source, 15 cases were closed in 2017 and 10 cases are still ongoing;

- the Court issued an emphasis of matter paragraph in relation to the two London-based agencies, concerning the United Kingdom’s decision to withdraw from the European Union; notes that the seat of the Agency will move to Amsterdam at the beginning of 2019 and that the Agency’s accounts include provisions for related costs amounting to EUR 18 600 000. Members regretted that the lease agreement for the London based premises sets a rental period until 2039 with no exit clause. Efforts should be made to minimise the financial, administrative and operational impact of the unfavourable lease agreement.