# 2015 discharge: European Medicines Agency (EMA)

2016/2169(DEC) - 28/03/2017 - Committee report tabled for plenary, single reading

The Committee on Budgetary Control adopted the report by Inés AYALA SENDER (S&D, ES) on discharge in respect of the implementation of the budget of the European Medicines Agency (EMA) for the financial year 2015.

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 2015.

Noting that the Court of Auditors stated that it had obtained reasonable assurance that the annual accounts of the Agency for the financial year 2015 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**: Members note the final budget of the European Medicines Agency for the financial year 2015 was EUR 308 097 000 representing an increase of 9.07 % compared to 2014.
- **Prevention and management of conflicts of interests and transparency**: Members acknowledged that the revised policy on the handling of declarations of interests of scientific committees' members and experts entered into force in 2015. They reminded the Agency that Directive 2003/63 /EC states that medicines can only be considered for Union marketing authorisation if they have been tested in accordance with ethical guidelines. They also reminded it of its commitment to perform extra checks on clinical trials carried out outside the European Union before granting a drug market authorisation. The Agency is asked to report to the discharge authority every year on actions taken to ensure drugs for the Union market were tested ethically.

Members also made a series of observations regarding the budgetary and financial management, commitments and carry-overs, transfers, procurement and recruitment procedures, the prevention and management of conflicts of interests and internal audits and controls.

**Impact of Brexit**: on 23 June 2016, the citizens of the United Kingdom voted to leave the European Union. Members noted that following the outcome of the UK referendum on 23 June 2016, the Agency established a dedicated task force to focus on **relocation** preparedness, operational and financial preparedness, HR-related matters and communication (internal and external) aspects. They observed that the work currently ongoing is focussed on the impact of a loss of EMA staff in the event of relocation and loss of external expertise due to the potential unavailability of UK expertise in the scientific committees and other EMA fora. An impact assessment including remedial solutions should be available by the end of the first quarter of 2017.

Lastly, Members noted with concern that the Agency's rental contract until 2039 does not include an **early termination clause to release the Agency** from the liabilities of rent and associated costs, and that the payable rent for the remaining period from 2017 to 2039 is estimated at EUR 347.6 million. They asked the Agency to report to the discharge authority on any developments on this matter.