2014 discharge: European Medicines Agency (EMA)

2015/2171(DEC) - 08/04/2016 - Committee report tabled for plenary, single reading

The Committee on Budgetary Control adopted the report by Derek VAUGHAN (S&D, UK) on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2014.

The parliamentary committee calls 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 2014.

Noting that the Court of Auditors issued a statement of assurance as to the reliability of the accounts and the legality and regularity of the underlying transactions for the financial year 2014, Members call 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 2014 was EUR 282 474 000, representing an increase of 12.29 % compared to 2013. 12.53 % of the Agency's budget derives from the Union budget.

- **Legality and regularity of transactions:** Members note that the Agency's Fee Regulation provides due dates for the collection of fees from applicants and the Agency's related payments to national competent authorities. They note that these due dates were not respected for most of the transactions audited by the Court. They call on the Agency to report to the discharge authority on measures implemented to remedy this issue

Members also made a series of observations regarding commitments and carryovers, procedures for contract awards, recruitment, internal control and audit.

Members note the Agency revised its policy on handling of **declarations of interests** of scientific committee members and experts. It defined what are direct and indirect interests and ordered all experts to declare all direct and indirect interests in their annual declaration of interests. They note, moreover, that **restrictions are applied to experts declaring direct or indirect interests which depend on the activity in which they are involved**, maintaining the policy distinction between those interests in line with the relevant legislation.

Lastly, Members recall that the Pharmacovigilance Fee Regulation was published in the Official Journal of the European Union on 27 June 2014 and has applied to procedures starting from 26 August 2014, although annual fees to support information technology systems and literature monitoring activities will not be levied until 2015. They stress that that Regulation now allows the Agency to collect fees from marketing authorisation holders to finance these pharmacovigilance activities conducted at Union level in respect of medicinal products for human use. They point out that the income is used to **remunerate national competent authorities for the scientific assessment** carried out by the rapporteurs of the Agency's Pharmacovigilance Risk Assessment Committee and contributes to the pharmacovigilance costs of the Agency.