2014 discharge: European Medicines Agency (EMA)

2015/2171(DEC) - 28/04/2016 - Text adopted by Parliament, single reading

The European Parliament decided to grant discharge to the Executive Director of the European Medicines Agency (EMA) in respect of the implementation of its budget for the financial year 2014. The vote on the decision on discharge covers the closure of the accounts (in accordance with Annex V, Article 5 (1)(a) to Parliament's Rules of Procedure.

Noting that the Court of Auditors has stated that it has obtained reasonable assurances that the Agency's annual accounts for the financial year 2014 are reliable and that the underlying transactions are legal and regular, Parliament adopted by 516 votes to 113 with 10 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**: Parliament noted 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**: Parliament noted 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. It noted that these due dates were not respected for most of the transactions audited by the Court. It called on the Agency to report to the discharge authority on measures implemented to remedy this issue.
- Parliament also made a series of observations regarding commitments and carryovers, procedures for contract awards, recruitment, internal control and audit.
- **Conflicts of interest**: Parliament acknowledged that the Agency has defined what are direct and indirect interests and ordered all experts to declare all direct and indirect interests in their annual declaration of interests. Moreover, it noted 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, Parliament recalled 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. It stressed 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. It pointed 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.