2014 discharge: European Medicines Agency (EMA)

2015/2171(DEC) - 08/09/2015 - Court of Auditors: opinion, report

PURPOSE: presentation of the EU Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2014, together with the Agency's reply.

CONTENT: in accordance with the tasks conferred on the Court of Auditors by the Treaty on the Functioning of the European Union, the Court presents to the European Parliament and to the Council, in the context of the discharge procedure, a Statement of Assurance as to the reliability of the annual accounts of each institution, body or agency of the EU, and the legality and regularity of the transactions underlying them, on the basis of an independent external audit.

This audit concerned, amongst others, the annual accounts of the European Medicines Agency (EMA).

Statement of assurance: pursuant to the provisions of Article 287 of the Treaty on the Functioning of the European Union (TFEU), the Court has audited:

- the annual accounts of the Agency, which comprise the financial statements and the reports on the implementation of the budget for the financial year ended 31 December 2014, and
- the legality and regularity of the transactions underlying those accounts.

Opinion on the reliability of the accounts: in the Court's opinion, the Agency's annual accounts present fairly, in all material respects, its financial position as at 31 December 2014 and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its Financial Regulation and the accounting rules adopted by the Commission's accounting officer.

Opinion on the legality and regularity of the transactions underlying the accounts: in the Court's opinion, the transactions underlying the annual accounts for the year ended 31 December 2014 are legal and regular in all material respects.

The report also makes a series of observations on the budgetary and financial management of the Agency, accompanied by the latter's response. The main observations may be summarised as follows:

The Court's observations:

- **legality and regularity of transactions**: the Court noted that due dates for the collections fees from applicants and the Agency's related payments to National Competent Authorities were not respected;
- **public procurement**: the Court noted that in 2014, the Agency concluded a EUR 15 million framework contract (covering the years 2014 to 2017) for high-level management consultancy services. The objectives and activities to be carried out were not sufficiently specific to justify the procurement decision or the volume of the contract.

The Agency's response:

- **legality and regularity of transactions**: the Agency stated that during 2013-14, the Agency has redesigned and streamlined its main operational processes including financial authorisations and fee collections. The further planned automation of the latter was delayed because of the Agency's

reorganisation in 2014. To ensure compliance with the Agency's fee regulation concerning due dates, this automation is now planned to be implemented by the end of 2015;
- **public procurement**: the Agency rejected the Court's position and stated that it had clearly assessed the needs to justify a call for tender.

Lastly, the Court of Auditors' report contains a summary of the **Agency's activities in 2014**. This is focused on the following:

Budget: EUR 282.47 of which the Union contribution amounts to 8.2 %.

Activities:

- applications for marketing authorisations for 100 medicines for human use;
- applications for marketing authorisations for 12 medicinal products for veterinary use;
- 506 inspections;
- herbal medicinal product studies;
- 329 applications for orphan medicinal products;
- requests for SME status: 499 requests and 333 applications for fee reduction or deferrals.