2013 discharge: European Medicines Agency (EMA)

2014/2102(DEC) - 01/07/2014 - 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 2013, 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 2013;
- 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 2013 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 2013 are legal and regular in all material respects.

The Court's report makes no observations on the budgetary and financial management of the Agency.

Lastly, the Court of Auditors' report contains a summary of the **Agency's activities in 2013**. This is focused on the following:

Budget: EUR 251.56 million of which the Union subsidy is 13%.

Activities:

- applications for marketing authorisations for 80 medicines for human use ;
- applications for marketing authorisations for 23 medicinal products for veterinary use;
- pharmacovigilance activities;
- mutual recognition procedures and decentralised procedures: started 6991; (ended 6709);
- 480 inspections;
- herbal medicinal product studies;
- 201 applications for orphan medicinal products (139 favourable opinions);
- requests for SME status: 401 requests and 336 applications for fee reduction or deferrals.