2011 discharge: European Medicines Agency (EMA)

2012/2190(DEC) - 05/09/2012 - 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 2011, 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).

In the Court's opinion, the **Agency's Annual Accounts fairly present, in all material respects, its financial position as of 31 December 2011** and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its Financial Regulation.

The Court also considers that the **transactions underlying the annual accounts** of the Agency for the financial year ended 31 December 2011 are, in all material respects, **legal and regular**.

The report confirms that the Agency's 2011 budget amounted to EUR 208.863 million and that the number of staff employed by the Agency at the end of the year was 728.

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:

Court's comments:

- carry-overs: the Court notes again that the level of carry- over is excessive and at odds with the principle of annuality;
- public procurement: the Agency increased in 2011 the financial envelope of an irregular framework contract for IT services concluded in 2009 for which the Court had qualified its opinion on the legality and regularity of the transactions underlying the Agency's 2009 accounts. According to the Court, there is scope for improving the transparency of procurement procedures as regards the justification of the estimated contract volumes and the definition, publication and application of selection criteria;
- recruitment: the Court identified a need to improve the transparency of staff selection procedures.

Agency's replies:

- the Agency states that since 2008 it has made every effort to reduce its level of carry-over to an acceptable level. It has in fact achieved a continuous reduction. As the operations of the Agency are of a multi-annual nature and not linked to the calendar year, a certain level of carry-overs is unavoidable;
- the Agency considers that the IT framework contract was not irregular. As a consequence, the extension of the framework contract is considered not irregular as well;

- the Agency has taken note of the Court's comments and updated its procedures with a view to transparency and timely documentation.

Lastly, the Court of Auditors' report contains a summary of the **Agency's activities in 2011**. This is focused on the following:

- applications for marketing authorisations for 100 medicines for human use ;
- pharmacovigilance activities;
- mutual recognition procedures and decentralised procedures: started 6 401; (6 715 ended positively);
- scientific advice;
- applications for paediatric investigation plans: 187 relating to 220 indications;
- applications for marketing authorisations for 11 medicinal products for veterinary use;
- 449 inspections;
- herbal medicinal products;
- 166 applications for orphan medicinal products (111 favourable opinions);
- requests for SME status: 433 requests and 350 applications for fee reduction or deferrals.