

2009 discharge: European Medicines Agency (EMA)

2010/2173(DEC) - 05/10/2010 - Court of Auditors: opinion, report

PURPOSE: presentation by the Court of Auditors of its report on the annual accounts of the European Medicines Agency for the financial year 2009, together with the Agency's replies.

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

This audit also covered the annual accounts of the **European Medicines Agency (EMA)**.

In the Court's opinion, the **Agency's annual accounts presented "fairly, in all material respects", its financial position as of 31 December 2009** 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 stated that the **transactions underlying Eurojust's annual accounts** for the financial year ended 31 December 2009 were, "in all material respects, **legal and regular**".

The Court considers however that this statement of assurance should be accompanied by a qualified opinion on the legality and the regularity of the transactions underlying the accounts.

Elements evoking a qualified opinion from the Court:

- lack of transparency in procurement procedures: in 2009, the Agency concluded a number of procedures for the procurement of large IT framework contracts. The audit showed errors which affected the regularity of 4 operations examined: (i) in the case of a procurement of a large framework contract for IT services (value = EUR 30 million), the conditions for applying a negotiated procedure following an open procedure where tenders were assessed to be of an unacceptable quality were not satisfied; (ii) in another case, there was a lack of evidence regarding the method used for the evaluation of the selection criteria which was thus open to interpretation; (iii) in another case of negotiated procurement with a single supplier for technical reasons, no formal invitation to tender was issued; (iv) in an another similar case, the technical specifications did not clearly define all the products to be purchased before the negotiation started.

The report confirmed that the Agency's 2009 final budget amounted to EUR 194.389 million of which 18.7% representing a Union contribution. The number of staff employed by the Agency at the end of the year was 664.

The report also included comments on the EMA's budgetary and financial management, together with its replies. The main comments are as follows:

The Court's comments:

- carry-over and cancellation of appropriations: EUR 19.5 million (representing 38%) of commitments for buildings, equipment and miscellaneous operating expenditure activities were

carried forward to the budgetary year 2010. According to the accounting information, approximately EUR 14.8 million of the appropriations carried forward corresponded to activities not yet implemented at the year-end. This situation was not in keeping with the budgetary principle of annuality;

- late recovery orders;
- long-standing policy of entering into forward foreign-exchange contracts in order to hedge part (50 %) of its administrative budget against unfavourable fluctuations in the exchange rate for Sterling: this situation caused financial loss for the Agency.

The Agency's replies:

- as regards the issue of the lack of transparency in the procurement procedures: a multiannual procurement plan will be set up and will also ensure stronger technical and procedural controls; the results of procurement procedures are verified before contracts are awarded; a comprehensive and detailed evaluation guide was used in draft form by all members of the evaluation committee. Experience with this draft evaluation guide showed that it was too strict leading to unreasonably low marks;
- significant efforts have been made to reduce its carry-overs. Taking account of the growth in overall budget, in relative terms the carry-over in Title II (operating expenditure) decreased from 42.6% (2008 to 2009) to 38.1% (2009 to 2010);
- temporary control measures have been put in place pending the new financial database SAP's ability to automatically create and update fee data from the operational database once validation of applications is completed;
- the treasury policy has been revised, adopted and formally approved by the agency's Audit Advisory Committee.

Lastly, the Court of Auditor's report contained a summary of the **EMEA's activities in 2009** in the following areas:

- medicinal products for human use: applications for marketing authorisations: 96;
- pharmaco-vigilance activities;
- periodic safety update reports;
- mutual recognition procedures and decentralised procedures;
- medicinal products for veterinary use: applications for marketing authorisations: 15;
- herbal medicinal products;
- orphan medicinal products: 164 applications.