2010 discharge: European Medicines Agency (EMA)

2011/2220(DEC) - 06/09/2011 - Court of Auditors: opinion, report

PURPOSE: presentation of the EU Court of Auditors' report on the annual accounts of the European Medicines Agency, 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 2010** 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 2010 are, in all material respects, **legal and regular.**

The report confirms that the Agency's 2010 budget amounted to EUR 208.4 million and that the number of staff employed by the Agency at the end of the year was 698.

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:

- **budgetary and financial management**: the Agency experienced delays in implementing 'Administrative expenditure' of its budget. Appropriations carried forward to 2011 totalled EUR 17.6 million, 33.3 % of the corresponding appropriations. Just 36 % of the appropriations carried forward correspond to accrued expenditure of the year, meaning 64 % of the amounts carried over did not relate to the 2010 financial year. This situation was at odds with the budgetary principle of annuality;
- **recruitment**: the Agency did not distinguish sufficiently between employment-agency staff and contract staff recruitments;
- **follow-up on previous findings**: in previous reports, the Court had noted the need for the Agency to introduce a system of remuneration for services provided by national Member State authorities based on the Member States' real costs. Up to now, despite some efforts by the Agency, this has not been done.

The Agency's response:

- the Agency indicates that it has continuously improved its administrative carry-over since 2008. The amounts in question for 2010 are for multiannual Telematics ICT projects. These Telematics

projects are of an operational nature and as a consequence will be accounted for from 2011. Therefore from 2011/12 the Agency expects a reduction in carry-over in administrative expenditure to a maximum of around 30 % (corresponding to a reduction of EUR 10 million);

- the Agency notes that action has been taken to improve transparency by ensuring that all contract agent positions are more clearly publicised externally prior to being filled and that the EMA implementing rules on selection and recruitment of contract agents are correctly followed;
- a proposal for a new payment system was presented to the Management Board at their meeting of 10 December 2009. The Management Board rejected the proposal. EMA will try again to instigate the discussions at forthcoming Management Board meetings and remind the Board of the need to move forward on this topic.

Lastly, the Court of Auditors' report contains a summary of the Agency's activities in 2010. This is focused on the following:

- applications for marketing authorisations for 91 medicines for human use ;
- pharmacovigilance activities;
- mutual recognition procedures and decentralised procedures: started 21 433; (ended positively 11100);
- scientific advice finalised;
- applications for paediatric investigation plans: 326 relating to 403 indications;
- applications for marketing authorisations for 18 medicinal products for veterinary use;
- 300 inspections;
- herbal monographs;
- 174 applications for orphan medicinal products (123 favourable opinions);
- requests for SME status: 251 requests and 161 applications for fee reduction or deferrals.