2012 discharge: European Medicines Agency (EMA)

2013/2215(DEC) - 10/09/2013 - 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 2012, 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 2012** and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its financial rules and the accounting rules adopted by the Commission's accounting officer.

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 resources made available to the Agency's in 2012 amounted to EUR 222.5 million.

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:

- reliability of the accounts: the Agency noted that it applies differing recognition criteria for fee revenue and associated expenditure. This is in contradiction with the matching principle. It states that it has not yet validated its accounting system in the area of intangible fixed assets. Given the considerable investment in the ICT development (2012 investments in ICT development amounted to EUR 11.6 million), this is a crucial part of the whole accounting system;
- staff: in 2011 and 2012, the Council refused salary increases for EU staff. The Commission appealed this decision to the Court of Justice which did not yet rule on the matter. Since the Agency is located in London, the salary increases in question will be paid in GBP whereas the Agency's accounts are prepared in Euros. Given the fluctuations in the exchange rate over the period concerned, the possible back pay to staff would lead to an estimated exchange rate loss for the Agency of EUR 2.09 million. The Agency has included this amount in the calculation of its budgetary outturn account, leading to an equivalent understatement of funds to be paid back to the Commission;
- legality of the operations: in 2012, the Agency issued cascading framework contracts for the provision of services. The procurement procedure presented some irregularities affecting the principle of transparency;

- budgetary management: the rate of committed appropriations carried over was high at 27 %, this primarily relates to the Agency's planned move to new premises in 2014 (EUR 4 million) and the development of ICT systems (EUR 1.6 million).

The Agency's response:

- reliability of the accounts: in light of the Court's observation the Agency will review its accounting policy on recognising fee revenue and associated expenditure to ensure future compliance with the matching principle;
- staff: the Agency states that the amount was included in the Agency's accounts following an instruction from the Accounting Officer of the EU Commission that all unrealised exchange losses should be included in the budgetary accounts as well as the financial accounts. The Agency expects to need this money in order to cover the salaries payable in GBP to EMA staff when the 2011 and 2012 rappels are adopted. The Agency is aware that DG BUDG considers the 'rappel' an unforeseeable expenditure, but judges this position to be untenable because the adaptation of exchange rates and weightings which are part of any 'rappel' is not only foreseeable, but legally required and long overdue. For the budgetary accounts the Agency applies the same methodology used to calculate the provision in the financial accounts. The Agency's primary concern is that if these figures are not included in the 2012 budgetary accounts it will find itself returning funds to the Commission when in fact those funds will be needed to pay salary liabilities once the weighting and applicable exchange rates are adapted to real levels;
- legality of operations: the Agency **does not share the view of the Court that the principle of transparency was infringed in its tender procedure**. It stated that it will make improvements on the issues highlighted by the Court to ensure even greater transparency in the future;
- budgetary implementation: the Agency noted that it has already substantially reduced its carry over levels as the equivalent carry over in 2011 was 33% and 36% in 2010 (27% in 2012). The Agency strives by respecting its operational requirements to further reduce its carry over to a level within tolerable margins of the Financial Regulation.

Lastly, the Court of Auditors' report contains a summary of the **Agency's activities in 2012**. This is focused on the following:

- applications for marketing authorisations for 96 medicines for human use ;
- pharmacovigilance activities;
- mutual recognition procedures and decentralised procedures: started 6991; (ended 6709);
- scientific advice finalised;
- applications for paediatric investigation plans: 178 relating to 218 indications;
- applications for marketing authorisations for 13 medicinal products for veterinary use;
- 450 inspections;
- herbal medicinal product studies;
- 197 applications for orphan medicinal products (139 favourable opinions);
- requests for SME status: 684 requests and 361 applications for fee reduction or deferrals.