2006 discharge: European Medicines Agency EMEA

2007/2054(DEC) - 15/11/2007

PURPOSE: presentation of the report by the Court of Auditors on the 2006 annual accounts of the European Medicines Agency.

CONTENT: the report indicates that the appropriations entered in the Agency's budget for the financial year in question are **EUR 138.676 million**, EUR 136.147 million were committed and EUR 106.733 million paid. Of this overall amount, EUR 29.414 million was carried over to 2007 and EUR 2.529 million was cancelled.

The Court notes that the annual accounts are reliable in all material respects and that the underlying transactions of the Agency's accounts, taken as a whole, are legal and regular.

Analysis of the accounts by the Court: in the Court's opinion, as regards the implementation of the budget for administrative expenditure (Title II of the budget), the utilisation rate for commitment appropriations was less than 60%. More than 40% of the commitments, in particular in the area of Information Technology, were carried over to the financial year 2007. Thus, the budgetary principle of **annuality** was not strictly observed.

The Court also indicates that, in accordance with the Fee Regulation, "Any review of the fees shall be based on an evaluation of the Agency's costs and on the basis of the related costs of the services provided for by the Member States. Those costs shall be calculated in accordance with generally accepted international costing methods". However, according to the Court, in 2006 the Agency's customers were billed an amount which was divided in two parts: one part covering the Agency's costs, and the other being repaid to the Member States' rapporteurs to cover their own expenses. As the Member States' rapporteurs never provided full evidence or documentation of their real costs, this situation was in breach of the Fee Regulation, according to the Court.

Moreover, the Court emphasises that the Agency has not been in a position to make a comprehensive analysis of the costs incurred by Member States' rapporteurs in order to obtain an objective and documented basis on which to adapt the payments it makes to them and, consequently, the fees charged to its customers.

The Agency's replies: the Agency recalls that the total automatic carryover to 2007 under Title II amounted to EUR 15 million, of which EUR 8 million was for Information Technology (Chapter 21). The Agency indicates that it is in the process of developing and implementing a multi-annual programme of EU Telematics for the regulation of medicinal products. It also indicates that its governance process and the nature of its projects make it difficult to strictly observe the principle of annuality, especially as many governance actions are outside of its control. However, it indicates that every effort is being made to lower the level of automatic carryovers in the future.

Concerning the costs incurred by Member States' rapporteurs, the Agency indicates that it has, together with the national competent authorities, made great effort to assess the costs incurred by rapporteurs. At its December 2006 meeting, the Management Board of the Agency took the decision to revise the scale of fees system and decided to establish a costing group in order to prepare and agree on generally accepted costing methods, referred to in Article 12 of the Fee Regulation. Finally, the Agency indicates that representatives from all national competent authorities will be invited to participate in this work.