2009 discharge: European Medicines Agency (EMEA)

2010/2173(DEC) - 03/10/2011

The Committee on Budgetary Control adopted the second report drafted by Georgios STAVRAKAKIS (S&D, EL) **granting he Executive Director of the European Medicines Agency discharge in respect of the implementation of the Agency's budget for the financial year 2009**.

This report is the follow up to the postponement of the discharge decision on 11 May 2011.

Stating that the Court of Auditors had reserved its opinion on the legality and reliability of the underlying transactions, Members made a series of recommendations (other than those outlined in the draft resolution as regards the performance, financial management and the controls – see DEC/2010/2271) which accompanies the decision postponing the discharge.

General considerations: Members acknowledges receipt of a letter of the Chair of the Agency's Management Board of 17 June 2011 in which it is stated that the **Agency has taken actions to address the 2009 shortcomings**. They regret, however, that not all the information requested was submitted and call on the Agency should continue to inform on a three-monthly basis the discharge authority on the results of the actions requested by the discharge authority.

Members underline that the discharge authority shall continue to carefully monitor during the upcoming discharge procedures the level of implementation of the measures undertaken to address the Agency's serious weaknesses disclosed by the reports from both the Court of Auditors and the IAS. They expect, therefore, the Agency to inform the discharge authority on the actions implemented and their results and to submit the documents requested, especially with regard to the following issues:

- the process of the adoption by the Management Board of the action plan with specific measures and a timetable for implementation to remedy the shortcomings in the procurement procedures;
- the thorough verification of the effective use of the existing procedures regarding the identification and management of **conflicts of interest** for its staff and experts;
- the submission of the IAS reports according to the Financial Regulation.

Specific comments: Members made the following observations:

Procurement procedures: Members remind the Agency to continue improving the quality of its procurement system and to comply strictly with the requirements of the relevant rules on public procurement, so as to rectify the shortcomings pointed out by the Court of Auditors. Noting the initiation of the actions to develop an action plan on improving procurement procedures, Members call on the Agency to proceed promptly with the adoption of an action plan to **remedy the shortcomings in the procurement procedures**, in particular the errors in managing contract award procedures, by providing for more rigorous technical and procedural checks, and to inform the discharge authority accordingly. According to the 2009 annual report, the Agency did not carry out enough checks to mitigate the risk of errors on a number of procedures for the procurement of large IT framework contracts.

Carryover appropriations: Members note that the Court of Auditors reported that approximately EUR 14 800 000 of a carryover of EUR 19 500 000 (38 % of the Agency's commitments in 2009) was for

activities as yet not implemented (or, in some cases, goods not received for services which may spread across more than one financial year) at the year-end. They remind the Agency therefore to take action in this respect and looks forward to receiving assurance from the Court of Auditors on this.

Foreign-exchange contracts: Members acknowledge the Agency's commitment to limit its risks due to exchange rate variance and that as of 11 June 2010 it revised its Treasury Policy by: establishing an internal consultation committee to advise the accounting officer on hedging strategies; limiting the hedging to 50 % of estimated requirement; and ensuring that achievable market rates match or are above the budget costing rate.

Management of conflicts of interest: overall Members take note of the Agency's replies on the compliance with its Code of Conduct by setting out principles and guidance on independence and confidentiality applicable to the Management Board and members of committees, experts and the Agency's staff. Members acknowledge the Agency's reply in which it is stated that **there is no onus on it to request or monitor the annual declaration of financial interests of experts responsible for evaluating medicinal products, as this lies with the Member States' competent authorities** (Article 126b of Directive 2001/83/EC as amended by Directive 2004/27/EC).

The report stresses that it is not only the Agency's reputation that could be affected in cases where evaluations can be challenged on the grounds of possible conflicts of interest but also that such **conflicts of interest do not guarantee the optimal protection of European citizens' health**.

Members note that, as of 1 July 2011, the new electronic Declaration of Interests (e-DoI) form went live and all experts were requested to fill in the new e-DoI and that the e-DoIs of all experts included in the Experts database have been made publicly available on the Agency's website as of 30 September 2011. Members insist, but also warn the Agency, that all the actions mentioned in the respective audit reports, including the one for the year 2010, should be fully implemented before the start of the next discharge procedure.

Human resources management: lastly, Members welcome the fact that the Agency had stated that it has corrected the deficiencies identified by the IAS for contract agent selection and call on the Agency to keep the discharge authority updated on the level of implementation of these actions.