2010 discharge: European Medicines Agency (EMA)

2011/2220(DEC) - 04/04/2012 - Committee report tabled for plenary, single reading

The Committee on Budgetary Control adopted the report by Monica Luisa MACOVEI (EPP, RO) on discharge to be granted in respect of the implementation of the budget of the European Medicines Agency for the financial year 2010. The committee calls on the Parliament to **postpone** its decision on granting the Executive Director of the European Medicines Agency discharge in respect of the implementation of the Agency's budget for the financial year 2010. However, they make a number of recommendations, in addition to the general recommendations that appear in the draft resolution on performance, financial management and control of EU agencies:

- **Budget and financial management**: Members acknowledge that the Agency's budget is financed both from the Union budget and from fees paid by the pharmaceutical industry when applying for, obtaining or maintaining Union marketing authorisations. They state that in 2010, 73% of the revenue of the Agency is estimated to have derived from the fee revenue and that, in parallel with the increase in the fee-based revenue, the relative percentage income from the Union contribution fell from 23 % in 2006 to 14 % in 2010. They also note weaknesses in the Agency's system for validating creditor claims in respect of IT contractors and invite the Court of Auditors to verify this issue and inform Parliament in this respect;
- **Carryover appropriations and cancellations**: Members note that automatic carryovers to the 2011 financial year totalled EUR 41 655 049,44, or 20.90 % of the appropriation committed, and that one non-automatic carryover to the 2011 financial year was requested totalling EUR 3 500 000, or 1.68 % of the final appropriation. They state that the Agency is not complying with the budgetary principle of annuality. They note with concern the additional comment from the Court of Auditors that only 36 % of the appropriations carried forward to 2011 correspond to expenditure accrued from 2010, while the remaining 64 % of amounts carried over did not relate to the 2010 financial year. Members urge the Agency to take immediate action to reduce the level of cancelled appropriations and to adopt an Action Plan with concrete measures;
- **System of remuneration for services**: Members urge the Agency to introduce a system of remuneration for services provided by national Member State authorities based on the Member States' real costs. They note in this regards that a new payment system was already presented to the Management Board at their meeting of 10 December 2009 but it, in the end, rejected the proposal. By refusing a new payment system, the Management Board accepts and takes direct responsibility for very important risks, such as **non-compliance with legislative requirements, the potential financial impact of the current remuneration system, and reputation**. Members are therefore not ready to accept this questionable attitude from the Management Board and call on the Agency to adopt an Action Plan on this matter and to inform the discharge authority by 30 June 2012;
- **Human resources management**: Members call on the Agency to improve the documentation of the recruitment files for contract agents and on the Appointing Authority to adopt the reserve lists proposed by the selection committees. They also call on the Agency to use employment-agency staff to cover short-term needs only and grant transparent access for contract staff positions;
- **Management of conflict of interest**: Members call on the Agency to report on its involvement in the organisation of conferences by private organisations such as the Organisation for Professionals in Regulatory Affairs. They note with concern that in the financial circuits there are also potential conflicts of interests in processing payments due to insufficient segregation of duties and urge the Agency therefore to duly take into account this very significant risk and take immediate action to address this deficiency. Members urge the Court of Auditors to finalise and present its current audit of conflict of interest in the Agency. They regret the fact that many of the experts failed to publish

their declarations of interests, and that the comparison of declarations of interests published by the relevant national agencies and by the Agency shows significant differences in some cases. They deplore, furthermore, the fact that at least one member of the Management Board of the Agency, also substitute member of the Committee for Medicinal Products for Human Use, failed to declare his recent management responsibilities in a pharmaceutical firm. They therefore call on the Agency to establish a genuine mechanism enabling proper scrutiny of the declarations of interest received by the Agency and to inform the discharge authority on this matter by 30 June 2012. They also urge the Agency to apply its conflict of interest policy to its Management Board. Lastly, Members are of the opinion that, given the extent of criticisms questioning conflict of interest issues in the Agency, the de**cision on discharge should be postponed until the publication of the Special Report to take into account the findings of the Court of Auditors in this respect**;

- **Internal audit**: Members acknowledge from the Agency that 11 "very important" recommendations from the IAS still need to be implemented. Efforts should be made as regards this issue.