

2010 discharge: European Medicines Agency (EMA)

2011/2220(DEC) - 10/05/2012 - Text adopted by Parliament, single reading

The European Parliament adopted by 340 votes to 268, with 14 abstentions, a decision to postpone the granting of the discharge to the Executive Director of the European Medicines Agency in respect of the implementation of the Agency's budget for the financial year 2010. The Parliament also postponed the closure of the accounts for this agency.

Parliament also adopted by 467 votes to 139, with 23 abstentions, a resolution containing observations that are an integral part of the decision to postpone the discharge.

These observations may be summarised as follows:

- **Budget and financial management:** Parliament acknowledges 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. It notes 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. It also notes weaknesses in the Agency's system for validating creditor claims in respect of IT contractors and invites the Court of Auditors to verify this issue and inform Parliament in this respect;
- **Carryover appropriations and cancellations:** Parliament notes that automatic carryovers to the 2011 financial year totalled EUR 41.6 million or 20.90 % of the appropriation committed, and that one non-automatic carryover to the 2011 financial year was requested totalling EUR 3.5 million or 1.68 % of the final appropriation. It considers that the Agency is not complying with the budgetary principle of annuality. It notes 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. It urges 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:** Parliament urges the Agency to introduce a system of remuneration for services provided by national Member State authorities based on the Member States' real costs. It notes in this regard that a new payment system was already presented to the Management Board at its 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**. Parliament is therefore not ready to accept this questionable attitude from the Management Board and calls on the Agency to adopt an Action Plan on this matter and to inform the discharge authority by 30 June 2012;
- **Human resources management:** Parliament calls 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. It also calls on the Agency to use employment-agency staff to cover short-term needs only and to grant transparent access for contract staff positions;
- **Management of conflict of interest:** Parliament calls 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. Noting the measures taken in 2012, Parliament invites the Agency to inform the discharge authority of the concrete measures that it has taken to ensure that it can evaluate the procedures in place to manage any eventual conflicts of interest. It notes with concern that in the

financial circuits **there are also potential conflicts of interests in processing payments due to insufficient segregation of duties** and urges the Agency therefore to duly take into account this very significant risk and take immediate action to address this deficiency.

- **Former director:** Parliament considers the opportunity given to the Agency's former Executive Director to engage in new activities that are in conflict with his previous position (he was recruited almost immediately after his departure from the Agency, by a consultancy firm working for pharmaceutical companies) to be a **breach of Union rules relating to conflicts of interest** in regard to members of scientific committees and experts, as well as a breach of trust procedure for Committee members and experts. It believes that the Agency should verify, during 2012, all declarations of interest of experts and Scientific Committee members and calls on it to provide the discharge authority with detailed information on the verification results and with an Action Plan with a calendar concerning the rest of the verification process for declarations of interest by the end of August 2012. Overall, Parliament has **concerns over the actual independence of the Agency**. It calls for greater transparency in this regard and welcomes the fact that the Agency has decided to publish on its website the declarations of interest of experts involved in the evaluation of medicinal products even if the Agency's approach vis-à-vis the scrutiny of declarations of interest is primarily based on trust rather than on verification. It also calls 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.

Parliament notes that the Agency has been audited by the Court of Auditors in the framework of the Special Report on conflicts of interest management in the Union agencies. The Report will be published by the end of June 2012. It is of the opinion that, given the extent of criticisms questioning conflict of interest issues in the Agency, the decision 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.