2009 discharge: European Medicines Agency (EMEA)

2010/2173(DEC) - 11/04/2011

The Committee on Budgetary Control adopted the report by Georgios STAVRAKAKIS (S&D, EL) **recommending that its decision regarding the discharge to be granted to the Executive Director of the European Medicines Agency for implementation of the Agency's budget for the financial year 2009 be postponed**.

Noting that the Court of Auditors qualified its opinion on the legality and regularity of the underlying transactions, Members **postpone the closure of the Agency's accounts**. They also make a number of recommendations (in addition to the general recommendations that appear in the draft resolution on financial management and control of EU agencies - see DEC/2010/2271) that are attached to the decision to postpone the discharge:

General considerations: Members cite serious shortcomings in the responses to issues raised by the Court of Auditors such as:

- the management of procurement procedures,
- the lack of respect to, and frequent lack of, implementing procedures regarding the identification and management of conflicts of interest for its staff and experts,
- the criteria used for recruiting staff.

These could result in:

- persistent errors in the management of procurement procedures,
- potential risks to the independence of experts/staff involved in the evaluation of medicinal products that might have negative effects on public health,
- potential deficiencies in staff/experts' recruitment which could not only lead to disqualification of competent candidates but also might have adverse effects on the quality of the Agency's scientific assessment work.

Budgetary and financial management: as far as the Agency's management is concerned, Members make the following comments:

Procurement procedures: Members note serious errors in the procurement procedures corresponding to a significant amount of the Agency's total budget for the financial year of 2009 (notably the procurement of large IT framework contracts of an estimated value of EUR 30 million as well as two other negotiated procurements of EUR 5.3 million and EUR 4 million). They note that the Agency again failed to comply with various requirements of the relevant procurement regulations. They do not accept the Agency's attempts to justify itself on this point and expect it to improve the quality of its procurement procedures and to draw up a multiannual procurement plan which shall ensure stronger technical and procedural controls;

Carryover appropriations: in regard to a carryover of EUR 19.5 million (38% of the Agency's commitments, approximately EUR 14.8 million of which was for activities as yet not implemented or, in some cases, goods not received), Members stress that this situation indicates delays in the implementation of activities financed from the Agency's budget. They point out that this has also occurred in the past;

Revenue from fees: Members expect the Agency to ensure better coordination between its financial and scientific services in order to remedy the unacceptable, long delay for recovery orders;

Foreign exchange contracts: Members expect the Agency to prudently manage its longstanding policy of entering into a forward foreign exchange contract in order to hedge part of its administrative budget against unfavourable fluctuations in the sterling exchange rate; expects the Agency to manage such transactions to avoid exchange losses (such as those in 2009 of EUR 900 000). They also call for an improvement in the Agency's treasury management;

Management of conflicts of interest: Members consider it unacceptable that the Agency does not apply the relevant rules effectively, resulting in the fact that there is no guarantee that the evaluation of human medicines is performed by independent experts. They particularly deplore the **recruitment of the Agency' s former Executive Director by a consultancy that advises, among others, pharmaceutical companies on developing new medication and reducing the period to their market introduction**. In their view, this casts some doubt on the **actual independence of the Agency**. Members await further information on this matter from the Agency and that it assesses thoroughly, before the allocation of project team leaders to products, whether the interests declared by staff members might influence their impartiality and independence. They urge the Agency, in addition, to document and assess its controls and file the relevant allocation decisions which must be made available on its website. Members stress that the Agency's reputation could be affected in cases where evaluations can be challenged on the grounds of possible conflicts of interest. They urge the Agency to inform the discharge authority of the steps it has taken to ensure the independence of its experts since its inception and wonder why the Court of Auditors' reports since 2006 make no mention of any deficiencies in this respect;

The Mediator case: Members point out that any final decision on whether or not to grant discharge cannot be taken before Parliament has been fully informed about the circumstances which led to the very late withdrawal from the market of Mediator (benfluorex), a so-called slimming pill. **They expect a full and extensive report from the Agency explaining why it took 10 years from the date when the first warning of the possible dangerous side effects of this drug was communicated to the Agency**, before the final decision was taken to withdraw the drug in 2009. They ask to be informed if and how the experts and staff dealing with the "Mediator case" were screened on their independence and how their interests declared were verified;

Procedures supporting the provision of scientific evaluation for human medicines: Members consider it unacceptable for the Agency to allow the information in its files on human medicines to be incomplete. They urge the Agency to guarantee that key information is easily retrieved, that all relevant guidelines on the filing system are in place, as well as to complete and regularly update the European Experts Database;

Role of the Agency and national competent authorities: Members urge the Agency to inform the discharge authority of the terms of its agreement with Member States on the roles and transfer of tasks to national competent authorities when facing subjects such as the independence of committees, experts and the evaluation process, since the agreement came into effect. **They consider the Agency responsible for the implementation of pre-existing procedures on the identification and management of conflicts of interest for its experts** until this agreement with Member States is fully implemented. Members emphasise that the European Medicines Agency's budget is financed both from the Union budget and fees paid by the pharmaceutical industry applying for or maintaining a Union marketing authorisation. They note, however, that the contribution from the Union budget represents only 18.7 % of the overall budget and has decreased over the years. Noting the volume of carried forward appropriations to the budget year 2010 for Title II - Buildings, equipment and miscellaneous operating expenditure activities, Members encourage the Agency to continue this process in order to apply fully the principle of annuality;

Human resources management: Members call on the Agency to ensure that sensitive tasks are not assigned to interim staff. They stress the risks of potential security breaches linked to interim staff's access

to sensitive information or unawareness by interim staff of the procedure to follow. They call on the Agency to strengthen its recruitment process and ensure its documentation is correctly managed. They stress, also, that insufficient documentation in recruitment procedures reduces the possibility for the Agency to respond to allegations of unequal treatment of candidates and/or arbitrary decisions on recruitment of staff. They consider, furthermore, that to the extent that competition is limited, resulting recruitment may not represent the optimal choice and human and that financial resources may be used inefficiently. They consider it unacceptable that the Executive Director's statement of assurance, dated 13 May 2010, does not mention any reservations. They wonder whether these requirements were fulfilled in previous years;

Internal audit: Members note that out of the 32 recommendations of the Internal Audit Service (IAS), one is "critical" on the implementing procedures involving experts and twelve are "very important" mainly on human resources management, on management of staff's conflicts of interest. They call, therefore, on the Agency to inform the discharge authority about the precise content of these recommendations without delay;

Actions to be taken by the Agency by 30 June 2011: Members urge the Agency's Executive Director to undertake a thorough verification of the effective use of the existing procedures regarding the identification and management of conflicts of interest for its staff and experts and to communicate the results to the discharge authority by 30 June 2011. They urge the Governing Board to swiftly adopt an action plan to remedy the shortcomings in the procurement procedures, as well as measures to improve the Agency's management by the same date.