2009 discharge: European Medicines Agency (EMEA)

2010/2173(DEC) - 10/05/2011 - Text adopted by Parliament, single reading

The European Parliament adopted by 626 votes to 23, with one abstention, a decision **to postpone granting to the Executive Director of the European Medicines Agency discharge for the implementation of the Agency's budget** for the financial year 2009.

Noting that the Court of Auditors qualified its opinion on the legality and regularity of the underlying transactions, Parliament **postpones the closure of the Agency's accounts**. It also adopted by 620 votes to 7, with 12 abstentions, a resolution in which it makes a series 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: Parliament cites serious shortcomings in the responses to issues raised by the Court of Auditors such as: i) the management of procurement procedures, ii) 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, and iii) 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,
- 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, Parliament makes the following comments:

- **Procurement procedures:** Parliament notes serious errors in the procurement procedures corresponding to a significant amount of the Agency's total budget for the financial year of 2009. It notes that the Agency again failed to comply with various requirements of the relevant procurement regulations. It does not accept the Agency's attempts to justify itself on this point and expects 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. It also invites the Agency to ensure that the results of procurement procedures are checked before contracts are concluded;
- **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), Parliament stresses that this situation indicates delays in the implementation of activities financed from the Agency's budget. It points out that this has also occurred in the past;
- **Revenue from fees:** Parliament expects 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:** Parliament expects 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. It expects the Agency to manage such transactions to avoid exchange losses (such as those in 2009 of EUR 900 000). It also calls for an improvement in the Agency's treasury management;

Performance: Parliament considers the assessment of the adequacy and effectiveness of the systems in place to support the provision of scientific advice for human medicines in the Agency as an important tool to measure the Agency's performance; acknowledges that the IAS performed audits and found critical deficiencies in this respect, in particular in the following areas:

- **Management of conflicts of interest:** Parliament considers 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. It particularly deplores t**he 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 its view, this casts some doubt on the actual **independence of the Agency**. It considers it unacceptable that the Agency is not complying effectively with its Code of Conduct by **setting out principles and guidance on independence and confidentiality** applicable to the Management Board and committees' members, experts and Agency's staff. Parliament awaits that the Agency assesses thoroughly, before the allocation of project team leaders to products, whether the interests declared by staff members might influence their impartiality and independence. It urges the Agency, in addition, to document and assess its controls and file the relevant allocation decisions which must be made available on its website. Parliament stresses that the Agency's reputation could be affected in cases where evaluations can be challenged on the grounds of possible conflicts of interest. It urges the Agency to inform the discharge authority of the steps it has taken to ensure the independence of its experts since its inception and wonders why the Court of Auditors' reports since 2006 make no mention of any deficiencies in this respect;
- **The Mediator case:** on this issue, the plenary asks, in an amendment, to be informed if and how the experts and staff dealing with any of the benfluorex group of drugs were screened on their independence and how their interests declared were verified;
- **Procedures supporting the provision of scientific evaluation for human medicines:** Parliament considers it unacceptable for the Agency to allow the information in its files on human medicines to be incomplete. It urges the Agency to be more transparent, as well as to complete and regularly update the European Experts Database;
- **Role of the Agency and national competent authorities:** Parliament urges 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. **It considers 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;
- **Human resources management:** Parliament calls on the Agency to ensure that sensitive tasks are not assigned to interim staff. It stresses the risks of potential security breaches linked to interim staff's access to sensitive information or lack of awareness by interim staff of the procedure to follow. It calls on the Agency to strengthen its recruitment process and ensure its documentation is correctly managed. It stresses, 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;

Internal audit: Parliament considers it unacceptable that the Executive Director's statement of assurance, dated 13 May 2010, does not mention any reservations, and is consequently inconsistent with the undertaking given in the Code of Conduct adopted by the Agency in the light of the statements of assurance from the IAS and the Court of Auditors. It recalls that the Executive Director's report is required to contain a summary of the content of the reports from the IAS to the discharge authority and wonders if these requirements were met in previous years. Parliament calls on the Agency to forward the IAS reports since 2007 to the discharge authority by 30 June 2011. Parliament acknowledges that, out of the 32 recommendations of the 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 and on other procedures supporting the provision of scientific evaluation for human medicines in the Agency. It calls, 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: Parliament urges 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. It expects the Governing Board swiftly to adopt an action plan to remedy the shortcomings in the procurement procedures, as well as measures to improve the Agency’s management.