

P7_TA-PROV(2011)0202

2009 discharge: European Medicines Agency

1. European Parliament decision of 10 May 2011 on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2009 (C7-0233/2010 – 2010/2173(DEC))

The European Parliament,

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2009,
 - having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2009, together with the Agency's replies¹,
 - having regard to the Council's recommendation of 15 February 2011 (05892/2011 – C7-0052/2011),
 - having regard to Article 276 of the EC Treaty and Article 319 of the Treaty on the Functioning of the European Union,
 - having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities², and in particular Article 185 thereof,
 - having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004³ establishing a European Medicines Agency, and in particular Article 68 thereof,
 - having regard to Commission Regulation (EC, Euratom) No 2343/2002⁴ of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Regulation (EC, Euratom) No 1605/2002, and in particular Article 94 thereof,
 - having regard to Rule 77 of, and Annex VI to, its Rules of Procedure,
 - having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on the Environment, Public Health and Food Safety (A7-0153/2011),
1. Postpones 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 2009;
 2. Sets out its observations in the resolution below;
 3. Instructs its President to forward this Decision and the resolution that forms an integral part

¹ OJ C 338, 14.12.2010, p. 28.

² OJ L 248, 16.9.2002, p. 1.

³ OJ L 136, 30.4.2004, p. 1.

⁴ OJ L 357, 31.12.2002, p. 72.

of it to the Executive Director of the European Medicines Agency, the Council, the Commission and the Court of Auditors, and to arrange for their publication in the *Official Journal of the European Union* (L series).

2. European Parliament decision of 10 May 2011 on the closure of the accounts of the European Medicines Agency for the financial year 2009 (C7-0233/2010 – 2010/2173(DEC))

The European Parliament,

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2009,
 - having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2009, together with the Agency's replies¹,
 - having regard to the Council's recommendation of 15 February 2011 (05892/2011 – C7-0052/2011),
 - having regard to Article 276 of the EC Treaty and Article 319 of the Treaty on the Functioning of the European Union,
 - having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities², and in particular Article 185 thereof,
 - having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004³ establishing a European Medicines Agency, and in particular Article 68 thereof,
 - having regard to Commission Regulation (EC, Euratom) No 2343/2002⁴ of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Regulation (EC, Euratom) No 1605/2002, and in particular Article 94 thereof,
 - having regard to Rule 77 of, and Annex VI to, its Rules of Procedure,
 - having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on the Environment, Public Health and Food Safety (A7-0153/2011),
1. Postpones the closure of the accounts of the European Medicines Agency for the financial year 2009;
 2. Instructs its President to forward this Decision to the Executive Director of the European Medicines Agency, the Council, the Commission and the Court of Auditors, and to arrange for its publication in the *Official Journal of the European Union* (L series).

¹ OJ C 338, 14.12.2010, p. 28.

² OJ L 248, 16.9.2002, p. 1.

³ OJ L 136, 30.4.2004, p. 1.

⁴ OJ L 357, 31.12.2002, p. 72.

3. European Parliament resolution of 10 May 2011 with observations forming an integral part of its Decision on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2009 (C7-0233/2010 – 2010/2173(DEC))

The European Parliament,

- having regard to the final annual accounts of the European Medicines Agency (EMA) for the financial year 2009,
 - having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2009, together with the Agency's replies¹,
 - having regard to the Council's recommendation of 15 February 2011 (05892/2011 – C7-0052/2011),
 - having regard to Article 276 of the EC Treaty and Article 319 of the Treaty on the Functioning of the European Union,
 - having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities², and in particular Article 185 thereof,
 - having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004³ establishing a European Medicines Agency, and in particular Article 68 thereof,
 - having regard to Commission Regulation (EC, Euratom) No 2343/2002⁴ of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Regulation (EC, Euratom) No 1605/2002, and in particular Article 94 thereof,
 - having regard to the Internal Audit Service's Annual Internal Audit Report on the European Medicines Agency for 2009;
 - having regard to Rule 77 of, and Annex VI to, its Rules of Procedure,
 - having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on the Environment, Public Health and Food Safety (A7-0153/2011),
- A. whereas the Court of Auditors, in its report on the annual accounts of the European Medicines Agency for the financial year 2009, qualified its opinion on the legality and regularity of the underlying transactions,

¹ OJ C 338, 14.12.2010, p. 28.

² OJ L 248, 16.9.2002, p. 1.

³ OJ L 136, 30.4.2004, p. 1.

⁴ OJ L 357, 31.12.2002, p. 72.

- B. whereas on 5 May 2010 Parliament granted the Executive Director of the Agency discharge for implementation of the Agency's budget for the financial year 2008¹, and in its resolution accompanying the discharge decision, inter alia:
- was concerned by the Court of Auditors' findings that the budget appropriations carried over and cancelled have amounted to EUR 36 000 000 (19,7 % of the budget) and EUR 9 700 000 (5,3 % of the budget) respectively,
 - called on the Agency to improve the quality of its procurement procedures in order to put an end to the shortcomings identified by the Court of Auditors (for instance, as regards the application of evaluation methods for the price criteria and as regards the essential need for justifications for the choice of procedures),
- C. whereas the budget of the Agency for 2009 was EUR 194 000 000, which is an increase of 6,28 % on the financial year 2008,
- D. whereas the Agency's budget is financed both from the Union budget, which accounted for 18,52 % of total revenue in 2009, and, to a greater extent, from fees paid by pharmaceutical companies, and whereas the Union's general contribution consequently decreased by 9,2 % between 2008 and 2009,

General considerations

1. Is seriously concerned with the Agency's replies to significant issues raised by the Court of Auditors and the Internal Audit Service (IAS), such as:
 - (i) the management of procurement procedures,
 - (ii) the lack of respect to implementing procedures regarding the identification and management of conflicts of interest for its staff and experts,
 - (iii) the criteria used for recruiting staff;
2. Considers, in particular, that the above-mentioned aspects could lead to the possibility of:
 - (i) persistent errors in the management of procurement procedures, such as the ones found in 2009 corresponding to a significant amount of the Agency's total budget, which could compromise the legality and regularity of the transactions underlying the Agency's accounts,
 - (ii) potential risks to the independence of experts/staff involved in the evaluation of medicinal products,
 - (iii) potential deficiencies in staff/experts' recruitment which could not only lead to disqualification of competent candidates and/or recruitment of less qualified candidates but also might have negative effects on the quality of the Agency's scientific assessment work;

Budgetary and financial management

¹ OJ L 252, 25.9.2010, p. 164.

Procurement procedures

3. Is concerned at the Court of Auditors' findings of errors in the procurement procedures corresponding to a significant amount of the Agency's total budget for the financial year of 2009; stresses that in 2008 the Court of Auditors already identified shortcomings in this matter and, in particular, in the application of evaluation methods for the price criteria and in the justification for the choice of procedures;
4. Acknowledges, in particular, that in a number of procedures for the procurement of large IT framework contracts of an estimated value of EUR 30 000 000 the Agency made several errors in 2009 at the moment of opening the procedure such as:
 - (i) arithmetical errors in the evaluation of the award criteria,
 - (ii) inappropriate documentation of the evaluation by a member of the evaluation committee,
 - (iii) a lack of evidence that the evaluation method of the selection criteria had been applied consistently which was thus open to interpretation,
 - (iv) a lack of checks to mitigate the risk of errors when opening a negotiated procedure which, in turn, did not guarantee that best value for money was achieved as a result of errors in the implementation of the award criteria;
5. Acknowledges, also, that in two other negotiated procurements of EUR 5 300 000 and EUR 4 000 000 with a single supplier, several errors were again made at the moment of opening the procedure such as:
 - (i) no formal invitation to tender being issued,
 - (ii) no detailed technical specifications being prepared in advance,
 - (iii) technical specifications not clearly defining all the products to be purchased before the negotiation started,
 - (iv) no evaluation committee being appointed,
 - (v) no evaluation report being prepared;
6. Takes note therefore, that the Agency failed to comply with various requirements of the relevant procurement regulations;
7. Is not ready to accept that the Agency was not able to put in place a control system to avoid or detect in time the above persistent errors which undermine the legality and regularity of the transaction underlying the Agency's accounts; accordingly, urges the Agency to improve the quality of its procurement procedures in order to put an end to the shortcomings identified by the Court of Auditors;
8. Calls on the Agency to set up a multiannual procurement plan which shall ensure stronger technical and procedural controls and to report to the discharge authority on this matter by 30 June 2011;

9. Calls on the Agency to ensure that the results of procurement procedures are verified before contracts are awarded; expects that detailed technical specifications shall always be prepared, in view of the Court of Auditors' findings;

Carryover appropriations

10. Is concerned that the Court of Auditors has reported a carryover of EUR 19 500 000 (38 % of the Agency's commitments) and that approximately EUR 14 800 000 of this carryover was for activities as yet not implemented (or, in some cases, goods not received) at the year-end; stresses that this situation indicates delays in the implementation of activities financed from Title II (Buildings, equipment and miscellaneous operating expenditure activities) of the Agency's budget and that the Agency is not in accordance with the budgetary principle of annuality; has assessed the answer by the Agency on the observations and welcomes the efforts to reduce carryovers by the Agency; encourages the Agency to continue this process in order to apply fully the principle of annuality;
11. Points out that the Court of Auditors had already reported high level of carryovers in previous financial years and is concerned that this situation is at odds with the annuality principle; notes, in particular, that the 2008 budget appropriations carried over and cancelled amounted to EUR 36 000 000 (19,7 % of the 2008 budget) and EUR 9 700 000 (5,3 % of the 2008 budget) respectively;

Revenue from fees

12. Calls on the Agency to ensure better coordination between its financial and scientific services in order to remedy the unacceptable, long delay for recovery orders; notes, in fact, that the Court of Auditors reported that two recovery orders (EUR 226 200 and EUR 110 200), out of ten tested, had a very long delay (21 and 5 months respectively), in breach of the Agency's internal rules;
13. Emphasises that the 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; notes, however, that the contribution from the Union budget represents only 18,7 % of the overall budget and has decreased over the years, for example, in 2005 the contribution represented 22,7 %; stresses that the overall budget available to the Agency was EUR 194 389 000;

Foreign-exchange contracts

14. 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; expects the Agency to prudently manage such transactions to avoid exchange losses, such as those in 2009 of EUR 900 000; points out that this is a recurrent observation made by the Court of Auditors; requests the Agency to communicate its revised treasury policy to Parliament's competent committee without delay; will monitor the revised treasury policy;
15. Notes from the Agency that the treasury policy has been revised, adopted and formally approved by the Agency's Audit Advisory Committee; calls on the Agency to provide Parliament with an overview of the implementation of the revised treasury policy before 30 June 2011;

Performance

16. 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;

Management of conflicts of interest

17. Finds 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; points out that twelve "very important" and one "critical" recommendation from several earlier IAS Annual Audit Reports on the Agency, most of them concerning the independence of experts, were still not implemented in 2009, while the oldest recommendation dates back to 2005;
18. Takes note of the employment 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; stresses that this move casts some doubt on the actual independence of the Agency; notes that Article 16 of the Staff Regulations of Officials of the European Union¹ grants wide discretionary power on the Management Board to allow or forbid this type of employment; notes that after consenting to the future employment of the Agency's former Executive Director, the Management Board eventually decided to set limitations with regards to his new and future professional activities; asks, nevertheless, that the Agency provides the discharge authority, by 30 June 2011, with a report that lists all comparable cases that have occurred since the creation of the Agency and explains thoroughly the Management Board's decision in each case;
19. 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; expects the Agency to assess thoroughly, before the allocation of project team leaders to products, whether the interests declared by staff members might influence their impartiality and independence; urges, in addition, the Agency to document and assess its controls and file the relevant allocation decisions which must be made available on its website;
20. Stresses that the Agency's reputation could be affected in cases where evaluations can be challenged on the grounds of possible conflicts of interest;
21. Urges the Agency to inform the discharge authority of the steps it has taken to ensure the independence of its experts since its inception;
22. Wonders why the Court of Auditors' reports since 2006 on the Agency's annual accounts make no mention of any deficiencies with regard to the assessment of experts' independence;

¹ OJ L 56, 4.3.1968, p. 1.

23. Asks 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

24. Considers it unacceptable for the Agency to allow the information in its files on human medicines to be incomplete; urges, in this respect, the Agency to guarantee that key information is easily retrieved and all relevant guidelines on the filing system are in place;
25. Asks the Agency, moreover, to complete and regularly update the European Experts Database as required by Regulation (EC) No 726/2004, and to keep the discharge authority informed; urges also the Agency to allow SIAMED and Product Overview databases for efficient retrieval of information;

Role of the Agency and national competent authorities

26. 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, and of the level of its implementation, including a detailed record of how it has evolved over time; 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;

Scientific advice

27. Welcomes the efforts of the Agency to provide more scientific advice at the early stages of the development of new medicines as well as the introduction of measures to accelerate the assessment of medicines that are of critical importance to public health and to accelerate the development and implementation of telematics' programmes;

Human resources management

28. Calls on the Agency to ensure that sensitive tasks are not assigned to interim staff; acknowledges, in fact, that the Agency hires interim staff (32 in 2009) on the condition that the candidates have passed the tests for contract agents and some of the interim staff perform sensitive tasks or have access to sensitive information; stresses 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;
29. Calls on the Agency to strengthen its recruitment process and ensure its documentation is correctly managed; acknowledges, in fact, that the IAS found deficiencies in this respect; 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; considers, furthermore, that to the extent that competition is limited, resulting recruitment may not represent the optimal choice and human and financial resources may be used inefficiently;

Internal audit

30. 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;
31. Points out that the Executive Director's report is required to contain a summary of the reports from the IAS to the discharge authority, including:
- (i) the number and types of internal audits conducted by the IAS,
 - (ii) all the recommendations made (including any that may have been rejected by the Agency), and
 - (iii) all the measures taken on the basis of those recommendations;
- wonders whether these requirements were fulfilled in previous years, and asks the Agency to forward the IAS reports since 2007 to the discharge authority by 30 June 2011;
32. Notes the Agency's initiative of providing the discharge authority with the IAS Annual Internal Audit Report on the Agency; considers that this should be the normal practice of transparency and expects that all other agencies will follow this practice;
33. 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; calls, therefore, on the Agency to inform the discharge authority about the precise content of these recommendations without delay; urges the Agency to rapidly implement the IAS recommendations and to provide the discharge authority with a complete overview of measures taken and implemented to properly address these recommendations by 30 June 2011; asks, in addition, the Court of Auditors to monitor and inform the discharge authority of the efficiency of the measures taken;

Actions to be taken by the Agency by 30 June 2011

34. Urges the Agency's Executive Director, in cooperation with the IAS, 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;
35. Expects the Governing Board swiftly to adopt an action plan to remedy the shortcomings in the procurement procedures; asks, in particular, the Agency's Executive Director, in cooperation with the IAS and the parent directorate-general (DG), to draft this action plan which shall include specific measures and a timetable for implementation; expects the Agency to communicate these specific measures to the discharge authority by 30 June 2011;
36. Calls on the Agency, therefore, to inform the discharge authority by 30 June 2011 of the measures taken and the improvements made in respect of all these areas of concern;

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37. Refers, in respect of the other observations accompanying its Decision on discharge, which are of a horizontal nature, to its resolution of 10 May 2011¹ on the performance, financial management and control of the agencies.

¹ Texts adopted, P7_TA-PROV(2011)0163.