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*Plenary sitting*

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**A7-0329/2011**

6.10.2011

## **SECOND REPORT**

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))

Committee on Budgetary Control

Rapporteur: Georgios Stavrakakis

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## 1. PROPOSAL FOR A EUROPEAN PARLIAMENT 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 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 replies<sup>1</sup>,
- having regard to the Council's recommendation of 15 February 2011 (05892/2011 – C7-0052/2011),
- having regard to its decision of 10 May 2011<sup>2</sup> postponing the discharge decision for the financial year 2009, and the replies by the Executive Director of the European Medicines Agency,
- 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 Communities<sup>3</sup>, 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 2004<sup>4</sup> establishing a European Medicines Agency and in particular Article 68 thereof,
- having regard to Commission Regulation (EC, Euratom) No 2343/2002<sup>5</sup> 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 letter of the Chair of the Agency's Management Board to the Chair of the Committee on Budgetary Control of the European Parliament of 17 June 2011 (EMA/441533/2011),
- having regard to the Agency's replies to Parliament's resolution of 10 May 2011<sup>6</sup> accompanying its abovementioned Decision on discharge for the financial year 2009,

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<sup>1</sup> OJ C 338, 14.12.2010, p. 28.

<sup>2</sup> OJ L 250, 27.9.2011, p. 173.

<sup>3</sup> OJ L 248, 16.9.2002, p. 1.

<sup>4</sup> OJ L 136, 30.4.2004, p. 1.

<sup>5</sup> OJ L 357, 31.12.2002, p. 72.

<sup>6</sup> OJ L 250, 27.9.2011, p. 182.

- having regard to the Annual Internal Audit Reports for 2009, 2008 and 2007 of the Commission's Internal Audit Service (IAS) on the Agency,
  - having regard to the final follow-up report on the audits of 2009, 2008 and 2006 of the IAS on the Agency,
  - having regard to Rule 77 of, and Annex VI to, its Rules of Procedure,
  - having regard to the second report of the Committee on Budgetary Control (A7-0329/2011),
1. Grants 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 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. PROPOSAL FOR A EUROPEAN PARLIAMENT DECISION

**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 replies<sup>1</sup>,
- having regard to the Council's recommendation of 15 February 2011 (05892/2011 – C7-0052/2011),
- having regard to its decision of 10 May 2011<sup>2</sup> postponing the discharge decision for the financial year 2009, and the replies by the Executive Director of the European Medicines Agency,
- 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 Communities<sup>3</sup>, 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 2004<sup>4</sup> establishing a European Medicines Agency and in particular Article 68 thereof,
- having regard to Commission Regulation (EC, Euratom) No 2343/2002<sup>5</sup> 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 letter of the Chair of the Agency's Management Board to the Chair of the Committee on Budgetary Control of the European Parliament of 17 June 2011 (EMA/441533/2011),
- having regard to the Agency's replies to Parliament's resolution of 10 May 2011<sup>6</sup> accompanying its abovementioned Decision on discharge for the financial year 2009,

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<sup>1</sup> OJ C 338, 14.12.2010, p. 28.

<sup>2</sup> OJ L 250, 27.9.2011, p. 173.

<sup>3</sup> OJ L 248, 16.9.2002, p. 1.

<sup>4</sup> OJ L 136, 30.4.2004, p. 1.

<sup>5</sup> OJ L 357, 31.12.2002, p. 72.

<sup>6</sup> OJ L 250, 27.9.2011, p. 182.

- having regard to the Annual Internal Audit Reports for 2009, 2008 and 2007 of the Commission's Internal Audit Service (IAS) on the Agency,
  - having regard to the final follow-up report on the audits of 2009, 2008 and 2006 of the IAS on the Agency,
  - having regard to Rule 77 of, and Annex VI to, its Rules of Procedure,
  - having regard to the second report of the Committee on Budgetary Control (A7-0329/2011),
1. Approves 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).

### 3. MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

**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 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 replies<sup>1</sup>,
- having regard to the Council's recommendation of 15 February 2011 (05892/2011 – C7-0052/2011),
- having regard to its decision of 10 May 2011<sup>2</sup> postponing the discharge decision for the financial year 2009, and the replies by the Executive Director of the European Medicines Agency,
- 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 Communities<sup>3</sup>, 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 2004<sup>4</sup> establishing a European Medicines Agency and in particular Article 68 thereof,
- having regard to Commission Regulation (EC, Euratom) No 2343/2002<sup>5</sup> 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 letter of the Chair of the Agency's Management Board to the Chair of the Committee on Budgetary Control of the European Parliament of 17 June 2011 (EMA/441533/2011),
- having regard to the Agency's replies to Parliament's resolution of 10 May 2011<sup>6</sup> accompanying its abovementioned Decision on discharge for the financial year 2009,

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<sup>1</sup> OJ C 338, 14.12.2010, p. 28.

<sup>2</sup> OJ L 250, 27.9.2011, p. 173.

<sup>3</sup> OJ L 248, 16.9.2002, p. 1.

<sup>4</sup> OJ L 136, 30.4.2004, p. 1.

<sup>5</sup> OJ L 357, 31.12.2002, p. 72.

<sup>6</sup> OJ L 250, 27.9.2011, p. 182.

- having regard to the Annual Internal Audit Reports for 2009, 2008 and 2007 of the Commission's Internal Audit Service (IAS) on the Agency,
  - having regard to the final follow-up report on the audits of 2009, 2008 and 2006 of the IAS on the Agency,
  - having regard to Rule 77 of, and Annex VI to, its Rules of Procedure,
  - having regard to the second report of the Committee on Budgetary Control (A7-0329/2011),
- 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,
- B. whereas in its abovementioned Decision of 10 May 2011 Parliament decided to postpone its decision on granting the Executive Director of the Agency discharge in respect of the implementation of the Agency's budget for the financial year 2009,
- 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's annual budget, which accounted for 18,52 % of total revenue in 2009, and, to a greater extent, from fees paid by pharmaceutical companies for services which may spread across more than one financial year, and whereas the Union's general contribution consequently decreased by 9,2 % between 2008 and 2009,
- E. whereas the discharge authority received replies from the Agency following Parliament's abovementioned resolution of 10 May 2011,
- F. whereas in its replies to Parliament the Agency updated the discharge authority on the level of implementation of the IAS' recommendations, stating that:
- from the 2009 IAS audit on Human Resources Management, one of the three "very important" recommendations has now been implemented and the other two are under way,
  - from the 2008 IAS audit on Selection administrative procedures supporting the provision of scientific evaluation for human medicines in the Agency, the "critical" recommendation and one "very important" recommendation (management of conflicts of interest of staff & specific guidelines) have respectively been downgraded to "very important" and "important", while three "very important" recommendations have now been implemented,
  - from the 2005 IAS audit on Implementation of the Internal Control Standards (ICS), one of the two "very important" recommendations has now been implemented,

## ***GENERAL ASSESSMENT***



1. Acknowledges receipt of a letter of the Chair of the Agency's Management Board of 17 June 2011 in which it is stated that the Agency has taken actions to address the 2009 shortcomings; also takes note of the documents and annexes received from the Agency in response to Parliament's abovementioned resolution of 10 May 2011; also acknowledges receipt of a letter of the Agency's Acting Executive Director of 10 August 2011, following the questions raised during the debate on discharge to the Agency for 2009 at the meeting of Parliament's Committee on Budgetary Control of 13 July 2011; regrets, however, that not all the information requested was submitted;
2. Notes, however, that the Agency should continue to inform on a three-monthly basis the discharge authority on the results of the actions requested by the discharge authority;
3. Underlines that the discharge authority shall continue to carefully monitor during the upcoming discharge procedures the level of implementation of the measures undertaken to address the Agency's serious weaknesses disclosed by the reports from both the Court of Auditors and the IAS; expects, therefore, the Agency to inform the discharge authority on the actions implemented and their results and to submit the documents requested, especially with regard to the following issues:
  - a. the process of the adoption by the Management Board of the action plan with specific measures and a timetable for implementation to remedy the shortcomings in the procurement procedures;
  - b. the thorough verification of the effective use of the existing procedures regarding the identification and management of conflicts of interest for its staff and experts;
  - c. the submission of the IAS reports according to the Financial Regulation;

### ***SPECIFIC COMMENTS***

#### *Procurement procedures*

4. Notes the information received relating to the control system which sets out to avoid or detect in time the persistent errors in procurement procedures; expects to receive the multi-annual procurement plan; accordingly reminds the Agency to continue improving the quality of its procurement system and to comply strictly with the requirements of the relevant rules on public procurement, so as to rectify the shortcomings pointed out by the Court of Auditors;
5. Notes the initiation of the actions to develop an action plan on improving procurement procedures; calls on the Agency to proceed promptly with the adoption of an action plan to remedy the shortcomings in the procurement procedures, in particular the errors in managing contract award procedures, by providing for more rigorous technical and procedural checks, and to inform the discharge authority accordingly;
6. Recalls that in its 2009 annual report the Court of Auditors stated that the Agency did not carry out enough checks to mitigate the risk of errors on a number of procedures for the procurement of large IT framework contracts; also recalls that the audit showed errors

which affected the regularity of these operations and formed the basis for the qualified opinion on the legality and regularity of the transactions underlying the Agency's accounts by the Court of Auditors;

#### *Carryover appropriations*

7. Points out that in its annual report on the Agency for 2009, the Court of Auditors reported that approximately EUR 14 800 000 of a carryover of EUR 19 500 000 (38 % of the Agency's commitments in 2009) was for activities as yet not implemented (or, in some cases, goods not received for services which may spread across more than one financial year) at the year-end; reminds the Agency therefore to take action in this respect and looks forward to receiving assurance from the Court of Auditors on this;

#### *Revenue from fees*

8. Takes note of information from the Agency that as of 1 January 2011, the Agency introduced an integrated Enterprise Resource Planning System (ERP) with SAP as the provider to remedy its long delay for recovery orders; takes note that with this new system the Agency feeds the data from its current operational systems (e.g. SIAMED) via a dashboard directly into the financial module SAP;

#### *Foreign-exchange contracts*

9. Acknowledges the Agency's commitment to limit its risks due to exchange rate variance and that as of 11 June 2010 it revised its Treasury Policy by: establishing an internal consultation committee to advise the accounting officer on hedging strategies; limiting the hedging to 50 % of estimated requirement; and ensuring that achievable market rates match or are above the budget costing rate;

#### *Management of conflicts of interest*

10. Takes note of the Agency's replies on the compliance with its Code of Conduct by setting out principles and guidance on independence and confidentiality applicable to the Management Board and members of committees, experts and the Agency's staff; accordingly 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; expects that the Agency's documents on the conflicts of interest shall be updated;
11. Takes note of the Agency's intention to apply the IAS' recommendation from its 2010 follow-up audit by adopting a risk-based approach and focusing checks on staff who declare interests; calls on the Agency to inform the discharge authority on the timing and plan to apply this IAS' recommendation before the end of 2011;
12. Acknowledges, nevertheless, the Agency's reply in which it is stated that there is no onus on it to request or monitor the annual declaration of financial interests of experts responsible for evaluating medicinal products, as this lies with the Member States' competent authorities (Article 126b of Directive 2001/83/EC<sup>19</sup> as amended by Directive 2004/27/EC<sup>20</sup>); calls therefore on the Commission to remind the respective authorities in the Member States of their obligations in this matter;

13. Stresses that it is not only the Agency's reputation that could be affected in cases where evaluations can be challenged on the grounds of possible conflicts of interest but also that such conflicts of interest do not guarantee the optimal protection of European citizens' health;
14. Notes that, as of 1 July 2011, the new electronic Declaration of Interests (e-DoI) form went live and all experts were requested to fill in the new e-DoI and that the e-DoIs of all experts included in the Experts database have been made publicly available on the Agency's website as of 30 September 2011; also notes that the Memorandum of Understanding between the Agency and each National Competent Authority on the monitoring of the scientific level and independence of the evaluation carried out by the National Competent Authority for services to be provided to the Agency became effective as of 4 July 2011;
15. Calls on the Agency to inform the discharge authority on actions taken on issues relating to the effective compliance with its Code of Conduct as regards the management of conflicts of interest;
16. Insists, but also warns the Agency, that all the actions mentioned in the respective audit reports, including the one for the year 2010, should be fully implemented before the start of the next discharge procedure;

#### *Human resources management*

17. Takes note of the Agency's reply in which it is stated that it has corrected the deficiencies identified by the IAS for contract agent selection and that revised work instructions and templates have been put in place and the staff have received specific training; accordingly calls on the Agency to keep the discharge authority updated on the level of implementation of these actions; looks forward to the 2010 report of the Court of Auditors to establish whether the assurance from the Agency is well founded;

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18. Refers, in respect of the other observations accompanying its Decision on discharge, which are of a horizontal nature, to its resolution of 10 May 2011<sup>1</sup> on the performance, financial management and control of the agencies.

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<sup>1</sup> OJ L 250, 27.9.2011, p. 269.

## RESULT OF FINAL VOTE IN COMMITTEE

<b>Date adopted</b>	3.10.2011
<b>Result of final vote</b>	+ : 15 - : 0 0 : 2
<b>Members present for the final vote</b>	Marta Andreasen, Jean-Pierre Audy, Jorgo Chatzimarkakis, Tamás Deutsch, Jens Geier, Gerben-Jan Gerbrandy, Ingeborg Gräßle, Ville Itälä, Jan Mulder, Jan Olbrycht, Crescenzo Rivellini, Bart Staes, Georgios Stavrakakis, Søren Bo Søndergaard
<b>Substitute(s) present for the final vote</b>	Zuzana Brzobohatá, Edit Herczog, Véronique Mathieu, Theodoros Skylakakis