

2008 discharge: European Medicines Agency

1. European Parliament decision of 5 May 2010 on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2008 (C7-0189/2009 – 2009/2118(DEC))

The European Parliament,

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2008,
 - having regard to the Court of Auditors' report on the final annual accounts of the European Medicines Agency for the financial year 2008, together with the Agency's replies¹,
 - having regard to the Council's recommendation of 16 February 2010 (5827/2010 – C7-0061/2010),
 - 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 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Regulation (EC, Euratom) No 1605/2002⁴, 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 (A7-0078/2010),
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 2008;
 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

¹ OJ C 304, 15.12.2009, p. 27.

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.

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 5 May 2010 on the closure of the accounts of the European Medicines Agency for the financial year 2008 (C7-0189/2009 – 2009/2118(DEC))

The European Parliament,

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2008,
 - having regard to the Court of Auditors' report on the final annual accounts of the European Medicines Agency for the financial year 2008, together with the Agency's replies¹,
 - having regard to the Council's recommendation of 16 February 2010 (5827/2010 – C7-0061/2010),
 - 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 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Regulation (EC, Euratom) No 1605/2002⁴, 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 (A7-0078/2010),
1. Approves the closure of the accounts of the European Medicines Agency for the financial year 2008;
 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 304, 15.12.2009, p. 27.

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 5 May 2010 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 2008 (C7-0189/2009 – 2009/2118(DEC))

The European Parliament,

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2008,
 - having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2008, together with the Agency's replies¹,
 - having regard to the Council's recommendation of 16 February 2010 (5827/2010 – C7-0061/2010),
 - 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 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Regulation (EC, Euratom) No 1605/2002⁴, 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 (A7-0078/2010),
- A. whereas the Court of Auditors states that it has obtained reasonable assurances that the annual accounts for the financial year 2008 are reliable, and that the underlying transactions are legal and regular,
- B. whereas on 23 April 2009 Parliament granted the Executive Director of the European Medicines Agency discharge in respect of the implementation of the Agency's budget for the financial year 2007⁵, and in its resolution accompanying the discharge decision noted, *inter alia*:
- weaknesses in budgetary management concerning the Telematics Programme,

¹ OJ C 304, 15.12.2009, p. 27.

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.

⁵ OJ L 255, 26.9.2009, p. 117.

- weaknesses as regards procurement procedures,
 - progress towards ensuring compliance with the fee regulation;
1. Notes that in 2008 the Agency's budget amounted to EUR 182 900 000, compared to EUR 163 100 000 in the previous year; notes furthermore that the Agency received 2,4 % less by way of Community contribution than in 2007, the Community contribution amounting to EUR 34 000 000 in 2008;

Performance

2. Congratulates the Agency on having put in place sophisticated activity-based budgeting and user-satisfaction monitoring; also notes that the Agency is currently examining the functioning of its committee structure to enhance interactions in the light of an increase in the number of scientific committees and related scientific work;

Carry-over of appropriations

3. Is concerned that the Court of Auditors has pointed out that the budget appropriations carried over and cancelled have amounted respectively to EUR 36 000 000 (19,7 % of the budget) and EUR 9 700 000 (5,3 % of the budget); points out, as noted in previous financial years, that the high level of carry-overs for administrative expenditure – EUR 21 400 000 – was mainly due to IT expenditure for setting up a telematics programme for the regulation of medical products; is consequently concerned, as this situation has existed for a number of years and is at odds with the annuality principle;

Procurement procedures

4. Calls on the Agency to improve the quality of its procurement procedures so as 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);
5. Takes note of the Agency's longstanding policy of entering into a forward foreign exchange contract in order to hedge part of its administrative budget against unfavourable fluctuations in the exchange rate of sterling; expects the Agency to manage such transactions prudently; recommends that a working group be set up to observe and closely monitor the hedging strategy;

Revenue from fees

6. Points out that the fees charged for evaluation services are the main source of the Agency's revenue, accounting for 70,2 % of its total revenue in 2008; draws attention in this context to the importance of the instrument for assigned revenue, designed for agencies whose revenue derives from fees, for dealing with unforeseeable market trends;
7. Notes that the Agency reported EUR 2 046 000 in income from interest in 2008; concludes from the financial statements and from the level of the interest payments that the Agency has a permanently extremely high level of cash holdings; notes that on 31 December 2008 the Agency's cash holdings amounted to EUR 41 887 000; asks the Commission to examine what scope there is for helping to ensure that the cash holdings are managed entirely on a needs-orientated basis, in accordance with Article 15(5) of Regulation (EC, Euratom)

No 2343/2002, and what changes of approach are necessary in order to keep the Agency's cash holdings permanently as low as possible;

Human resources

8. Observes that the authorised establishment plan provided for 481 posts in 2008, of which 469 were filled by the end of 2008; notes that an additional 41 support staff (auxiliary, contractual, national experts on secondment) were recruited in 2008, and that the total number of staff thus amounted to 587;

Internal audit

9. Acknowledges that the Commission's Internal Audit Service in its audit report made one 'critical' recommendation, relating to the area of experts' conflicts of interests, and eight 'very important' recommendations, in the areas of documentation of conflicts of interest for the Agency's staff, databases used to support the administrative procedures for evaluation and development of guidelines for filing and full implementation of such guidelines;
10. Congratulates the Agency on having adopted a code of conduct setting out principles and guidance on independence and confidentiality applicable to Board and Committee members, experts and the Agency's staff;

o

o o

11. Refers, for other observations accompanying its Decision on discharge, which are of a horizontal nature, to its resolution of 5 May 2010¹ on the performance, financial management and control of the agencies.

¹ Texts adopted, P7_TA(2010)0139.