European Parliament
2014 - 2019

TEXTS ADOPTED

P8_TA(2015)0147

Discharge 2013: European Medicines Agency (EMA)

1. European Parliament decision of 29 April 2015 on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2013 (2014/2102(DEC))

The European Parliament,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2013,

– having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2013, together with the Agency's replies[1],

– having regard to the statement of assurance[2] as to the reliability of the accounts and the legality and regularity of the underlying transactions provided by the Court of Auditors for the financial year 2013, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of 17 February 2015 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2013 (05304/2015 – C8-0054/2015),

– having regard to 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[3],

– having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002[4], and in particular Article 208 thereof,

– having regard to Regulation (EC) No 726/2004 of the European Parliament and of the

1 OJ C 442, 10.12.2014, p. 193.
2 OJ C 442, 10.12.2014, p. 193.
3 OJ L 248, 16.9.2002, p. 1.
4 OJ L 298, 26.10.2012, p. 1.

Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], 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 Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities[2],

– having regard to Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council[3], and in particular Article 108 thereof,

– having regard to Rule 94 of and Annex V 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 (A8-0075/2015),

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 2013;

2. Sets out its observations in the resolution below;

3. Instructs its President to forward this decision, and the resolution forming 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).

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 357, 31.12.2002, p. 72.
3 OJ L 328, 7.12.2013, p. 42.

2. European Parliament decision of 29 April 2015 on the closure of the accounts of the European Medicines Agency for the financial year 2013 (2014/2102(DEC))

The European Parliament,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2013,

– having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2013, together with the Agency's replies[1],

– having regard to the statement of assurance[2] as to the reliability of the accounts and the legality and regularity of the underlying transactions provided by the Court of Auditors for the financial year 2013, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of 17 February 2015 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2013 (05304/2015 – C8-0054/2015),

– having regard to 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[3],

– having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002[4], and in particular Article 208 thereof,

– having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[5], 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 Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities[6],

– having regard to Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and

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1 OJ C 442, 10.12.2014, p. 193.
2 OJ C 442, 10.12.2014, p. 193.
3 OJ L 248, 16.9.2002, p. 1.
4 OJ L 298, 26.10.2012, p. 1.
5 OJ L 136, 30.4.2004, p. 1.
6 OJ L 357, 31.12.2002, p. 72.

of the Council[1], and in particular Article 108 thereof,

– having regard to Rule 94 of and Annex V 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 (A8-0075/2015),

1. Notes that the final annual accounts of the European Medicines Agency are as annexed to the Court of Auditors' report;

2. Approves the closure of the accounts of the European Medicines Agency for the financial year 2013;

3. 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 L 328, 7.12.2013, p. 42.

3. European Parliament resolution of 29 April 2015 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2013 (2014/2102(DEC))

The European Parliament,

– having regard to its decision on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2013,

– having regard to Rule 94 of and Annex V 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 (A8-0075/2015),

A. whereas, according to its financial statements, the final budget of the European Medicines Agency ("the Agency") for the financial year 2013 was EUR 251 560 000, representing an increase of 13,07 % compared to 2012;

B. whereas according to its financial statements, the overall contribution of the Union to the Agency's budget for 2013 amounted to EUR 40 937 951, (17,03 %), representing a decrease of 3,54 % compared to 2012;

C. whereas the Court of Auditors, in its report on the annual accounts the European Medicines Agency for the financial year 2013 ("the Court's report"), has stated that it has obtained reasonable assurances that the Agency's annual accounts are reliable and that the underlying transactions are legal and regular;

D. whereas the Agency operates through a network and coordinates the scientific resources made available by the national authorities in order to ensure the evaluation and supervision of medicinal products for human or veterinary use;

1. Reiterates the Agency's important role in protecting and promoting public and animal health by assessing and supervising medicines for human or veterinary use;

Follow-up of 2012 discharge

2. Notes from the Court's report that regarding three comments made in the Court's 2011 report and marked as "Ongoing" or "Outstanding" in the Court's 2012 report, corrective actions were taken and those comments are now marked in the Court's 2013 report as "Completed"; notes furthermore that regarding the six comments made in the Court's 2012 report, two corrective actions were taken and two comments are now marked as "Completed", three as "Not Applicable" and one as "Ongoing";

3. Acknowledges from the Agency that:

   – its accounting system in the area of intangible fixed assets, which is a fully integrated part of the Agency's global enterprise and resource planning financial and accounting system, was validated during 2013;

– the involvement of individual patient, consumer and healthcare professionals in the evaluation of specific products is conditioned by the submission of a declaration of interests according to the Agency's policy on conflicts of interests;

– in order to improve its communication with Union citizens, the Agency has recently implemented several initiatives such as the publication of strategic documents including summaries for the public, meeting highlights, newsletters or annual reports; notes furthermore in this regard the development of IT communication tools such as 'Public health communication' which provides the public with key information on medicines, mainly on their safety; in this regard encourages the Agency to set the pharmacovigilance public hearings;

Budget and financial management

4. Notes that budget monitoring efforts during the financial year 2013 resulted in a budget implementation rate of 96,76 %, and in a payment appropriations execution rate of 83,49 %;

5. Notes that 83% of the Agency´s budget comes from industry fees, representing a gradual increase; emphasises the importance of complete transparency about this aspect of the budget in order to avoid any risks for consumers´ rights or the Agency´s reputation;

Commitments and carry-overs

6. Acknowledges that the Court of Auditors' annual audit has found no notable issues as regards the level of carry-overs in 2013; takes note of the Agency's compliance with the principle of annuality and the timely execution of its budget;

Transfers

7. Notes with satisfaction that according to the Agency's annual activity report, as well as the Court of Auditors' audit findings, the level and nature of transfers in 2012 have remained within the limits of the financial rules;

Procurement and recruitment procedures

8. Acknowledges from the Agency that during 2013, a total of 30 new procurement contracts, each exceeding EUR 25 000, were concluded following procurement procedures as compared to 43 in 2012 and 28 in 2011; notes that the total value of these new contracts was EUR 36 789 410;

9. Welcomes the fact that 583 of 611 available posts had been filled by the end of 2013 and that 144 contract agents, seconded national experts and employment agency staff were employed by the Agency; notes that the occupation rate has decreased compared to 2012 and that the proportion of contract staff, seconded national experts and employment agency staff has decreased compared to 2012; notes that the Agency is dedicating 81 % of its human resources to operational tasks and that this represents a slight increase compared to the situation in 2012; encourages the Agency to make further progress on this path;

10. Notes that the Agency faced some controversy regarding several cases concerning recruitment procedures in the past; calls on the Agency to always ensure complete transparency and clarification with regard to the recruitment procedure;

Prevention and management of conflicts of interests and transparency

11. Acknowledges from the Agency that the transparency criteria for partner, patient, healthcare and consumer organisations has been revised during 2014 in order to increase the transparency of funding; notes the adoption of the document with detailed criteria regarding the evaluation of financial information from patients, consumers and healthcare professionals organisations; notes furthermore that this document is used to assess the organisations' eligibility to participate in the dialogue with the Agency; recalls that the document also states that the organisations have to declare any conflicts of interests at the start of the meetings through which the dialogue is commenced; notes with regret the reduction of the cooling-off period from five years to three years; notes with regret that the arbitrary distinction between direct and indirect conflicts of interests has been kept; calls on the Agency to furthermore introduce a list of the patients´ organisations it is working with and to place it on its website, linking it to the funding sources of these organizations in order to enhance transparency;

12. Acknowledges that the Agency complied with the recommendation made by the discharge authority that a specific part of its annual activity report be devoted to the prevention and management of conflicts of interests;

13. Notes that the Agency's Management Board has endorsed a revised policy on the handling of declarations of interests of members of scientific committees and experts; notes with satisfaction that this policy entered into force on 30 January 2015; regrets that the main loopholes, such as the distinction between direct and indirect conflicts of interests prevail, while the Agency mainly takes into account direct conflicts of interests; encourages the Agency to actively address this issue; notes that the electronic declaration of interests form and the procedural guidelines were to be finalised during 2014; calls on the Agency to inform the discharge authority on the outcomes of this issue as soon as they are available;

14. Welcomes the fact that the revised policy includes an improved distinction of the declared interest: a person with an executive or leading role in the development of a medicine during a previous employment has a lifetime bar of non-involvement with the concerned company or product and for the majority of declared interests, a three-year cooling-off period is foreseen;

15. Regrets that the policies on proactive publication of clinical trial data recently adopted by the Agency go against the transparency provisions of Regulation (EU) No 536/2014 of the European Parliament and the Council[1] (the Clinical Trials Regulation) by allowing companies to redact data based on potential jeopardy of commercial interests; calls on the Agency to report to the discharge authority on this issue;

16. Notes with regret the Agency's understanding of what constitutes commercial confidential information (CCI) is far too broad and includes companies to redact key data about the trial design, methods, and calls on the Agency to properly implement the provisions of the Clinical Trials Regulation especially with regard to clinical trial data not to be considered CCI;

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[1] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

17. Calls on the Agency to publish on its website detailed reports of the scientific advice provided by the Agency to pharmaceutical companies during the drug development and pre-registration process at the time of trial authorisation and in any case not later than 12 months after the end of the trial; notes that advice provided by regulators to companies on drug development and pre-registration plans cannot be considered CCI since there is an overriding public interest in disclosure;

Internal audit

18. Acknowledges that in 2013, the Commission's Internal Audit Service (IAS) carried out a consultancy engagement and a follow-up engagement according to its Strategic Audit Plan for the Agency for 2012 – 2014 on Stakeholders Management & Communication;

19. Takes note that in the course of the risk analysis, the IAS identified certain processes of a high inherent risk which could not be considered as auditable within the audit plan as the controls were assessed as absent or insufficient; notes furthermore that in response to these weaknesses, the Agency's management submitted an action plan; acknowledges that the actions will be followed-up by the IAS during its next in-depth risk analysis;

20. Notes from the IAS report that its follow-up was done through an audit on its earlier recommendations marked as "Very Important" or "Important" and through a desk review on the status of earlier recommendations marked as "Important" or "Desirable"; notes furthermore that the follow-up engagement revealed that neither "Critical" nor "Very Important" recommendations were open as of 31 December 2013;

21. Takes note that the Agency has adopted a set of internal-control standards (ICS) which are intended to guarantee a consistent level of internal control of all business activities throughout the Agency, and define the management rules that all services must follow in their management of resources;

Internal controls

22. Acknowledges that since 2012, the Agency's "Verifying Office" performs *ex ante* checks focused on valuable commitments, sensitive contracts and complex procurement procedures where higher risks have been identified; notes that during 2013, no delays have been reported by the “Verifying Office” and that all transactions were checked using checklists in line with the financial regulations and the charter of the verifying officer;

23. Takes note that the Agency, after completing a series of *ex post* controls during 2013, found no significant weaknesses in its internal controls;

24. Acknowledges that in 2013, the Agency's internal audit function carried out audits in several areas; notes that the recommendations produced by the internal audit function have been already partially addressed while others are being implemented;

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25. Refers, for other observations of a cross-cutting nature accompanying its decision on

discharge, to its resolution of 29 April 2015[1] on the performance, financial management and control of the agencies.

[1] Texts adopted of that date, P8_TA(2015)0130.