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DRAFT REPORT

on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2013
(2014/2102(DEC))

Committee on Budgetary Control

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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 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 replies¹,
- having regard to the statement of assurance² 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 ... on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2013 (00000/2015 – C8-0000/2015),
- 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 Communities³,
- 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 1605/2002⁴, 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 Agency⁵, 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

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.

Regulation applicable to the general budget of the European Communities¹,

- 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 Council², 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 (A8-0000/2015),
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 / 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 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).

1 OJ L 357, 31.12.2002, p. 72.

2 OJ L 328, 7.12.2013, p. 42.

2. PROPOSAL FOR A EUROPEAN PARLIAMENT DECISION

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 replies¹,
- having regard to the statement of assurance² 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 ... on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2013 (00000/2015 – C8-0000/2015),
- 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 Communities³,
- 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 1605/2002⁴, 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 Agency⁵, 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

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.

Regulation applicable to the general budget of the European Communities¹,

- 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 Council², 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 (A8-0000/2015),
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 / Postpones 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 357, 31.12.2002, p. 72.

2 OJ L 328, 7.12.2013, p. 42.

3. MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

**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 (A8-0000/2015),
- 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,

Follow-up of 2012 discharge

1. 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";
2. 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 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;

Budget and financial management

3. 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 %;

Commitments and carry-overs

4. 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

5. Notes with satisfaction that according to the 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

6. 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;

Prevention and management of conflicts of interests and transparency

7. 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 for assessing the organisations' eligibility to participate in the dialogue with the Agency; recalls that the document also states that the organisations have to declare any conflict of interests at the start of the meetings through which the dialogue is commenced;
8. Notes that the Agency's Management Board has endorsed the revised the policy on the handling of declarations of interests of members of scientific committees and experts; notes that the electronic declaration of interests form and the procedural guidance were to be finalised during 2014; calls on the Agency to inform the discharge authority on the

outcomes as soon as they are available;

Internal audit

9. 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;
10. 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;
11. 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;

Internal controls

12. 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;
13. Takes note that the Agency, after completing a series of ex post controls during 2013, found no significant weaknesses in its internal controls;
14. 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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15. Refers, for other observations of a cross-cutting nature accompanying its decision on discharge, to its resolution of ... 2015¹ on the performance, financial management and control of the agencies.

1 Texts adopted of that date, P8_TA-PROV(2015)0000