



TEXTS ADOPTED

Provisional edition

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Discharge 2014: European Medicines Agency (EMA)

1. European Parliament decision of 28 April 2016 on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2014 (2015/2171(DEC))

The European Parliament,

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2014,
- having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2014 together with the Agency's reply¹,
- 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 2014, pursuant to Article 287 of the Treaty on the Functioning of the European Union,
- having regard to the Council's recommendation of 12 February 2016 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2014 (05584/2016 – C8 - 0069/2016),
- having regard to Article 319 of the Treaty on the Functioning of the European Union,
- 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 1605/2002³, 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

¹ OJ C 409, 9.11.2015, p. 197.

² OJ C 409, 9.11.2015, p. 197.

³ OJ L 298, 26.10.2012, p. 1.

supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹, 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 Communities²,
 - 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 Council³, 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 (A8-0114/2016),
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 2014;
 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 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 28 April 2016 on the closure of the accounts of the European Medicines Agency for the financial year 2014 (2015/2171(DEC))

The European Parliament,

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2014,
- having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2014 together with the Agency's reply¹,
- 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 2014, pursuant to Article 287 of the Treaty on the Functioning of the European Union,
- having regard to the Council's recommendation of 12 February 2016 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2014 (05584/2016 – C8 - 0069/2016),
- having regard to Article 319 of the Treaty on the Functioning of the European Union,
- 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 1605/2002³, 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 Agency⁴, 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 Communities⁵,
- 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 Council⁶, and in particular Article 108 thereof,
- having regard to Rule 94 of and Annex V to its Rules of Procedure,

¹ OJ C 409, 9.11.2015, p. 197.

² OJ C 409, 9.11.2015, p. 197.

³ OJ L 298, 26.10.2012, p. 1.

⁴ OJ L 136, 30.4.2004, p. 1.

⁵ OJ L 357, 31.12.2002, p. 72.

⁶ OJ L 328, 7.12.2013, p. 42.

- 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 (A8-0114/2016),
- 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 2014;
- 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).

3. European Parliament resolution of 28 April 2016 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 2014 (2015/2171(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 2014,
 - 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 (A8-0114/2016),
- A. whereas, according to its financial statements, the final budget of the European Medicines Agency (“the Agency”) for the financial year 2014 was EUR 282 474 000, representing an increase of 12,29 % compared to 2013; whereas 12,53 % of the Agency's budget derives from the Union budget;
- B. whereas the Court of Auditors (“the Court”), in its report on the annual accounts of the Agency for the financial year 2014 (“the Court's report”), has stated that it has obtained reasonable assurances that the Agency's annual accounts for the financial year 2014 are reliable and that the underlying transactions are legal and regular;

Follow-up of 2013 discharge

1. Notes from the Court's report that regarding one comment made in the Court's 2012 report and marked as "Ongoing" in the Court's 2013 report, corrective actions were taken and that comment is now marked in the Court's report as “Completed”;

Comments on the legality and regularity of transactions

2. Notes from the Court's report that the Agency's Fee Regulation¹ provides due dates for the collection of fees from applicants and the Agency's related payments to national competent authorities; notes that these due dates were not respected for most of the transactions audited by the Court; ascertains from the Agency that it has redesigned and streamlined its main operational processes including financial authorisations and fee collections; takes note that the further automation of these processes was planned to be implemented by the Agency by the end of 2015; calls on the Agency to take all further steps needed in order to ensure that its pharmacovigilance responsibilities are fully met and to effectively report to the discharge authority on measures implemented to remedy this issue;

Budget and financial management

3. Recalls that, as stipulated in its financial regulation, budget revenue of the Agency is based on cash received for contributions from the Union, fees for marketing authorisation

¹ Article 10(1) and 11(1) of Regulation (EC) No 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products.

applications for pharmaceutical products and for post-authorisation activities as well as for various administrative activities;

4. Notes that budget monitoring efforts during the financial year 2014 resulted in a budget implementation rate of 94,32 %; regrets, however that this represents a decrease of 2,44 % compared with the previous year; notes furthermore that the payment appropriations execution rate was at 82,30 %; regrets that, here again, this represents a decrease of 3,98 %;
5. Notes that the cancelled appropriations in 2014 were EUR 16 054 189 (5,68 % of final appropriations); notes furthermore that the Agency is reliant on fee income and that the level of cancelled appropriations does not indicate delays in the implementation of the Agency's work programme; points out that these cancellations correlate with uncollected revenue appropriations of EUR 10 688 070 at year-end creating a positive overall outturn balance of 1,90 % of final appropriations;

Commitments and carry-overs

6. Notes with satisfaction the rates of committed appropriations carried over realised by the Agency; notes in particular that the automatic carry-overs to financial year 2015 were at 17,7 % of committed appropriations as well as the absence of non-automatic carry-overs; acknowledges furthermore that the Court's annual audit found no notable issues with regard to the level of carry-overs in 2014 and commends the Agency for its compliance with the principle of annuality and the timely execution of its budget;
7. Calls on the Agency to reduce the level of committed appropriations carried over in the future as far as possible in order to strengthen transparency and accountability;

Transfers

8. Notes that according to the annual activity report, as well as the Court's findings, the level and nature of transfers in 2014 remained within the limits of the financial rules; ascertains from the Agency that during 2014 it made nine transfers totalling EUR 29 811 800 or 11,85 % of final appropriations; notes in particular that the transferred appropriations were primarily used for expenditure on business IT development, rapporteur payments and other adjustments to administrative budget items;

Procurement and recruitment procedures

9. Takes note from the Agency that, in order to increase the level of human resources allocated to operational tasks, it is further improving its recruitment and resource planning procedures; ascertains from the Court's Report that in 2014 the Agency concluded an EUR 15 000 000 framework contract for high-level management consultancy services covering the 2014-2017 period; notes that the objectives and activities to be carried out were not sufficiently specific to justify the procurement decision or the volume of the contract; calls on the Agency therefore, in the interests of transparency and accountability, to ensure that the objectives and activities to be carried out are in fact specified; notes furthermore that the Court found no evidence that the Agency's Management Board had been consulted on the procurement decision; acknowledges from the Agency that consulting its Management Board in this case was not required by the financial rules;
10. Asks the Agency to apply strictly the measures pertaining to discretion and exclusion in public procurement, with proper background checks being carried out in every instance,

and to apply the exclusion criteria so as to debar companies in the event of any conflict of interest, this being essential to protect the financial interests of the Union;

11. Ascertains that the Agency increased transparency in relation to its recruitment procedures by publishing the status of ongoing external procedures and the status of reserve lists on the Agency's external website, and that it also improved the documentation related to the recruitment procedures;
12. Notes that the Advisory Committee on Procurements and Contracts (ACPC), set up in 2012 in order to examine procurement contracts prior to signature on behalf of the Agency, reviewed 73 dossiers during the year 2014; takes note that during 2014, 28 new procurement contracts exceeding EUR 25 000 in value were concluded by the Agency following procurement procedures, compared to 30 in 2013 and 43 in 2012;
13. Ascertains that the Agency uses the Early Warning System of the Commission and has access to a database which enables the Agency to check the financial status of potential contractors; notes that any risks identified are alerted to the ACPC and the relevant authorising officer; welcomes the creation of the Central Sourcing Office in December 2014, which is aimed at improving the efficiency and effectiveness of the Agency's procurement and contract management, whilst ensuring compliance with the relevant Regulation;
14. Welcomes that 580 of 599 available posts had been filled by the end of 2014 and that 210 contract agents, seconded national experts and employment agency staff were employed by the Agency; welcomes that the occupation rate has increased compared to 2013; notes that the proportion of contract agents, seconded national experts and employment agency staff has increased compared to 2013; congratulates the Agency for dedicating about 79 % of its human resources to operational tasks, and notes that this represents a slight decrease compared to the situation in 2013;

Prevention and management of conflicts of interests and transparency

15. Notes from the Agency the publication of its revised policy on handling of declarations of interests of scientific committee members and experts in November 2014 which entered into force in January 2015; acknowledges that the Agency has defined what are direct and indirect interests and ordered all experts to declare all direct and indirect interests in their annual declaration of interests; notes moreover that restrictions are applied to experts declaring direct or indirect interests which depend on the activity in which they are involved, maintaining the policy distinction between those interests in line with the relevant legislation;
16. Encourages the Agency further to raise awareness of the conflict-of-interest policy among its staff, alongside ongoing awareness-raising activities and the inclusion of integrity and transparency as an obligatory item to be discussed during recruitment procedures and performance reviews;
17. Calls for an overall improvement in the prevention of, and the fight against, corruption through a holistic approach, commencing with better public access to documents and more stringent rules on conflicts of interest, the introduction or strengthening of transparency registers and the provision of sufficient resources for law enforcement measures, and also through improved cooperation among Member States and with relevant third countries;

18. Calls on the Agency to enhance its procedures and practices aimed at safeguarding the financial interests of the Union and to actively contribute to a results-oriented discharge process;
19. Notes that in December 2014, the Agency's Management Board adopted an anti-fraud strategy, developed within the framework of the Common Approach on decentralised agencies, adopted in July 2012 by the Parliament, the Council and the Commission; notes furthermore that the scope of the anti-fraud strategy does not encompass "regulatory fraud", which is dealt with through other mechanisms such as inspections; ascertains from the Agency that a possible widening of the strategy's scope so as to include this type of fraud will be reconsidered;
20. Calls on the Agency to pay special attention to the protection of whistle-blowers in the context of the soon-to-be-adopted Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure;
21. Stresses that the Agency should ensure maximum transparency in providing access to clinical reports, and welcomes the Agency's decision to proactively publish data on clinical trials;

Internal controls

22. Takes note that in 2014, the Agency carried out an administrative procedure with respect to its Information, Communication and Technology (ICT) Division; notes that significant weaknesses in management control were reported, implying considerable operational and financial risks to the Agency; notes from the Agency that no considerable financial risks were reported in the administrative enquiry to the Agency's Executive Director; observes that an action plan to address the issue was established and implemented; calls on the Agency to report to the discharge authority on the effectiveness of the measures taken after they have been evaluated;
23. Observes that the Agency assessed the effectiveness of its key internal control systems during the year 2014; notes that the findings of the review demonstrated the Agency's internal controls performed well during the year, with no control failure exposing the Agency to the identified risks;

Internal audit

24. Acknowledges that in 2013, the Commission's Internal Audit Service (IAS) carried out an audit on stakeholder management and communication at the Agency, which showed these areas as being managed effectively; notes furthermore that the IAS submitted its report on consultancy engagement related to IT project management carried out at the end of 2013; observes that this report showed several weaknesses which the Agency set out to resolve by implementing changes in its structure and internal accountability; notes with satisfaction that no critical recommendations were open at year-end, and that the actions on very important recommendations were within the agreed timeline as specified in the Agency's action plans;
25. Takes note that in 2014, the Agency's Internal Audit Capability carried out audits in several areas, with no critical recommendations open at year-end;

Other comments

26. Welcomes the Agency's annual environmental reporting;
27. Recalls that the Pharmacovigilance Fee Regulation¹ was published in the *Official Journal of the European Union* on 27 June 2014 and has applied to procedures starting from 26 August 2014, although annual fees to support information technology systems and literature monitoring activities will not be levied until 2015; likes to stress that that Regulation now allows the Agency to collect fees from marketing authorisation holders to finance these pharmacovigilance activities conducted at Union level in respect of medicinal products for human use; points out that the income is used to remunerate national competent authorities for the scientific assessment carried out by the rapporteurs of the EMA's Pharmacovigilance Risk Assessment Committee and contributes to the pharmacovigilance costs of the Agency;

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28. Refers, for other observations of a cross-cutting nature accompanying its decision on discharge, to its resolution of 28 April 2016² on the performance, financial management and control of the agencies.

¹ Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use (OJ L 189, 27.6.2014, p. 112).

² Texts adopted of that date, P8_TA-PROV(2016)0159.