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REPORT

on discharge in respect of the implementation of the budget of the European
Medicines Agency for the financial year 2012
(C7-0293/2013 – 2013/2215(DEC))

Committee on Budgetary Control

Rapporteur: Petri Sarvamaa

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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 2012
(C7-0293/2013 – 2013/2215(DEC))**

The European Parliament,

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2012,
- having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2012, together with the Agency's replies¹,
- having regard to the Council's recommendation of 18 February 2014 (05849/2014 – C7-0054/2014),
- 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 Communities², and in particular Article 185 thereof,
- 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 Council⁴ 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 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 77 of, and Annex VI to, its Rules of Procedure,

¹ OJ C 365, 13.12.2013, p. 150.

² OJ L 248, 16.9.2002, p. 1.

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 (A7-0227/2014),
- 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 2012;
- 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 2012

(C7-0293/2013 – 2013/2215(DEC))

The European Parliament,

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2012,
- having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2012, together with the Agency's replies¹,
- having regard to the Council's recommendation of 18 February 2014 (05849/2014 – C7-0054/2014),
- 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 Communities², and in particular Article 185 thereof,
- 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 Council⁴ 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 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 77 of, and Annex VI to, its Rules of Procedure,

¹ OJ C 365, 13.12.2013, p. 150.

² OJ L 248, 16.9.2002, p. 1.

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 (A7-0227/2014),
- 1. Approves the closure of the accounts of the European Medicines Agency for the financial year 2012;
- 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 2012

(C7-0293/2013 – 2013/2215(DEC))

The European Parliament,

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2012,
- having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2012, together with the Agency's replies¹,
- having regard to the Council's recommendation of 18 February 2014 (05849/2014 – C7-0054/2014),
- 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 Communities², and in particular Article 185 thereof,
- 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 Council⁴ 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 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,

¹ OJ C 365, 13.12.2013, p. 150.

² OJ L 248, 16.9.2002, p. 1.

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 its previous discharge decisions and resolutions,
 - 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 (A7-0227/2014),
- A. whereas, according to its financial statements, the final budget of the European Medicines Agency (“the Agency”) for the financial year 2012 was EUR 222 489 000, representing an increase of 6,52 % compared to 2011,
 - B. whereas according to its financial statements, the overall contribution of the Union to the Agency's budget for 2012 amounted to EUR 31 341 107,18, representing a decrease of 6,50 % compared to 2011,
 - C. whereas the Court of Auditors has stated that it has obtained reasonable assurances that the Agency's annual accounts for the financial year 2012 are reliable and that the underlying transactions are legal and regular,
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 2011 discharge

2. Notes from the Court of Auditors' report that one corrective action taken in response to the previous year's comments is marked as 'completed', one as 'outstanding' and one as 'ongoing';
3. Acknowledges from the Agency that:
 - a new systematic *ex ante* control on the correct completion of the electronic declaration of interests submitted by the experts has been performed for all new appointed experts as from June 2013, the results having demonstrated that new experts completed their electronic declarations of interests correctly,
 - the *ex post* control on handling conflicts of interest of experts carried out in 2013 resulted in minor findings with no impact on the experts' participation in the Agency's activities and has given useful information to the Agency on how to further strengthen its internal controls, while providing reassurance on the robustness of the Agency's handling of conflicts of interest;

Comments on the reliability of the accounts

4. Notes with concern that the Agency applies differing recognition criteria for fee revenues and associated expenditure and that the revenue from application fees is recognised on a straight-line basis over a set time period; observes, however, that expenditure for the evaluation of such applications by the competent national authorities is accrued when a specific milestone in service delivery is reached; believes that this is in contradiction with the matching principle;

5. Regrets that the Agency has not yet validated its accounting system in the area of intangible fixed assets, which, given the considerable investment in the development of information and communications technology (ICT), is a crucial part of the whole accounting system; calls on the Agency to inform the discharge authority on progress in this regard within the framework of the 2012 discharge follow-up;

Comments on the legality and regularity of transactions

6. Notes with concern that in order to cover higher school fees, the Agency grants staff whose children attend primary or secondary school a top-up allowance, which amounted to some EUR 389 000 in 2012, in addition to the education allowances provided for in the Staff Regulations of Officials of the European Communities ("the Staff Regulations"); notes that these allowances are not covered by the Staff Regulations and are, therefore, considered irregular by the Court of Auditors; acknowledges, however, that this situation is due to the lack of European Schools in the city the Agency is based in and that the purpose of these top-ups is to ensure equal treatment of the Agency's employees under the Staff Regulations;

Budget and financial management

7. Notes that the Agency's budget implementation rates for the year 2012 were satisfactory for titles I and III; notes with concern that the rate of committed appropriations carried over was high for title II at 27 %; acknowledges that this relates primarily to the Agency's planned move to a new premises in 2014 (EUR 4 205 000) and to the development of ICT systems (EUR 1 596 000);

Commitments and carryovers

8. Notes the reduced amount carried over to 2013 in comparison with 2010 and 2011; appreciates that the carry-over is partly related to the new building project; reminds the Agency of the importance of respecting the budgetary principle of annuality;

Transfers

9. 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; commends the Agency for its good budgetary planning;

Procurement and recruitment procedures

10. Notes with concern that in 2012, the Agency issued multiple framework contracts for the provision of services; expresses concern that the procurement procedure presented some irregularities affecting the principle of transparency;
11. Notes that the Court of Auditors made no comments in its annual audit report for 2012 as regards the Agency's recruitment procedures;
12. Is satisfied that 575 of 590 available posts were filled and notes that 160 contract agents and seconded national experts were employed by the end of 2012, which is 17 less than in 2011;

Prevention and management of conflicts of interests and transparency

13. Welcomes the fact that for the second year in a row, the Agency held a public workshop on conflicts of interests, aimed at defining the right balance between ensuring the impartiality and independence of experts involved in the Agency's work and securing the best possible scientific expertise;
14. Acknowledges that the Agency revised its policy on the handling of conflicts of interests by the Scientific Committees' members and experts which is expected for endorsement by the Management Board in March 2014; calls on the Agency to present that revised policy to the discharge authority once adopted;
15. Notes that the Agency works together closely with a variety of patient, healthcare and consumer organisations in order to take their opinions into account; calls on the Agency to request public disclosure regarding the funding of any patient, consumer and healthcare organisation it works with, and to carry out a conflict of interests check regarding those organisations;

Internal audit

16. Acknowledges from the Agency that in 2012 the Commission's Internal Audit Service (IAS) carried out an operation audit on planning and budgeting in the Agency, as well as a follow-up audit on the recommendations concerning internal control standards, the provision of scientific advice, human resources management, the 2010 follow-up audit and operational business continuity in the Agency audits; notes that the audit on planning and budgeting identified strengths as regards revenue forecasting and monitoring and raised seven recommendations, two of which were rated as "very important" and five as "important"; acknowledges that all recommendations were accepted by the management and that the Agency prepared an action plan which the IAS considered to be adequate; notes that the follow-up concluded that three recommendations from the previous audits remain open, one of which was downgraded to 'important';

Performance

17. Requests that the Agency communicate the results and impact its work has on European citizens in an accessible way, mainly through its website;

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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 ... 2014¹ on the performance, financial management and control of the agencies.

¹ Texts adopted, P7_TA-PROV(2014).

23.1.2014

OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND FOOD SAFETY

for the Committee on Budgetary Control

on the discharge in respect of the implementation of the budget of the European Medicines
Agency for the financial year 2012
(2013/2215(DEC))

Rapporteur: Jutta Haug

SUGGESTIONS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on Budgetary Control, as the committee responsible, to incorporate the following suggestions in its motion for a resolution:

1. Notes that in 2012 the European Medicines Agency had resources available of EUR 222.489 000 of which EUR 28.966 000 had been EU budget contributions; likes to stress that this amount represents 0.021% of the overall EU budget; is satisfied that 575 of 590 available posts had been occupied and notes that 160 contract agents and seconded national experts were employed by the end of 2012 which are 17 less than in 2011;
2. Welcomes that the Court of Auditors announces the transactions underlying the annual accounts of the European Medicines Agency for the financial year 2012 as legal and regular in all material respect;
3. Recognises the three comments made by the Court of Auditors which focus on the reliability of the accounts, on the legality and regularity of transactions and on the budget management; recognises the Agency's reply; considers the explanations given by the Agency on the introduction of the SAP accounting system to recognise revenue for all fee application types with more precision as well as the information on the validation of its accounting system for intangible assets as sufficient; points out that the decision taken by the European Court of Justice on the salary method for 2011 from 19 November 2013 has also consequences for payments with regard to the correction coefficient as well as for the applicable exchange rate from EUR to GBP as the salary

adjustment package includes also these two issues; insists that the Agency, in close cooperation with the Commission, finds a solution in the interest of the employees and in compliance with the rules; wonders why the Court has not commented on the issue of fees payable to schools in previous years, supports the argumentation of the Agency with regard to the payment of school fees in the absence of a European School; has taken note of the reduced amount carried over to 2013 in comparison with 2010 and 2011; is aware that the carry-over is partly related to the new building project; reminds the Agency on the annuality principle for the budget;

4. Reiterates the important role of the Agency in protecting and promoting public and animal health by assessing and supervising medicines for human or veterinary use; welcomes the policy on the handling of conflict of interests, last updated and endorsed by the Management Board in March 2012;
5. Advises to explore if the discharge decision should be based upon OECD guidelines to ensure high quality internationally recognised accounting, audit and financial disclosure standards; invites the European institutions to incorporate and commit to introducing OECD guidelines within a common framework for all European institutions and bodies; if the assessment recommends so;
6. Recommends, on the basis of the facts available, that discharge be granted to the Executive Director of the European Medicines Agency in respect of the implementation of the Agency's budget for the financial year 2012.

RESULT OF FINAL VOTE IN COMMITTEE

Date adopted	22.1.2014
Result of final vote	+: 56 -: 5 0: 0
Members present for the final vote	Elena Oana Antonescu, Sophie Auconie, Pilar Ayuso, Paolo Bartolozzi, Sandrine Bélier, Lajos Bokros, Franco Bonanini, Biljana Borzan, Yves Cochet, Spyros Danellis, Chris Davies, Anne Delvaux, Bas Eickhout, Edite Estrela, Jill Evans, Elisabetta Gardini, Gerben-Jan Gerbrandy, Matthias Groote, Françoise Grossetête, Satu Hassi, Jolanta Emilia Hibner, Karin Kadenbach, Martin Kastler, Christa Kläß, Claus Larsen-Jensen, Jo Leinen, Peter Liese, Kartika Tamara Liotard, Zofija Mazej Kukovič, Linda McAvan, Radvilė Morkūnaitė-Mikulėnienė, Miroslav Ouzký, Vladko Todorov Panayotov, Gilles Pargneaux, Antonia Parvanova, Andrés Perelló Rodríguez, Pavel Poc, Anna Rosbach, Oreste Rossi, Dagmar Roth-Behrendt, Kārlis Šadurskis, Daciana Octavia Sârbu, Carl Schlyter, Horst Schnellhardt, Richard Seeber, Dubravka Šuica, Salvatore Tatarella, Thomas Ulmer, Glenis Willmott, Sabine Wils, Marina Yannakoudakis
Substitute(s) present for the final vote	Gaston Franco, Jutta Haug, Filip Kaczmarek, Marusya Lyubcheva, Miroslav Mikolášik, Vittorio Prodi, Giancarlo Scottà, Alda Sousa, Vladimir Urutchev, Andrea Zannoni

RESULT OF FINAL VOTE IN COMMITTEE

Date adopted	17.3.2014
Result of final vote	+ : 14 - : 6 0 : 0
Members present for the final vote	Marta Andreasen, Jean-Pierre Audy, Zuzana Brzobohatá, Martin Ehrenhauser, Jens Geier, Gerben-Jan Gerbrandy, Ingeborg Gräßle, Rina Ronja Kari, Monica Luisa Macovei, Jan Mulder, Eva Ortiz Vilella, Paul Rübig, Petri Sarvamaa, Bart Staes, Georgios Stavrakakis, Derek Vaughan
Substitute(s) present for the final vote	Amelia Andersdotter, Philip Bradbourn, Markus Pieper
Substitute(s) under Rule 187(2) present for the final vote	Thomas Ulmer