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REPORT

on discharge in respect of the implementation of the budget of the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines for the financial year 2013
(2014/2133(DEC))

Committee on Budgetary Control

Rapporteur: Ryszard Czarnecki

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1. PROPOSAL FOR A EUROPEAN PARLIAMENT DECISION

**on discharge in respect of the implementation of the budget of the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines for the financial year 2013
(2014/2133(DEC))**

The European Parliament,

- having regard to the final annual accounts of the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines for the financial year 2013,
- having regard to the Court of Auditors' report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2013, together with the Joint Undertaking'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 17 February 2015 on discharge to be given to the joint undertaking in respect of the implementation of the budget for the financial year 2013 (05306/2015 – C8-0049/2015),
- 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 209 thereof,
- having regard to Council Regulation (EC) No 73/2008 of 20 December 2007 setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines⁵,
- having regard to Council Regulation (EC) No 557/2014 of 6 May 2014 establishing the

¹ OJ C 452, 16.12.2014, p. 35.

² OJ C 452, 16.12.2014, p. 36.

³ OJ L 248, 16.9.2002, p. 1.

⁴ OJ L 298, 26.10.2012, p. 1.

⁵ OJ L 30, 4.2.2008, p. 38.

Innovative Medicines Initiative 2 Joint Undertaking¹, and in particular Article 1(2) and Article 12 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 110/2014 of 30 September 2013 on the model financial regulation for public-private partnership bodies referred to in Article 209 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council³,
 - 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 (A8-0106/2015),
1. Postpones its decision on granting the Executive Director of the Innovative Medicines Initiative 2 Joint Undertaking discharge in respect of the implementation of the budget of the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines 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 Innovative Medicines Initiative 2 Joint Undertaking, 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 169, 7.6.2014, p. 54.

² OJ L 357, 31.12.2002, p. 72.

³ OJ L 38, 7.2.2014, p. 2.

2. PROPOSAL FOR A EUROPEAN PARLIAMENT DECISION

on the closure of the accounts of the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines for the financial year 2013 (2014/2133(DEC))

The European Parliament,

- having regard to the final annual accounts of the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines for the financial year 2013,
- having regard to the Court of Auditors' report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2013, together with the Joint Undertaking'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 17 February 2015 on discharge to be given to the joint undertaking in respect of the implementation of the budget for the financial year 2013 (05306/2015 – C8-0049/2015),
- 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 209 thereof,
- having regard to Council Regulation (EC) No 73/2008 of 20 December 2007 setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines⁵,
- having regard to Council Regulation (EC) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking⁶, and in particular Article 1(2) and

¹ OJ C OJ C 452, 16.12.2014, p. 35.

² OJ C OJ C 452, 16.12.2014, p. 36.

³ OJ L 248, 16.9.2002, p. 1.

⁴ OJ L 298, 26.10.2012, p. 1.

⁵ OJ L 30, 4.2.2008, p. 38.

⁶ OJ L 169, 7.6.2014, p. 54.

Article 12 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 Communities¹,
 - having regard to Commission Delegated Regulation (EU) No 110/2014 of 30 September 2013 on the model financial regulation for public-private partnership bodies referred to in Article 209 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council²,
 - 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 (A8-0106/2015),
1. Postpones the closure of the accounts of the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines for the financial year 2013;
 2. Instructs its President to forward this decision to the Executive Director of the Innovative Medicines Initiative 2 Joint Undertaking, 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 38, 7.2.2014, p. 2.

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 for the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines for the financial year 2013 (2014/2133(DEC))

The European Parliament,

- having regard to its decision on discharge in respect of the implementation of the budget of the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines 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 (A8-0106/2015),
- A. whereas the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines ("the Joint Undertaking") was set up in December 2007 for a period of 10 years to significantly improve the efficiency and effectiveness of the drug development process with the long-term aim that the pharmaceutical sector produces more effective and safer innovative medicines,
- B. whereas the Union, represented by the Commission, and the European Federation of Pharmaceutical Industries and Associations (EFPIA), are the Joint Undertaking's founding members,
- C. whereas the Joint Undertaking started to work autonomously on 16 November 2009,
- D. whereas the maximum contribution for the period of 10 years from the Union to the Joint Undertaking is EUR 1 000 000 000, to be paid from the budget of the Seventh Research Framework Programme and the founding members are to contribute equally to the running costs, each with an amount not exceeding 4 % of the total Union contribution and to the research activities with in-kind contributions at least equal to the financial contribution of the Union,

Budgetary and financial management

1. Notes that in the opinion of the Court of Auditors ("the Court"), the Joint Undertaking's annual accounts present fairly, in all material respects, its financial position as at 31 December 2013 and the results of its operations and cash flows for the year then ended, in accordance with the provisions of its financial rules and the accounting rules adopted by the Commission's accounting officer;
2. Takes note that the Joint Undertaking's ex post audit strategy was adopted by a Governing Board decision on 14 December 2010, and that it is considered as a key tool for assessing the legality and regularity of the underlying transactions;

3. Notes with concern that 14 out of 40 ex post audits of the second representative sample were finalised as of June 2014, covering EUR 3 000 000 and representing 11,8 % of the audited population; points out that the detected error rate resulting from these audits is 2,3 %; reminds that the error rate resulting from the 56 concluded audits of the first representative sample in 2012 was at 5,82 %;
4. Notes with concern that the Court, in its report on the annual accounts of the Joint Undertaking for the financial year 2013 (“the Court’s report”), issued a qualified opinion on the legality and the regularity of the transactions underlying the accounts of the Joint Undertaking on the basis of the detected error rate being above the materiality threshold of 2 %; notes with concern that the Court issued a qualified opinion for a third consecutive year;
5. Calls on the Joint Undertaking for a follow-up report on the reservations of the Joint Undertaking in the last three years;
6. Acknowledges from the Joint Undertaking that the follow-up actions related to audited beneficiaries with detected errors were launched and that all detected errors were communicated to these beneficiaries; notes furthermore that in order to mitigate the risk of future errors in beneficiaries' cost claims, the Joint Undertaking has taken specific measures, such as establishing financial workshops for beneficiaries as well as the regular updating of its Financial Guidelines for participants;
7. Asks for an action plan with clear objectives aimed at fixing the deficiencies and errors identified by the Court to be submitted to the discharge authority in a timely manner, to be followed by a first interim evaluation report on the implementation of the action plan;
8. Notes from the Court's report that the initial 2013 budget included EUR 226 000 000 in commitment appropriations and EUR 135 000 000 in payment appropriations; notes furthermore that at the year-end, an amended budget was adopted by the Governing Board which increased commitment appropriations to EUR 255 700 000 and decreased payment appropriations to EUR 130 600 000; takes note that after the budget was amended, the overall implementation rate was 99,5 % for commitment appropriations and 97,5 % for payment appropriations; ascertains from the Court's report that the implementation rate of commitment and payment appropriations in the case of operational activities was 100 % and 99 % respectively;
9. Calls on the Joint Undertaking to provide the discharge authority with detailed information on the in-kind contributions of EFPIA companies especially on the type of the in-kind contributions and their respective value;
10. Calls on the Joint Undertaking to submit a report to the discharge authority concerning the contributions of all members other than the Commission including the application of the methodology for evaluating in-kind contributions, together with an assessment by the Commission;

11. Calls on the Court to present a complete and appropriate financial assessment of rights and obligations of the Joint Undertaking for the period up to the date of the Innovative Medicines Initiative 2 Joint Undertaking starting activity;

Calls for proposals

12. Takes into consideration that under the Seventh Framework Programme (FP7)¹, 2013 was the last year in which calls for proposals could be launched; notes that the entire budget for research of EUR 970 000 000 was committed along with the requisite matching in-kind contributions from the EFPIA companies in the amount of EUR 982 000 000;

Legal Framework

13. Takes into consideration that the new Financial Regulation applicable to the general budget of the Union was adopted on 25 October 2012 and took effect on 1 January 2013 while the model financial regulation for public-private partnership bodies referred to in Article 209 of the new Financial Regulation did not enter into force until 8 February 2014; acknowledges that the Financial Rules of the Joint Undertaking have been amended to take into account the model financial regulation in July 2014;
14. Notes the Joint Statement by the Parliament, the Council and the Commission² and the subsequent political agreement reached on the separate discharge to be given by the Parliament upon recommendation of the Council, for Joint Undertakings under Article 209 of the Financial Regulation;

Internal control systems

15. Notes that in accordance with the strategic audit plan for 2012-2014 approved by the Joint Undertaking's Governing Board on 3 November 2011, the Commission's Internal Audit Service (IAS) performed an assurance engagement of project management and reporting on operational performance; points out that the final report which was dated 30 January 2014 includes recommendations regarding the Joint Undertaking's process of improving its monitoring systems on operational performance, such as reviewing the design and reporting of objectives and key performance indicators ("KPIs"), strengthening of the project monitoring and improving to the IT systems to enhance reporting;
16. Acknowledges that the IAS also performed an IT risk assessment of the Joint Undertaking's specific IT systems as well as the common infrastructure it shares with the FCH, Clean Sky, ENIAC and ARTEMIS Joint Undertakings; points out that in the case of the Joint Undertaking's specific IT systems, the IAS reports the need for more formal instructions on project management and on change control processes in the contracts in order to mitigate contract-management risk; notes from the Court's report that this recommendation was implemented in January 2014;

¹ OJ L 412, 30.12.2006, p.1;

² OJ L 163, 29.5.2014, p. 21.

17. Takes note that procedures regarding the protection, dissemination and transfer of search results in relation to the Article 7 of the FP7 have been developed by the Joint Undertaking; notes moreover that the Joint Undertaking defined the requirements regarding the general monitoring report of FP7, as well as transferring the data related to its projects to the Commission during 2013, in order for the data to be integrated in the Common Research Data Warehouse; is concerned, however, that the monitoring processes put in place require further development in order to fully comply with the required provisions;
18. Takes note that in order to prevent conflicts of interest in respect to its Governing Board members, experts and employees, the Joint Undertaking has put in place specific measures which are included in the rules of procedure of both the Governing Board and the Scientific Committee, as well as in the documentation on the code of conduct and conflicts of interest in the case of independent experts during evaluation; notes furthermore that the Joint Undertaking has adopted an updated and comprehensive policy on conflicts of interest for both management and staff members in April 2013;
19. Acknowledges that between March and July 2013, the Commission's Second Interim Evaluation was carried out in order to assess the Joint Undertaking in terms of relevance, effectiveness, efficiency and research policy and that the report on the evaluation was issued on 31 July 2013;
20. Points out that the report highlights the areas where improvements can be made; takes note however that the report considers the Joint Undertaking a success in achieving its objectives; notes in particular that as regards the Joint Undertaking's communication strategy, there is a need to develop additional KPIs which should help demonstrate its impact and socio-economic benefits, the optimisation of the organisational structure and a more flexible funding mechanism in a quantitative manner;
21. Notes from the Court's report that ex post audit corrections resulting from the first audits of the representative sample were implemented and are reflected in the 2013 financial accounts; observes that the validation of the accounting system does not yet cover the implementation of ex post audit results; calls on the Joint Undertaking to address this issue as a matter of urgency;
22. Takes note that the methodology for evaluating in-kind contributions, which specifies that the validation of the contributions is based on ex ante certifications and ex post audits, was approved by the Governing Board in 2011; notes moreover that the remaining eight certified methodologies for in-kind contributions were completed during 2013 and that the total number of EFPIA companies had been brought to 22; ascertains that the first three ex post audits covering in-kind contributions were completed during the course of 2013, one other ex post audit was initiated and two were in the process of being initiated at the year-end;

Other comments

23. Calls on the Joint Undertaking to submit a report to the discharge authority on the social-economic benefits of the already completed projects; calls for that report to be submitted to the discharge authority together with an assessment by the Commission;

24. Recalls that the discharge authority has previously requested the Court to draw up a special report on the capacity of the joint undertakings, together with their private partners, to ensure added value and efficient execution of Union research, technological development and demonstration programmes.

RESULT OF FINAL VOTE IN COMMITTEE

Date adopted	23.3.2015
Result of final vote	+: 16 -: 11 0: 0
Members present for the final vote	Nedzhmi Ali, Inés Ayala Sender, Ryszard Czarnecki, Dennis de Jong, Tamás Deutsch, Martina Dlabajová, Ingeborg Gräßle, Rina Ronja Kari, Bogusław Liberadzki, Verónica Lope Fontagné, Monica Macovei, Fulvio Martusciello, Dan Nica, Georgi Pirinski, Petri Sarvamaa, Claudia Schmidt, Igor Šoltes, Bart Staes, Michael Theurer, Marco Valli, Derek Vaughan, Anders Primdahl Vistisen, Joachim Zeller
Substitutes present for the final vote	Caterina Chinnici, Iris Hoffmann, Marian-Jean Marinescu, Andrey Novakov, Julia Pitera
Substitutes under Rule 200(2) present for the final vote	Laura Ferrara