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# Plenary sitting

A7-0200/2014

20.3.2014

# **REPORT**

on discharge in respect of the implementation of the budget of the Innovative Medicines Initiative Joint Undertaking for the financial year 2012 (C7-0339/2013 – 2013/2251(DEC))

Committee on Budgetary Control

Rapporteur: Paul Rübig

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# PR\_DEC\_Agencies

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#### 1. PROPOSAL FOR A EUROPEAN PARLIAMENT DECISION

on discharge in respect of the implementation of the budget of the Innovative Medicines Initiative Joint Undertaking for the financial year 2012 (C7-0339/2013 – 2013/2251(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 2012,
- having regard to the Court of Auditors' report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2012, together with the Joint Undertaking's replies<sup>1</sup>,
- having regard to the Council's recommendation of 18 February 2014 (05851/2014 C7-0053/2014),
- 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 Communities<sup>2</sup>, 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 1605/2002<sup>3</sup>, and in
  particular Article 208 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 Medicines<sup>4</sup>, and in particular Article 11(4) 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<sup>5</sup>,
- 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<sup>6</sup>, and in particular Article 108 thereof,

<sup>&</sup>lt;sup>1</sup> OJ C 369, 17.12.2013, p. 25.

<sup>&</sup>lt;sup>2</sup> OJ L 248, 16.9.2002, p. 1.

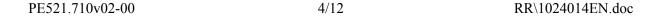
<sup>&</sup>lt;sup>3</sup> OJ L 298, 26.10.2012, p. 1.

<sup>&</sup>lt;sup>4</sup> OJ L 30, 4.2.2008, p. 38.

<sup>&</sup>lt;sup>5</sup> OJ L 357, 31.12.2002, p. 72.

<sup>&</sup>lt;sup>6</sup> OJ L 328, 7.12.2013, p. 42.

- 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 (A7-0200/2014),
- 1. Grants the Executive Director of the IMI Joint Undertaking discharge in respect of the implementation of the Joint Undertaking'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 IMI 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).



#### 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 2012 (C7-0339/2013 - 2013/2251(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 2012,
- having regard to the Court of Auditors' report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2012, together with the Joint Undertaking's replies<sup>1</sup>,
- having regard to the Council's recommendation of 18 February 2014 (05851/2014 C7-0053/2014),
- 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 Communities<sup>2</sup>, 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 1605/2002<sup>3</sup>, and in
  particular Article 208 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 Medicines<sup>4</sup>, and in particular Article 11(4) 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<sup>5</sup>,
- 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<sup>6</sup>,

<sup>&</sup>lt;sup>1</sup> OJ C 369, 17.12.2013, p. 25.

<sup>&</sup>lt;sup>2</sup> OJ L 248, 16.9.2002, p. 1.

<sup>&</sup>lt;sup>3</sup> OJ L 298, 26.10.2012, p. 1.

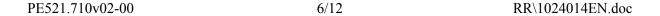
<sup>&</sup>lt;sup>4</sup> OJ L 30, 4.2.2008, p. 38.

<sup>&</sup>lt;sup>5</sup> OJ L 357, 31.12.2002, p. 72.

<sup>&</sup>lt;sup>6</sup> OJ L 328, 7.12.2013, p. 42.

and in particular Article 108 thereof,

- 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 (A7-0200/2014),
- 1. Approves the closure of the accounts of the IMI Joint Undertaking for the financial year 2012;
- 2. Instructs its President to forward this Decision to the Executive Director of the IMI 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).



#### 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 Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines for the financial year 2012 (C7-0339/2013 – 2013/2251(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 2012,
- having regard to the Court of Auditors' report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2012, together with the Joint Undertaking's replies<sup>1</sup>,
- having regard to the Council's recommendation of 18 February 2014 (05851/2014 C7-0053/2014),
- 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 Communities<sup>2</sup>, 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 1605/2002<sup>3</sup>, and in
  particular Article 208 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 Medicines<sup>4</sup>, and in particular Article 11(4) 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<sup>5</sup>,
- 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<sup>6</sup>,

<sup>&</sup>lt;sup>1</sup> OJ C 369, 17.12.2013, p. 25.

<sup>&</sup>lt;sup>2</sup> OJ L 248, 16.9.2002, p. 1.

<sup>&</sup>lt;sup>3</sup> OJ L 298, 26.10.2012, p. 1.

<sup>&</sup>lt;sup>4</sup> OJ L 30, 4.2.2008, p. 38.

<sup>&</sup>lt;sup>5</sup> OJ L 357, 31.12.2002, p. 72.

OJ L 328, 7.12.2013, p. 42.

- and in particular Article 108 thereof,
- 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 (A7-0200/2014),
- A. whereas the Innovative Medicines Initiative Joint Undertaking ("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 Joint Undertaking started to work autonomously on 16 November 2009,
- C. whereas the maximum contribution for the period of 10 years from the Union to the Joint Undertaking is EUR 1 billion to be paid from the budget of the Seventh Research Framework Programme,

## Budgetary and financial management

- 1. Notes that in the Court of Auditors' opinion, the Joint Undertaking's annual accounts present fairly, in all material respects, its financial position as at 31 December 2012 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. Appreciates that the Joint Undertaking completed as of June 2013 *ex post* audits covering EUR 4,4 million (37,3 % of accepted Joint Undertaking's contribution for the first call validated by the Joint Undertaking by June 2011); observes that these first audits focused on beneficiaries who were new or never audited under the Union research programmes and, therefore, a higher rate of error can be expected due to the complexity of the rules;
- 3. Is concerned that the error rate resulting from the *ex post* audits, performed by or on behalf of the Joint Undertaking was 5,82 %; recognises that most of these errors were relatively small in amounts to be adjusted (less than EUR 5 000 in favour of the Joint Undertaking; notes that steps have since been taken to recover or offset these amounts from subsequent claims and that the rate will continue to evolve on a multiannual basis as more projects, beneficiaries and claims are audited; points out that actions taken by the Joint Undertaking to prevent and correct these errors have a bearing on the residual error rate;
- 4. Takes note that the Court of Auditors issued a qualified opinion on the legality and the regularity of the transactions on that basis, underlying the annual accounts of the Joint Undertaking for the second consecutive year; notes that the Court of Auditors considers that the audit evidence obtained is sufficient and appropriate to provide a basis for its statement of assurance although the underlying payments audited were made prior to 2012;





5. Is concerned that a high level of payment and commitment appropriations for administrative expenditure in 2012 were still unused at year end (26,81 % of commitment appropriations and 39,8 % of payment appropriations); notes that the high level of unused appropriations of the administrative budget indicates that it was not based on realistic estimates defined through the Legislative Financial Statement;

#### Calls for proposals

- 6. Welcomes the fact that the time needed to sign agreements decreased in 2012 from 413 days for the final grant agreements under the fourth call to 161 days for the sixth call; emphasises the fact that in 2012, the Joint Undertaking committed EUR 351 million, or almost 37 % of its total available budget making good progress towards executing the total available Union contribution of EUR 960 million stipulated in Regulation (EC) No 73/2008 for research activities;
- 7. Notes that at the end of 2012, the Joint Undertaking cumulative total approved commitments for research costs was EUR 736 million and that the European Federation of Pharmaceutical Industries and Associations (EFPIA) had committed a further EUR 706 million;

#### Internal control systems

- 8. Emphasises the fact that the Court of Auditors' reports that the Joint Undertaking has continued developing adequate and comprehensive internal control systems but further work is needed in documenting and updating operational and administrative procedures (especially for *ex post* and accounting closure activities), which will mitigate the risks of error and inconsistent practices;
- 9. Recalls that the Commission's Internal Audit Service (IAS) is the Joint Undertaking internal auditor; points out that in 2012, the IAS carried out an assurance review of the (i) negotiation, (ii) grant agreement preparation and (iii) pre-financing processes of the Joint Undertaking; expects that the IAS directs its audits engagements to more high risk areas, especially to support the Joint Undertaking to overtake the material errors it detected through its first *ex post* audits in relation to interim payments and to ensure that a coherent control strategy is being implemented by the Joint Undertaking;
- 10. Welcomes that during 2012, the Joint Undertaking accounting officer reported on the validation of the accounting system on and most of the weaknesses identified were addressed by the end of the year;
- 11. Regrets that the CVs of the members of the Management Board and the Executive Director are not publicly available; calls on the Joint Undertaking to remedy the situation as a matter of urgency; acknowledges that the Joint Undertaking has Conditions that enforce a Code of Conduct on the independent experts that evaluate the research proposals; urges nevertheless the Joint Undertaking to develop and adopt a comprehensive policy on the prevention and management of conflicts of interests;
- 12. Believes that a high level of transparency is a key element in order to mitigate the risks of conflicts of interests; calls, therefore, on the Joint Undertaking to make its policy and/or

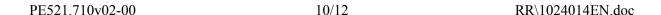
- arrangements on the prevention and management of conflicts of interests and its implementing rules as well as the list of the members of the management boards and CVs, available on its website;
- 13. Invites the Court of Auditors to monitor the Joint Undertaking's policies as regards the management and prevention of conflicts of interests by drafting a Special Report on the matter by the next discharge procedure;

## Audit rights of the Court of Auditors

14. Is surprised to learn that the provisions of the Council Regulation setting up the Joint Undertaking do not recognise the right of the Court of Auditors to audit the in-kind contributions of EFPIA companies, although they are recorded in the Joint Undertaking's financial statements; emphasises that it is estimated that these contributions will represent approximately EUR 1 billion over the Joint Undertaking's lifetime; invites the Court of Auditors to clarify the implications of that provision in the Court of Auditors' annual opinion on the accounts of the Joint Undertaking;

#### European Research Joint Undertakings horizontal aspects

- 15. Takes note that the audit approach taken by the Court of Auditors comprises analytical audit procedures, the assessment of key controls of the supervisory and control systems and the testing of transactions at the level of the Joint Undertaking but not at the level of the members or final beneficiaries of the Joint Undertaking;
- 16. Notes that audit testing at the level of the members or final beneficiaries is carried out either by the Joint Undertaking or by external audit firms contracted and monitored by the Joint Undertaking;
- 17. Welcomes the Court of Auditors' Special Report 2/2013: 'Has the Commission ensured efficient implementation of the Seventh Framework Programme for Research?' where the Court examined whether the Commission has ensured efficient implementation of the the Seventh framework programme for research and technological development (FP7);
- 18. Takes note that the audit also covered the setting-up of the Joint Technology Initiatives (JTIs);
- 19. Agrees with the Court of Auditors' conclusion that the JTIs have been set up to support long-term industrial investment in particular research areas; notes, however, that it has taken on average two years to grant financial autonomy to a JTI, with the Commission usually remaining responsible for one third of the expected operational lifetime of the JTIs;
- 20. Notes moreover that accordingly with the Court of Auditors some JTIs have been particularly successful in getting small and medium-sized enterprises (SMEs) involved in their projects and nearly 21 % of funding provided by the JTIs has gone to SMEs;
- 21. Draws attention to the fact that the total indicative resources deemed necessary for the seven European Research Joint Undertakings that have so far been established by the





- Commission under Article 187 of the Treaty on the Functioning of the European Union with the notable exception of the Galileo Joint Undertaking for their period of existence amounts to EUR 21 793 000 000;
- 22. Notes that the Joint Undertakings' total 2012 forecasted budgeted income amounted to some EUR 2,5 billion or about 1,8 % of the 2012 Union general budget while approximately EUR 618 million came from the general budget (cash contribution from the Commission) and approximately EUR 134 million came from the industrial partners and members of the Joint Undertakings;
- 23. Notes that the Joint Undertakings employ 409 permanent and temporary staff or less than 1 % of total Union officials authorised under the Union general budget (staff establishment plan);
- 24. Recalls that the total Union contribution deemed necessary for the Joint Undertakings for their period of existence amounts to EUR 11 489 000 000;
- 25. Invites the Court of Auditors to comprehensively analyse the JTIs and the other joint undertakings in a separate report in light of the substantial amounts involved and the risks-notably reputational presented; recalls that the Parliament has previously requested that the Court of Auditors 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; notes that the joint undertakings are deemed to ensure funding for long-term industrial investments and to foster private investments in research.

# **RESULT OF FINAL VOTE IN COMMITTEE**

Date adopted	18.3.2014	
Result of final vote	+: 22 -: 1 0: 1	
Members present for the final vote	Marta Andreasen, Jean-Pierre Audy, Inés Ayala Sender, Zuzana Brzobohatá, Tamás Deutsch, Martin Ehrenhauser, Jens Geier, Gerben- Jan Gerbrandy, Ingeborg Gräßle, Rina Ronja Kari, Jan Mulder, Eva Ortiz Vilella, Crescenzio Rivellini, Paul Rübig, Bart Staes, Georgios Stavrakakis, Michael Theurer, Derek Vaughan	
Substitute(s) present for the final vote	Amelia Andersdotter, Esther de Lange, Vojtěch Mynář, Markus Pieper	
Substitute(s) under Rule 187(2) present for the final vote	Fiona Hall, Annette Koewius	

