

2011 discharge: Initiative on Innovative Medicines Joint Undertaking

1. European Parliament decision of 17 April 2013 on discharge in respect of the implementation of the budget of the Innovative Medicines Initiative Joint Undertaking for the financial year 2011 (C7-0281/2012 – 2012/2219(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 2011,
- having regard to the Court of Auditors' report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2011, together with the replies of the Joint Undertaking¹,
- having regard to the Council's recommendation of 12 February 2013 (05755/2013 – C7-0040/2013),
- 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 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 Medicines⁴, 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 Communities⁵, and in particular Article 94 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 (A7-0088/2013),

1. Grants the Executive Director of the IMI Joint Undertaking discharge in respect of the

¹ OJ C 6, 10.1.2013, p. 27.

² OJ L 248, 16.9.2002, p. 1.

³ OJ L 298, 26.10.2012, p. 1.

⁴ OJ L 30, 4.2.2008, p. 38.

⁵ OJ L 357, 31.12.2002, p. 72.

implementation of the Joint Undertaking's budget for the financial year 2011;

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. European Parliament decision of 17 April 2013 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 2011 (C7-0281/2012 – 2012/2219(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 2011,
 - having regard to the Court of Auditors' report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2011, together with the replies of the Joint Undertaking¹,
 - having regard to the Council's recommendation of 12 February 2013 (05755/2013 – C7-0040/2013),
 - 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 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 Medicines⁴, 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 Communities⁵, and in particular Article 94 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 (A7-0088/2013),
1. Approves the closure of the accounts of the IMI Joint Undertaking for the financial year 2011;
 2. Instructs its President to forward this Decision to the Executive Director of the IMI Joint

¹ OJ C 6, 10.1.2013, p. 27.

² OJ L 248, 16.9.2002, p. 1.

³ OJ L 298, 26.10.2012, p. 1.

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⁵ OJ L 357, 31.12.2002, p. 72.

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. European Parliament resolution of 17 April 2013 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 2011 (C7-0281/2012 – 2012/2219(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 2011,
 - having regard to the Court of Auditors' report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2011, together with the replies of the Joint Undertaking¹,
 - having regard to the Council's recommendation of 12 February 2013 (05755/2013 – C7-0040/2013),
 - 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 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 Medicines⁴, 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 Communities⁵, and in particular Article 94 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 (A7-0088/2013),
- 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,

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⁵ OJ L 357, 31.12.2002, p. 72.

- B. whereas the Joint Undertaking started to work autonomously on 16 November 2009,
- C. whereas the Court of Auditors states that it has obtained reasonable assurances that the annual accounts of the Joint Undertaking for the financial year 2011 are reliable and that the underlying transactions are legal and regular,
- D. whereas the Court of Auditors has delivered a qualified opinion on the legality and the regularity of the transactions underlying the Joint Undertaking's accounts,
- E. 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,

Budgetary and financial management

1. Notes with concern that the budget of the Joint Undertaking for the financial year 2011 and the implementation plan was adopted by the Governing Board only on 4 April 2011 due to the time taken to establish and agree on the scientific priorities to be included in the annual implementation plan; notes that this delayed the launch of the call for proposals and for the entire first quarter of the year, the Joint Undertaking was obliged to use provisional twelfths budget rule to make payments;
2. Is concerned that the implementation rate for the EUR 159 000 000 commitment appropriations available for research activities was 66 % and that it was implemented through a global commitment covering the fourth call for proposals; reiterates its concern about the low implementation rate of the budget and, moreover, about the underlying activities of the Joint Undertaking; duly notes that the high level of unused appropriations of the administrative budget (44 %) indicates that it was not based on realistic estimates; calls for a detailed progress report on those shortcomings which makes specific proposals for a gradual improvement in the implementation rate and for a more realistic estimate of the financial resources needed;
3. Regrets, therefore, that commitment appropriations amounting to EUR 117 000 000 and payment appropriations amounting to EUR 65 000 000 not used in the financial year 2010 were carried over to 2011 and commitment appropriations amounting to EUR 62 000 000 and payment appropriations amounting to EUR 11 000 000 not used during the financial year 2011 were carried over to 2012; welcomes the improvements made for 2012, whereby the overall execution rates for commitment appropriations was 96% and for payment appropriations was 97%;
4. Is concerned that the annual accounts of the Joint Undertaking received a qualified opinion from the Court of Auditors on the legality and the regularity of the transactions underlying those accounts on the grounds that the error rate resulting from the ex post audits was 6,84%; takes note that the Joint Undertaking completed ex post audits covering EUR 2,2 million (18,8 % of accepted Joint Undertaking's contribution for the first call validated by the Joint Undertaking by June 2011); regrets that on the basis of the Joint Undertaking's first audits applying its own methodology, the detected error rate was 4,58 % while the residual error rate was 3,72 %; expects that the Court of Auditors and the Joint Undertaking agree on an audit methodology that for the same ex post audits delivers the same results; reiterates that the Joint Undertaking should reinforce without delay the quality of its ex ante controls, in particular for the grants management; requests that the discharge authority is informed of

the results of the following ex post audit processes conducted by the Joint Undertaking;

5. Calls, therefore, for a detailed progress report which makes specific proposals for a gradual reduction in the error rate;

Calls for proposals

6. Highlights the fact that the Joint Undertaking organised calls for proposals in 2008, 2009 and 2010 that resulted in signed grant agreements amounting to EUR 269 000 000 at the end of 2011 and that in 2012, the fifth call for proposals was launched with an indicative budgeted Union contribution of EUR 80 000 000; is concerned that if calls for proposals remain at the current level, it is highly likely that the total available Union contribution will not be used; calls the Joint Undertaking to make the best possible use of the resources that have been allocated for the implementation of the Joint Technology Initiative on Innovative Medicines;
7. Takes note of the inconsistencies between the Governing Board's decisions and the report on budgetary and financial management, namely the fact that in the report, the total amount of chapter 30-C2 "Research agenda" (EUR 117 000 000) is lower than the budget line B03000-C2 (EUR 141 000 000) which is part of that chapter; points out, furthermore, that the Governing Board's decision of 28 January 2011 only authorises the carry-over of EUR 115 000 000 of commitment appropriations, while the report on budgetary and financial management discloses a carry-over of EUR 117 000 000; calls on the Joint Undertaking to ensure that the decisions of its Governing Board are duly taken into account by the Executive Director;

Internal control systems

8. Points out that the Court of Auditors reports significant progress regarding internal control systems during 2011; notes, however, that further work is needed to establish and document the budget and accounting procedures and related controls and a formal assessment of the internal control system was carried out during 2011;
9. Takes note that the Accounting Officer of the Joint Undertaking reported on the validation of the accounting system on 27 September 2012 and underlined significant weaknesses which need to be addressed;

Evaluation of contributions in kind

10. Notes the Court of Auditors' finding that the methodology for evaluating in-kind contributions was approved by the Governing Board on 11 November 2011 and that the in-kind contributions are validated by way of an ex ante certification and ex post audits, however during 2011 no ex ante certification and no ex post audit were carried out by the Joint Undertaking;
11. Recalls that the Joint Undertaking was set up in December 2007 and started to work autonomously in November 2009; expresses concern that the methodology for evaluating contributions in-kind to be defined in the Joint Undertaking's internal rules and procedures in compliance with its Financial Rules has been approved by the Governing Board on 11 November 2011; emphasises the fact that the European Federation of Pharmaceutical Industries and Associations (EFPIA) members of the Joint Undertaking were, therefore,

unable to report on the costs incurred during the first reporting period as established in the grant agreements;

Internal audit and the Commission's Internal Audit Service

12. Takes note that in 2011, the Commission's Internal Audit Service and the Internal Audit Capability of the Joint Undertaking carried out a risk assessment exercise and the strategic audit plan for 2012-2014 was approved by the Governing Board on 3 November 2011;
13. Notes that the Joint Undertaking's Financial Rules have not yet been amended to include the provision of the Framework Regulation but the mission charter of the Commission's Internal Audit Service was adopted by the Governing Board on 8 March 2011;
14. Is concerned that while the Joint Undertaking obtained its autonomy in November 2009, no internal assurance audit work as such was performed until March 2012 either by the Internal Audit Service of the Commission or by the internal audit manager and the latter has been directly involved in operational activities (implementation of ex post strategy, KPI framework, review of ex ante certificate on in-kind contributions) and other consultancy engagements;

Audit rights of the Court of Auditors

15. Is surprised to learn that the provisions of the grant agreement 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 financial statements of the Joint Undertaking and are estimated at EUR 1 000 million over the lifetime of the Joint Undertaking; notes that in-kind contributions are audited by the Joint Undertaking in line with Article 12(4) and (5) of Regulation (EC) No 73/2008 and that the advice of the Commission was sought by the Joint Undertaking on the rights of the Court of Auditors to audit in-kind contributions of EFPIA companies;

Annual activity report

16. Emphasises the fact that the Executive Director's declaration of assurance was issued in February 2012 without reservation, despite the lack of information on the effectiveness of the ex post audit strategy, which is the key control for operational expenditure; notes that according to the Statutes and Financial Rules of the Joint Undertaking the Executive Director is required to draw up an annual activity report including a declaration of assurance stating that the information contained in the report presents a true and fair view except as otherwise specified in any reservation;

Other management matters

17. Notes that in 2011, the Joint Undertaking made progress on the formalisation of IT security policies; takes note that the business continuity plan and disaster recovery plan were not yet finalised;
18. Welcomes the fact that the Host State Agreement between the Joint Undertaking and the Belgian authorities concerning office accommodation, privileges and immunities and other support to be provided was signed on 3 February 2012;

Other issues

19. Reiterates its invitation for the Court of Auditors to provide, within a reasonable deadline, a special report to Parliament on common issues which occur due to the nature of the joint undertakings, and which should be addressed by the joint undertakings together with their partners in order to ensure their added value and efficient execution of Union research, technological development and demonstration programmes; notes, furthermore, that that report should include an assessment of the effectiveness of the joint undertakings' establishment and structure.