



---

**TEXTS ADOPTED**

*Provisional edition*

---

**P8\_TA-PROV(2016)0197**

**Discharge 2014 : Innovative Medicines Initiative 2 Joint Undertaking**

**1. European Parliament decision of 28 April 2016 on discharge in respect of the implementation of the budget of the Innovative Medicines Initiative 2 Joint Undertaking (formerly the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines) for the financial year 2014 (2015/2200(DEC))**

*The European Parliament,*

- having regard to the final annual accounts of the Innovative Medicines Initiative 2 Joint Undertaking (formerly the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines) for the financial year 2014,
- having regard to the Court of Auditors' report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2014, together with the Joint Undertaking's replies<sup>1</sup>,
- having regard to the statement of assurance<sup>2</sup> 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 Joint Undertaking in respect of the implementation of the budget for the financial year 2014 (05587/2016 – C8-0056/2016),
- 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 1605/2002<sup>3</sup>, and in particular Article 209 thereof,

---

<sup>1</sup> OJ C 422, 17.12.2015, p. 61.

<sup>2</sup> OJ C 422, 17.12.2015, p. 62.

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

- 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>1</sup>,
  - having regard to Council Regulation (EC) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking<sup>2</sup>, 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 Communities<sup>3</sup>,
  - 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 Council<sup>4</sup>,
  - 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 (A8-0081/2016),
1. Grants the Executive Director of the Innovative Medicines Initiative 2 Joint Undertaking (formerly the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines) discharge in respect of the implementation of the Joint Undertaking'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 Innovative Medicines Initiative 2 Joint Undertaking (formerly the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines), 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).

---

<sup>1</sup> OJ L 30, 4.2.2008, p. 38.

<sup>2</sup> OJ L 169, 7.6.2014, p. 54.

<sup>3</sup> OJ L 357, 31.12.2002, p. 72.

<sup>4</sup> OJ L 38, 7.2.2014, p. 2.

## **2. European Parliament decision of 28 April 2016 on the closure of the accounts of the Innovative Medicines Initiative 2 Joint Undertaking (formerly the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines) for the financial year 2014 (2015/2200(DEC))**

*The European Parliament,*

- having regard to the final annual accounts of the Innovative Medicines Initiative 2 Joint Undertaking (formerly the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines) for the financial year 2014,
- having regard to the Court of Auditors' report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2014, together with the Joint Undertaking's replies<sup>1</sup>,
- having regard to the statement of assurance<sup>2</sup> 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 Joint Undertaking in respect of the implementation of the budget for the financial year 2014 (05587/2016 – C8-0056/2016),
- 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 1605/2002<sup>3</sup>, 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 Medicines<sup>4</sup>,
- having regard to Council Regulation (EC) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking<sup>5</sup>, 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 Communities<sup>6</sup>,

---

<sup>1</sup> OJ C 422, 17.12.2015, p. 61.

<sup>2</sup> OJ C 422, 17.12.2015, p. 62.

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

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

<sup>5</sup> OJ L 169, 7.6.2014, p. 54.

<sup>6</sup> OJ L 357, 31.12.2002, p. 72.

- 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 Council<sup>1</sup>,
  - 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 (A8-0081/2016),
1. Approves the closure of the accounts of the Innovative Medicines Initiative 2 Joint Undertaking (formerly the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines) for the financial year 2014;
  2. Instructs its President to forward this decision to the Executive Director of the Innovative Medicines Initiative 2 Joint Undertaking (formerly the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines), 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).

---

<sup>1</sup> OJ L 38, 7.2.2014, p. 2.

**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 Innovative Medicines Initiative 2 Joint Undertaking (formerly the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines) for the financial year 2014 (2015/2200(DEC))**

*The European Parliament,*

- having regard to its decision on discharge in respect of the implementation of the budget of the Innovative Medicines Initiative 2 Joint Undertaking (formerly the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines) 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 (A8-0081/2016),
- A. whereas the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines ('IMI 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 following the adoption of Council Regulation (EU) No 557/2014<sup>1</sup> in May 2014 the Innovative Medicines Initiative 2 Joint Undertaking ('IMI 2 Joint Undertaking') replaced the IMI Joint Undertaking in June 2014 with the aim of finalising research activities of the Seventh Framework Programme ('FP 7') and extended the lifetime of the Joint Undertaking until 31 December 2024,
- C. whereas the Union, which is represented by the Commission, and the European Federation of Pharmaceutical Industries and Associations (EFPIA) are the founding members of the Joint Undertaking,
- D. whereas the Joint Undertaking started to work autonomously on 16 November 2009,
- E. whereas the maximum contribution for the period of 10 years from the Union to the IMI Joint Undertaking is EUR 1 000 000 000, to be paid from the budget of the FP 7 and the founding members are to contribute equally to the running costs, each with an amount not exceeding 4 % of the total Union contribution,
- F. whereas the maximum contribution for the period of 10 years from the Union to the IMI 2 Joint Undertaking is EUR 1 638 000 000, to be paid from the budget of Horizon 2020 and the Members, other than the Commission, have to contribute 50 % of the running costs and should contribute to operational costs through cash or in-kind contributions, or both, equal to the financial contribution of the Union,

***General remarks***

---

<sup>1</sup> Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (OJ L 169, 7.6.2014, p. 54).

1. Notes that the Court of Auditors' ('the Court') report is based on too many general remarks to the detriment of viable, specific ones; therefore calls for an audit with a more accentuated focus on the annual financial performance, the implementation status of multiannual projects (including a clear presentation of the implementation of the budget for the respective year and for previous years) and their the results and implementation;
2. Notes that the institutions and bodies are required to produce each year a Report on Budgetary and Financial Management and that the information provided by the Joint Undertaking in that report lacked harmonisation and was often incomplete; considers, in this respect, that guidance is required from the Commission as to the nature and content of the report;
3. Takes note that the 2016 Court's working programme includes a special report on performance audit of Joint Undertakings;

### ***Budgetary and financial management***

4. Notes that, in the Court's opinion, the Joint Undertaking's annual accounts present fairly, in all material respects, its financial position as on 31 December 2014 and the results of its operations and cash flows for the year then ended, in accordance with its financial rules and the accounting rules adopted by the Commission's accounting officer;
5. Notes the lack of information regarding the *ex-post* audits performed by IMI Joint Undertaking and IMI 2 Joint Undertaking; calls on the Court to include in the future reports information regarding the number of *ex-post* audits, the total amounts covered and the findings;
6. Notes the clean opinion of the Court on the legality and regularity of transactions underlying the annual accounts of the Joint Undertaking for the year 2014 and acknowledges that the Joint Undertaking has met the materiality threshold;
7. Notes from the Annual Activity report that, by the end of 2014, four *ex post* reviews and audits of selected companies belonging to the EFPIA had been finalised and a further two reviews and audits were ongoing; those engagements cover the largest contributors of in-kind contributions to Joint Undertaking's projects, thereby ensuring extensive coverage of the programme;
8. Notes with concern that the performance of operational *ex-ante* controls on the payment of project costs was insufficiently documented; the *ex-ante* control performed by the Joint Undertaking's Scientific Project Officers (SPO) did not clearly identify and comment upon the status of the project (on-going, on-going subject to deficiencies, suspended/cancelled) and its deliverables (no reservations, reservations requiring clarification, major reservations); and payment was made without an official listing of deliverables accepted by the SPO and without any reference to the assessment of deliverables by the SPO; takes note that the Joint Undertaking has established an action plan to address auditors' observations and enhance *ex ante* control system;
9. Notes that the Joint Undertaking's 2014 annual budget included commitment appropriations amounting to EUR 223 000 000 and payment appropriations amounting to EUR 171 000 000; the overall implementation rate was 92,4 % (99,5 % for 2013) for commitment appropriations and 73,9 % (97,5 % for 2013) for payment appropriations;

10. Notes that in the case of operational activities, the implementation rate was 93 % for commitment appropriations and 74 % for payment appropriations; however, commitment appropriations were committed at a global level, meaning that no corresponding grant agreements have been signed by the end of 2014;
11. Considers that, in the absence of a clear separation between FP 7 and Horizon 2020 implementation-related information, these indicators do not ensure a real evaluation of performance; calls on the Court to set out in its future reports information regarding the execution of the budget under FP 7 and that of Horizon 2020 separately;
12. Takes note that the commitment appropriations and payment appropriations for the FP 7 and Horizon 2020 are not presented separately in the Annual Activity report; takes note that in the context of operational budget execution, commitment appropriations presented in the Joint Undertaking's Annual Activity Report and Annual Accounts are broken down into FP 7 and Horizon 2020; calls on the Joint Undertaking to include more information on budget execution (commitment and payments) for FP 7 and Horizon 2020 programmes in the upcoming annual reports;
13. Regrets the lack of information regarding in-kind and cash contributions; calls on the Court to include, in its future reports, specific provisions regarding the evaluation procedure and the level of in-kind and cash contributions that are set out separately for FP 7 and Horizon 2020;
14. Notes that Joint Undertaking's programmes funded under FP 7 are still ongoing; takes note that these appropriations remain available until 2017 because of the Joint Undertaking's financial rules which allow Joint Undertaking to re-enter its commitment and payment appropriations up to three years after they have been cancelled from the Joint Undertaking's budget; encourages the Joint Undertaking to carefully conduct its budget planning, taking into due account the parallel process;

### ***Calls for proposals***

15. Welcomes the fact that the calls for proposals under the FP 7 for the 2008-2013 period resulted in 54 grant agreements totalling EUR 897 000 000, amounting to 93 % of the maximum Union contribution to the Joint Undertaking for research activities;
16. Notes that the involvement of the SMEs is increasing continuously, due to the promotion of their participation in its activities; by the end of 2014 SMEs accounted for 16 % (2013: 15 %) of all beneficiaries; moreover, the SMEs involved in the Joint Undertaking's projects received 15,8 % of the total budget; encourages the Joint Undertaking to continue this trend;
17. Points out that as IMI 2 Joint Undertaking took over the activity of IMI Joint Undertaking in June 2014, there is not enough clear information regarding the state of play of implementation of IMI Joint Undertaking 's projects (level of payments or payments plans for the next years);

### ***Conflicts of interest***

18. Notes that the policy governing conflicts of interest for the Executive Director and staff of the Joint Undertaking is publicly available on its website;

19. Welcomes the fact that the declaration of interests of the Executive Director was published on the Joint Undertaking's website; the names and the Curricula Vitae of the members of the Joint Undertaking's Governing Board, Scientific Committee and the names of the States Representatives Group are all publicly available via the website; encourages the Joint Undertaking to publish each Curriculum Vitae on the website;

### ***Legal framework***

20. Notes from the Court's report that the financial rules of the IMI 2 Joint Undertaking were adopted on 7 July 2014 on the basis of the model financial regulation for public-private partnership bodies;

### ***Internal control systems***

21. Notes from the Court's report that the Commission's Internal Audit Service (IAS) finalised an audit on monitoring and reporting operational performance and that all recommendations have been addressed by the Joint Undertaking;
22. Notes from the Court's report that two audits were completed in early 2015 – one on *ex ante* controls for operational expenditure and the other on risk assessment; the Joint Undertaking has addressed the recommendation on *ex ante* controls through an action plan that has been accepted by the IAS;
23. Welcomes the publication of a short analysis on Joint Undertaking's project outputs linked to socio-economic impacts in February 2016; takes note that an extended analysis of socio-economic impact is under preparation by external experts and should be published in May 2016 at the latest; calls on the Joint Undertaking to submit that report to the discharge authority.