



EUROPEAN  
COURT  
OF AUDITORS

Report on the annual accounts of the Innovative Medicines Initiative Joint  
Undertaking for the financial year 2017

Together with the Joint Undertaking's reply

## CONTENTS

	Paragraph
Introduction	1 - 12
Establishment of the IMI Joint Undertaking	1 - 2
Governance	3 - 5
Objectives	6
Resources	7 - 11
The Commission's evaluations	12
Opinion	13 - 25
Opinion on the reliability of the accounts	14
Opinion on the legality and regularity of revenue underlying the accounts	15
Opinion on the legality and regularity of payments underlying the accounts	16
Responsibilities of management and those in charge of governance	17 - 19
Auditor's responsibilities for the audit of the accounts and underlying transactions	20 - 25
Budgetary and financial management	26 - 36
Implementation of the 2017 budget	26 - 27
Multiannual budget implementation under FP7	28 - 32
Multiannual budget implementation under Horizon 2020	33 - 36
Internal controls	37 - 39
Internal control framework	37 - 39
Other issues	40
Leverage of contributions from industry members	40
Information on the Commission's evaluations	41 - 42

Annex - Follow-up of previous years' comments

The Joint Undertaking's reply

## **INTRODUCTION**

### ***Establishment of the IMI Joint Undertaking***

1. The Initiative on Innovative Medicines (IMI) Joint Undertaking, located in Brussels, was set up in December 2007<sup>1</sup> for a period of ten years and started working autonomously on 16 November 2009. In May 2014, the Council adopted a new founding Regulation and extended the lifetime of the Joint Undertaking to 31 December 2024<sup>2</sup>.
2. The IMI Joint Undertaking is a public-private partnership for health research and innovation. The founding members of the Joint Undertaking are the European Union (EU), represented by the Commission, and the pharmaceutical sector, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

### ***Governance***

3. The governance structure of the IMI Joint Undertaking includes the Governing Board, the Executive Director, the Scientific Committee, the States Representatives Group, the Strategic Governing Groups and the Stakeholder Forum.
4. The Governing Board is the main decision-making body and is responsible for the operations of the Joint Undertaking and oversight of its activities. The Board is composed of ten members representing the two founding members equally. The Executive Director is responsible for the day-to-day management of the Joint Undertaking.
5. The Scientific Committee, the States Representatives Group, the Strategic Governing Groups and the Stakeholder Forum are advisory bodies. The Scientific Committee is made up of scientific experts from diverse fields and provides recommendations to the Governing

---

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

<sup>2</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).

Board. The States Representatives Group, consisting of representatives of the EU Member States and the countries associated with the EU's research programmes, provides strategic opinions to the Governing Board. The Strategic Governing Groups, which comprise representatives of pharmaceutical companies, the European Commission and the Scientific Committee, coordinate IMI projects among themselves and with the EU's wider research programmes. The Stakeholder Forum is an annual event, where IMI stakeholders discuss the IMI's latest activities and plans.

### ***Objectives***

6. The objective of the IMI Joint Undertaking is to improve health by speeding up the development of, and patient access to innovative medicines, particularly in areas where there is an unmet medical or social need. The Joint Undertaking seeks to facilitate collaboration between the key players in healthcare research, including universities, the pharmaceutical and other industries, small- and medium-sized enterprises (SMEs), patient organisations and medicine regulators.

### ***Resources***

7. The maximum EU contribution to the activities of the IMI1 programme (2008-2013) is one billion euro, funded from the Seventh Research Framework Programme (FP7)<sup>3</sup>. Contributions from pharmaceutical sector members must be equal to the EU contribution.

8. The maximum EU contribution to the activities of the IMI2 programme (2014-2024) is 1 638 million euro, to be funded from the Horizon 2020 programme. Of this amount, a maximum of 1 425 million euro can be used to match the contribution of EFPIA, and up to 213 million euro can be used to match contributions from other companies and universities that decide to join the IMI Joint Undertaking as members or associated partners<sup>4</sup>.

---

<sup>3</sup> Article 5(1) of Regulation (EC) No 73/2008.

<sup>4</sup> Article 3(1) of Regulation (EU) No 557/2014.

9. EFPIA is to contribute resources of at least 1 425 million euro to the Joint Undertaking's operational and administrative costs. Future other members or associated partners of the IMI2 programme are to contribute resources corresponding to the amounts they committed when becoming a member or an associated partner.

10. The administrative costs of the Joint Undertaking are limited to 85,2 million euro, to be covered by the cash contributions of the members, divided equally on an annual basis between the EU and the industry members<sup>5</sup>.

11. In 2017, the final budget for the IMI Joint Undertaking was 206,4 million euro (2016: 263,4 million euro). At 31 December 2017, the Joint Undertaking employed 49 staff (2016: 41)<sup>6</sup>.

### ***The Commission's evaluations***

12. The Commission completed the final evaluation of the Joint Undertaking's FP7 activities and the interim evaluation of its Horizon 2020 activities in June 2017, which was followed by respective action plans prepared by the Joint Undertaking to address the recommendations raised in the evaluations. On this occasion, we include a section related to the Joint Undertaking's Action Plans in response to the evaluations, which is intended only for information purposes and does not form part of our audit opinion or observations.

---

<sup>5</sup> Article 13(2) of the Statutes of the IMI 2 Joint Undertaking (Annex I of Regulation (EU) No 557/2014.

<sup>6</sup> Further information on the Joint Undertaking's activities is available on its website: <https://www.imi.europa.eu>.

**OPINION**

13. We have audited:

- (a) the accounts of the Joint Undertaking which comprise the financial statements<sup>7</sup> and the reports on the implementation of the budget<sup>8</sup> for the financial year ended 31 December 2017, and
- (b) the legality and regularity of the transactions underlying those accounts, as required by Article 287 of the Treaty on the Functioning of the European Union (TFEU).

***Opinion on the reliability of the accounts***

14. In our opinion, the accounts of the Joint Undertaking for the year ended 31 December 2017 present fairly, in all material respects, the financial position of the Joint Undertaking at 31 December 2017, the results of its operations, its cash flows, and the changes in net assets for the year then ended, in accordance with its Financial Regulation and with accounting rules adopted by the Commission's accounting officer. These are based on internationally-accepted accounting standards for the public sector.

***Opinion on the legality and regularity of revenue underlying the accounts***

15. In our opinion, revenue underlying the accounts for the year ended 31 December 2017 is legal and regular in all material respects.

***Opinion on the legality and regularity of payments underlying the accounts***

16. In our opinion, payments underlying the accounts for the year ended 31 December 2017 are legal and regular in all material respects.

---

<sup>7</sup> The financial statements comprise the balance sheet, the statement of financial performance, the cash flow statement, the statement of changes in net assets and a summary of significant accounting policies and other explanatory notes.

<sup>8</sup> The reports on implementation of the budget comprise the reports which aggregate all budgetary operations and the explanatory notes.

***Responsibilities of management and those in charge of governance***

17. In accordance with Articles 310 to 325 of the TFEU and the Joint Undertaking's Financial Regulation, management is responsible for the preparation and presentation of the accounts on the basis of internationally-accepted accounting standards for the public sector and for the legality and regularity of the transactions underlying them. This responsibility includes the design, implementation and maintenance of internal control relevant to the preparation and presentation of financial statements that are free from material misstatement, whether due to fraud or error. Management is also responsible for ensuring that the activities, financial transactions and information reflected in the financial statements are in compliance with the authorities which govern them. The Joint Undertaking's management bears the ultimate responsibility for the legality and regularity of the transactions underlying the accounts.

18. In preparing the accounts, management is responsible for assessing the Joint Undertaking's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting.

19. Those in charge of governance are responsible for overseeing the entity's financial reporting process.

***Auditor's responsibilities for the audit of the accounts and underlying transactions***

20. Our objectives are to obtain reasonable assurance about whether the accounts of the Joint Undertaking are free from material misstatement and the transactions underlying them are legal and regular and, on the basis of our audit, to provide the European Parliament and the Council or other respective discharge authorities with a statement of assurance as to the reliability of the accounts and the legality and regularity of the transactions underlying them. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit will always detect a material misstatement or non-compliance when it exists. These can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these accounts.

21. An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the accounts and the legality and the regularity of the transactions underlying them. The procedures selected depend on the auditor's judgment, including an assessment of the risks of material misstatement of the accounts and of material non-compliance of the underlying transactions with the requirements of the legal framework of the European Union, whether due to

fraud or error. In making those risk assessments, internal control relevant to the preparation and fair presentation of the accounts and legality and regularity of underlying transactions is considered in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of internal control. An audit also includes evaluating the appropriateness of accounting policies used, the reasonableness of accounting estimates made by the management and the overall presentation of the accounts.

22. For revenue, we verify the subsidy received from the Commission and assess the Joint Undertaking's procedures for collecting fees and other income.

23. For expenditure, we examine payment transactions when expenditure has been incurred, recorded and accepted. This examination covers all categories of payments (including those made for the purchase of assets) other than advances at the point they are made.

24. In preparing this report and opinion, we considered the audit work of the independent external auditor performed on the Joint Undertaking's accounts as stipulated in Article 208(4) of the EU Financial Regulation<sup>9</sup>.

25. The comments which follow do not call the ECA's opinions into question.

## **BUDGETARY AND FINANCIAL MANAGEMENT**

### ***Implementation of the 2017 budget***

26. The final 2017 budget available for FP7 and Horizon 2020 programme implementation included commitment appropriations of 322,4 million euro and payment appropriations of 206,4 million euro. The implementation rates for commitment and payment appropriations were 97 % and 72 %, respectively. The low implementation rate for payment appropriations was mainly due to a reduction or postponement of clinical trials within some large and complex projects of the Anti-Microbial Resistance and Ebola programmes and to delays in concluding grant agreements for calls under Horizon 2020.

---

<sup>9</sup> Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council (OJ L 298, 26.10.2012, p. 1).

27. Near the end of 2017, the unused payment appropriations from previous years amounted to 78,7 million euro. Consequently, the Joint Undertaking's Governing Board approved in July 2017 to reduce the new operational payment appropriations of the year by 56 million euro<sup>10</sup>, and in November 2017 to reduce the accumulated unused payment appropriations from previous years by 25,8 million euro. This situation shows that during the last years, there were weaknesses when planning and monitoring the need for new payment appropriations.

### ***Multiannual budget implementation under FP7***

28. Out of the maximum 1 billion euro of FP7 funds allocated to the IMI Joint Undertaking, for the implementation of IMI 1, by the end of 2017, the EU contributed in cash a total amount of 827,2 million euro.

29. Out of the 1 billion euro of contributions to be made by the industry members to the activities of the IMI Joint Undertaking, by the end of 2017, the Joint Undertaking had validated in-kind contributions of 529,9 million euro and cash contributions of 21,9 million euro. Another 153,3 million euro of in-kind contributions have been declared by the industry member and will be validated beginning 2018.

30. Consequently, at the end of 2017, the total in-kind and cash contributions of the industry members amounted to 705,1 million euro, compared to the cumulative EU cash contribution to the FP7 activities of the IMI Joint Undertaking, which amounted to 827,2 million euro.

31. Out of the total operational and administrative budget of 1 billion euro for IMI 1 activities, by the end of 2017, the IMI 1 Joint Undertaking had made commitments of 966 million euro (96,6 % of the available budget) and payments of 720 million euro.

32. The high level of outstanding payments of 246 million euro (25 %) was mainly due to the delayed start of FP7 activities during the first years of the IMI Joint Undertaking.

---

<sup>10</sup> First amendment of the 2017 budget.

### ***Multiannual budget implementation under Horizon 2020***

33. Out of the maximum of 1 638 million euro of Horizon 2020 funds allocated to the IMI Joint Undertaking for the implementation of IMI 2, by the end of 2017, the EU contributed in cash a total amount of 157,3 million euro.

34. EFPIA committed to make at least 1 425 million euro of in-kind and cash contributions to the Joint Undertaking's Horizon 2020 operational and administrative activities over its lifespan. At the end of 2017, EPFIA and its associated partners reported in-kind contributions of 132,8 million euro of which 82,5 million euro had been validated. In addition, the Executive Director had validated cash contributions by the industry members (EFPIA and associated partners) of 7,6 million euro.

35. Consequently, by the end of 2017, the total contributions from industry members, amounted to 140,4 million euro compared to the EU cash contribution of 157,3 million euro.

36. Out of the maximum operational and administrative budget for the Joint Undertaking of 1 680<sup>11</sup> million euro<sup>12</sup>, by the end of 2017, the Joint Undertaking made commitments of 819,0 million euro and payments of 179,6 million euro. The relatively low level of payments is mainly due to the time required by project consortia to conclude Horizon 2020 grant agreements, which delayed the Joint Undertaking's planned pre-financing payments for the year.

---

<sup>11</sup> 1 638 million euro to cover administrative and operational costs (Article 3 of IMI2 regulation) plus half of 85 million euro (cash contribution – Article 13, Annex of IMI2 regulation).

<sup>12</sup> This amount includes the maximum EU cash contribution to the Joint Undertaking's operational and administrative costs and the industry members' cash contribution to the Joint Undertakings' administrative costs.

## **INTERNAL CONTROLS**

### ***Internal control framework***

37. The Joint Undertaking has set up reliable ex-ante control procedures based on financial and operational desk reviews. For FP7 interim and final payments, the Joint Undertaking performs ex-post audits at the beneficiaries whilst for Horizon 2020 project cost claims the Commission's Common Audit Service (CAS) is responsible for the ex-post audits. The residual error rates for the ex-post audits reported by the Joint Undertaking at the end of 2017 were 1,29 % for FP7 and 0,81 % for Horizon 2020<sup>13</sup>.

38. Based on an assessment of the Joint Undertaking's internal control system and substantive testing of revenue, payment, grant and procurement operations and a review of a sample of finalised ex-post audits including recoveries arising from the errors detected, the audit results provided us with reasonable assurance that the overall residual error rate for the Joint Undertaking is below materiality.

39. At the end of 2017, the Commission's Common Support Centre (CAS) had not finished specific developments in the Horizon 2020 grant management and monitoring tools to serve the Joint Undertaking's reporting and processing needs for in-kind contributions.

## **OTHER ISSUES**

### ***Leverage of contributions from industry members***

40. One of the main objectives of the Joint Undertaking is to leverage contributions from industry members in the area of its activities<sup>14</sup>. The minimum leverage factor to be achieved according to the Joint Undertaking's founding regulation is 1<sup>15</sup>.

---

<sup>13</sup> IMI Joint Undertaking 2017 Annual Activity Report, p. 103-104.

<sup>14</sup> Recital 4 of Regulation (EU) No 557/2014 states that this partnership should be based on a balanced contribution from all partners.

<sup>15</sup> Minimum in-kind contributions of the industry member (EFPIA) to the operational activities of the Joint Undertaking (1 425 million euro) divided by the maximum EU cash contribution to the

## **INFORMATION ON THE COMMISSION'S EVALUATIONS**

41. The Commission's Final Evaluation of IMI Joint Undertaking operating under FP7 covered the period between 2008 and 2016<sup>16</sup>, while the Interim Evaluation of IMI 2 Joint Undertaking operating under H2020 covered the period from 2014 to 2016<sup>17</sup>. The evaluations were carried out with the assistance of independent experts as foreseen in the IMI Council Regulations<sup>18</sup>, and covered the performance of the Joint Undertaking in terms of relevance, efficiency, effectiveness, coherence, and EU added value, with additional consideration of openness and transparency and research quality. The results of the evaluations were taken into account in the report that the Commission sent to the European Parliament and Council in October 2017<sup>19</sup>.

42. In response to the recommendations raised by the evaluators<sup>20</sup>, the Joint Undertaking prepared an Action Plan that was endorsed by the IMI 2 Governing Board in November 2017. The action plan includes a wide set of actions to be implemented by the Joint Undertaking<sup>21</sup>,

---

Joint Undertaking (1 425 million euro). Please note that in line with the IMI2 statutes, the industry members do not provide in-kind contributions to additional activities outside the work programme of the Joint Undertaking.

<sup>16</sup> Final evaluation of the IMI Joint Undertaking operating under FP7.

[https://ec.europa.eu/research/health/pdf/imi\\_final\\_evaluation.pdf](https://ec.europa.eu/research/health/pdf/imi_final_evaluation.pdf)

<sup>17</sup> Interim evaluation of the IMI 2 Joint Undertaking (2014-2016) operating under Horizon 2020

[https://ec.europa.eu/research/health/.../imi2\\_interim\\_evaluation.pdf](https://ec.europa.eu/research/health/.../imi2_interim_evaluation.pdf)

<sup>18</sup> Commission statutory evaluations in application of Article 11 of Council Regulation (EU) No 73/2008 on IMI Joint Undertaking, and article 11 of Council Regulation (EU) No 557/2014 establishing the IMI 2 Joint Undertaking.

<sup>19</sup> Commission Staff Working Document. Interim Evaluation of the Joint Undertakings operating under Horizon 2020 {SWD(2017) 339 final}.

<sup>20</sup> Recommendations raised by the evaluators include: the need to integrate other industries than the pharmaceutical industry in the collaborative projects; the need to increase participation of SMEs and the EU 13; the need to develop an accountable Performance Measurement Framework to assess the impacts and socio-economic benefits of the joint undertaking, the need to review the Intellectual Property Rights policy, and the need to improve and broaden access to project outcomes, in order to ensure sustainability and increase impact.

<sup>21</sup> Specific actions presented in the action plan to address the evaluator's recommendations include: to identify and develop topics better adapted to SMEs; to develop an IMI 2 webpage

for which a certain number of activities have already been initiated<sup>22</sup>, the majority should be implemented in 2018 and 2019, while a small number will be taken under consideration in the next programming period<sup>23</sup>.

This Report was adopted by Chamber IV, headed by Mr Neven MATES, Member of the Court of Auditors, in Luxembourg at its meeting of 2 October 2018.

*For the Court of Auditors*

Klaus-Heiner LEHNE

*President*

---

identifying all important assets generated by IMI projects in order to facilitate dissemination and further exploitation; to seek advice on how to best ensure sustainability of valuable outputs/outcome from IMI projects; to investigate the feasibility and potential added value for a brokerage platform in order to stimulate uptake of project results.

<sup>22</sup> Activities already initiated include: the development of specific webinars to enhance participation of SMEs in the Joint Undertaking's activities (<https://www.imi.europa.eu/news-events/events/webinars-imi2-call-13>); a catalogue of accessible tools generated by IMI projects to promote dissemination, and to further exploit project results and widen impact (IMI 2 Joint Undertaking web site); a new set of relevant, accepted, credible, easy and robust key performance indicators to be provided from 2018 financial year and beyond (IMI 2 Amended Annual Work Programme of March 2018).

<sup>23</sup> The review of the Intellectual Property rights policy to make it more flexible while respecting the Legal Framework.

Follow-up of previous years' comments

Year	The ECA's comment	Status of corrective action (Completed / Ongoing / Outstanding)
	<i>Management of Horizon 2020 grants</i>	
2016	At the end of 2016 – the third year of Horizon 2020 implementation – the Joint Undertaking had only partially completed the integration of its control systems with the Commission's common Horizon 2020 grant management and monitoring tools.	<b>Completed</b>
	<i>Ex-ante checks and monitoring of cost claims</i>	
2016	The Joint Undertaking experienced some delays in making payments to beneficiaries (universities, research organisations and SMEs). This indicates weaknesses in the internal control and monitoring procedures for project reports and related cost claims, adversely affecting the efficiency of project implementation.	<b>Completed</b>

### THE JU'S REPLY

27. The forecasting process under the Commission's annual budgeting procedure starts two years in advance. The IMI2 Joint Undertaking is requested to provide a forecast for payment appropriations in January year N-2, at a time where future needs cannot be identified with full accuracy and precision. In January of year N-1, payment appropriations are recorded in the Commission's "Fiche Financière" which forms the basis of the Commission's annual budget procedure.

The established budgetary process does not allow any adaptations even though the IMI2 Joint Undertaking revises its forecast in year N-1 according to the actual changes in project portfolio. The figures recorded in the Commission's "Fiche Financière" cannot be changed before the adoption of the next Commission's annual budget.

39. In agreement with the Internal Audit Service, the IMI2 Joint Undertaking is implementing an action plan. The IMI2 Joint Undertaking is collaborating with the Commissions Common Support Center in analysing the possible options of migrating industry in-kind contribution reporting into the H2020 tools and in seeking effective solutions in view of the continuity of H2020 type of reporting structures under Horizon Europe.