

**REPORT****on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2014, together with the Joint Undertaking's replies**

(2015/C 422/07)

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## INTRODUCTION

1. The Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines (IMI Joint Undertaking), located in Brussels, was set up in December 2007<sup>(1)</sup> for a period of 10 years and started working autonomously on 16 November 2009. In May 2014<sup>(2)</sup>, the Council repealed the original Regulation and entrusted the Joint Undertaking, referred to as the 'Initiative on Innovative Medicines 2 Joint Undertaking' (IMI 2 Joint Undertaking)<sup>(3)</sup>, with new tasks under the Horizon 2020 Framework programme for Research and Innovation<sup>(4)</sup> and extended the lifetime of the Joint Undertaking for the period up to 31 December 2024.

2. The objective of the IMI Joint Undertaking under the Seventh Framework Programme<sup>(5)</sup> is to significantly improve the efficiency and effectiveness of the drug development process, with the long-term aim that the pharmaceutical sector produce more effective and safer innovative medicines. Under Horizon 2020, the objective of the IMI 2 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. It does this by fostering collaboration between the key players involved in healthcare research, including universities, the pharmaceutical and other industries, small and medium-sized enterprises (SMEs), patient organisations and medicines regulators<sup>(6)</sup>.

3. The Founding Members of the Joint Undertaking are the European Union, represented by the European Commission, and the European Federation of Pharmaceutical Industries and Associations (EFPIA). Other Members and Associated Partners may also join the programme.

4. The maximum EU contribution to the IMI Joint Undertaking, to cover running costs and research activities, is one billion euro to be paid from the budget of the Seventh Framework Programme. The EU financial contribution to the IMI 2 Joint Undertaking under Horizon 2020 will be up to 1,638 billion euro, of which up to 1,425 billion to match the contribution<sup>(7)</sup> of the pharmaceutical sector and up to 213 million to match contributions from other companies that decide to join IMI 2 as Associated Partners. The Members are to contribute equally to the running costs (which should not exceed 85,2 million euro for the IMI 2 Joint Undertaking).

## INFORMATION IN SUPPORT OF THE STATEMENT OF ASSURANCE

5. The audit approach taken by the Court comprises analytical audit procedures, testing of transactions at the level of the Joint Undertaking and an assessment of key controls of the supervisory and control systems. This is supplemented by evidence provided by the work of other auditors (where relevant) and an analysis of management representations.

### STATEMENT OF ASSURANCE

6. Pursuant to the provisions of Article 287 of the Treaty on the Functioning of the European Union (TFEU), the Court has audited:

<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).

<sup>(3)</sup> This report refers to the 'Initiative on Innovative Medicines Joint Undertaking' unless it is necessary to distinguish between the two programmes.

<sup>(4)</sup> The Horizon 2020 Framework programme for Research and Innovation, adopted by Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104), is the research and innovation programme for 2014-2020 and brings together all existing EU research and innovation funding.

<sup>(5)</sup> The Seventh Framework Programme, adopted by Decision No 1982/2006/EC of the European Parliament and of the Council (OJ L 412, 30.12.2006, p. 1), brings all the research-related EU initiatives together under one roof and plays a crucial role in reaching the goals of growth, competitiveness and employment.

<sup>(6)</sup> The *Annex* summarises the Joint Undertaking's competences, activities and available resources. It is presented for information purposes.

<sup>(7)</sup> Article 13(3) of the Annex to Regulation (EU) No 557/2014 stipulates that the 'operational costs of the IMI 2 Joint Undertaking shall be covered through (a) a financial contribution by the Union (b) in-kind contributions by the Members other than the Union and the Associated Partners [...] consisting of the costs incurred by them in implementing indirect actions [...] less the contribution of the IMI 2 Joint Undertaking and any other Union contribution to those costs'.

- (a) the annual accounts of the IMI Joint Undertaking, which comprise the financial statements <sup>(8)</sup> and the reports on the implementation of the budget <sup>(9)</sup> for the financial year ended 31 December 2014, and
- (b) the legality and regularity of the transactions underlying those accounts.

### The management's responsibility

7. In accordance with Articles 16 and 22 of Commission Delegated Regulation (EU) No 110/2014 <sup>(10)</sup>, the management is responsible for the preparation and fair presentation of the annual accounts of the Joint Undertaking and the legality and regularity of the underlying transactions.

- (a) The management's responsibilities in respect of the Joint Undertaking's annual accounts include designing, implementing and maintaining an internal control system relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error, selecting and applying appropriate accounting policies on the basis of the accounting rules adopted by the Commission's accounting officer <sup>(11)</sup>, and making accounting estimates that are reasonable in the circumstances. The Director approves the annual accounts of the Joint Undertaking after its accounting officer has prepared them on the basis of all available information and established a note to accompany the accounts in which he declares, *inter alia*, that he has reasonable assurance that they present a true and fair view of the financial position of the Joint Undertaking in all material respects.
- (b) The management's responsibilities in respect of the legality and regularity of the underlying transactions and compliance with the principle of sound financial management consist of designing, implementing and maintaining an effective and efficient internal control system comprising adequate supervision and appropriate measures to prevent irregularities and fraud and, if necessary, legal proceedings to recover funds wrongly paid or used.

### The auditor's responsibility

8. The Court's responsibility is, on the basis of its audit, to provide the European Parliament and the Council <sup>(12)</sup> with a statement of assurance as to the reliability of the annual accounts and the legality and regularity of the underlying transactions. The Court conducts its audit in accordance with the IFAC International Standards on Auditing and Codes of Ethics and the INTOSAI International Standards of Supreme Audit Institutions. These standards require the Court to plan and perform the audit to obtain reasonable assurance as to whether the annual accounts of the Joint Undertaking are free from material misstatement and the underlying transactions are legal and regular.

9. The audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the accounts and the legality and regularity of the underlying transactions. The procedures selected depend on the auditor's judgement, which is based on an assessment of the risks of material misstatement of the accounts and material non-compliance by the underlying transactions with the requirements in the legal framework of the European Union, whether due to fraud or error. In assessing these risks, the auditor considers any internal controls relevant to the preparation and fair presentation of the accounts, as well as the supervisory and control systems that are implemented to ensure the legality and regularity of underlying transactions, and designs audit procedures that are appropriate in the circumstances. The audit also entails evaluating the appropriateness of accounting policies, the reasonableness of accounting estimates and the overall presentation of the accounts.

10. The Court considers that the audit evidence obtained is sufficient and appropriate to provide a basis for its statement of assurance.

<sup>(8)</sup> These include the balance sheet and the statement of financial performance, the cash-flow table, the statement of changes in net assets, a summary of the significant accounting policies and other explanatory notes.

<sup>(9)</sup> These comprise the reports on implementation of the budget, a summary of budgetary principles and other explanatory notes.

<sup>(10)</sup> OJ L 38, 7.2.2014, p. 2.

<sup>(11)</sup> The accounting rules adopted by the Commission's accounting officer are derived from the International Public Sector Accounting Standards (IPSAS) issued by the International Federation of Accountants or, where relevant, the International Accounting Standards (IAS)/International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board.

<sup>(12)</sup> Article 47 of Regulation (EU) No 110/2014.

**Opinion on the reliability of the accounts**

11. In the Court's opinion, the Joint Undertaking's annual accounts present fairly, in all material respects, its financial position as at 31 December 2014 and the results of its operations and its 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.

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

12. In the Court's opinion, the transactions underlying the annual accounts of the Joint Undertaking for the year ended 31 December 2014 are, in all material respects, legal and regular.

13. The comments which follow do not call the Court's opinions into question.

**COMMENTS ON BUDGETARY AND FINANCIAL MANAGEMENT****Implementation of the budget**

14. The 2014 budget included commitment appropriations amounting to 223 million euro and payment appropriations amounting to 171 million euro. The overall implementation rate was 92,4 % (99,5 % for 2013) for commitment appropriations and 73,9 % (97,5 % for 2013) for payment appropriations.

15. In the case of operational activities, the implementation rate was 93 % for commitment appropriations and 74 % for payment appropriations<sup>(13)</sup>. However, commitment appropriations were committed at a global level, meaning that no corresponding grant agreements have been signed by the end of 2014.

**Multi annual funding**

16. The FP7 calls for proposals organised in 2008 — 2013 resulted in grant agreements totalling 897 million euro, amounting to 93 % of the maximum EU contribution to the Joint Undertaking for research activities.

**OTHER MATTERS****Key controls and supervisory systems**

17. The performance of operational ex-ante controls on the payment of project costs was insufficiently documented in the following critical areas:

- (a) The ex ante control form used by the IMI Scientific Project Officers (SPO) focused on administrative compliance rather than on operational compliance as it 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);
- (b) 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.

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<sup>(13)</sup> As regards administrative expenditure, the appropriations available for 2014 amounted to 8,9 million euro. The IMI Joint Undertaking achieved an implementation rate of 84 % for commitment appropriations and 70 % for payment appropriations.

### **Legal framework**

18. 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<sup>(14)</sup> and taking into account the requirements of Council Regulation (EU) 557/2014 establishing the IMI 2 Joint Undertaking.

### **Internal audit function and the Commission's Internal Audit Service**

19. In January 2014, the Commission's Internal Audit Service (IAS) finalised an audit on project monitoring and the reporting of operational performance at the IMI Joint Undertaking. As at April 2015, all recommendations have been addressed through agreed actions<sup>(15)</sup>. The IAS is monitoring the implementation of the action plan and an assessment is expected during 2015 with regard to closing the recommendations.

20. In addition, two audits were completed in early 2015, one on ex ante controls for operational expenditure and the other on risk assessment. The IMI Joint Undertaking has addressed the recommendation on ex ante controls through an action plan that has been accepted by the IAS.

### **FOLLOW-UP OF PREVIOUS OBSERVATIONS**

#### **Monitoring and reporting of project research results**

21. As regards the monitoring and reporting of project research results<sup>(16)</sup>, the IMI Joint Undertaking uses its own tools, in order to integrate its research results into the overall reporting system of the Commission. For the first time, the latest Monitoring report from the Commission on FP7, published in March 2015<sup>(17)</sup>, includes quantitative data from IMI Joint Undertaking activities<sup>(18)</sup>. As regards qualitative data, in addition to the information provided on the IMI website, the Joint Undertaking produces a half yearly bibliometric analysis of ongoing projects<sup>(19)</sup>, aiming to benchmark research published by IMI-supported projects with other selected public private partnerships. The IMI Joint Undertaking has also developed key performance indicators for the various aspects of project achievement and it measures progress on this basis.

22. The Horizon 2020 legal framework requires specific monitoring of research results, based on quantitative and, where appropriate, qualitative evidence, including progress against performance indicators<sup>(20)</sup>. In order to meet the requirements of Horizon 2020 and to better contribute to the dissemination of FP7 research results, cooperation between the Joint Undertaking and the Commission must be developed as much as possible<sup>(21)</sup> with special regard to the further integration of IMI Joint Undertaking data in to the Commission's systems.

#### **Conflicts of interest**

23. The Commission is developing a common template for the Joint Undertakings. Meanwhile, IMI's procedure remains in force.

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<sup>(14)</sup> Regulation (EU) No 110/2014.

<sup>(15)</sup> These include the two recommendations classified as 'very important' dealing with the 'review of the design and reporting of objectives and Key Performance Indicators (KPIs)' and 'strengthening the project monitoring and IT systems to enhance reporting'. Some actions related to the latter are still on-going.

<sup>(16)</sup> Paragraph 21 of the Court's 2013 report (OJ C 452, 16.12.2014, p. 67).

<sup>(17)</sup> [http://ec.europa.eu/research/evaluations/pdf/archive/fp7\\_monitoring\\_reports/7th\\_fp7\\_monitoring\\_report.pdf#view=fit&pagemode=none](http://ec.europa.eu/research/evaluations/pdf/archive/fp7_monitoring_reports/7th_fp7_monitoring_report.pdf#view=fit&pagemode=none)

<sup>(18)</sup> In the EC Monitoring Report this information is presented in aggregated values together with the information from the other Joint Technology Initiatives.

<sup>(19)</sup> <http://www.imi.europa.eu/sites/default/files/uploads/documents/BibliometricsReport5.pdf>

<sup>(20)</sup> Article 31 of Regulation (EU) No 1291/2013, establishing Horizon 2020 and annex II (performance indicators) of Council Decision 2013/743/EU (OJ L 347, 20.12.2013, p. 965) of 3 December 2013 establishing the specific programme implementing Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020).

<sup>(21)</sup> See the Annual Progress Report from the European Commission to the European Parliament and Council on the activities of the JTI JUs (COM(2013) 935).

***The Commission's Second Interim Evaluation***

24. The recommendations of the Commission's Second Interim Evaluation were presented to the Governing Board on 29 October 2013. Follow up of the recommendation was proposed and some key actions <sup>(22)</sup> were integrated into the 2014 Annual Implementation Plan. The Executive Director has reported regularly to the Governing Board on the follow-up of the actions. Recommendations related to the establishment of the IMI2 JU <sup>(23)</sup> are currently being implemented and plans are in place for the Programme Office to carry out consolidated follow-up and assessment of the actions undertaken by the end of 2015.

This Report was adopted by Chamber IV, headed by Mr Milan Martin CVIKL, Member of the Court of Auditors, in Luxembourg at its meeting of 6 October 2015.

*For the Court of Auditors*

Vítor Manuel da SILVA CALDEIRA

*President*

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<sup>(22)</sup> E.g. review of the Communication Strategy, socio-economic impacts translated within KPIs, further involvement of industry and in particular of SMEs, increasing flexibility in launching calls and use of non-EU in-kind contribution.

<sup>(23)</sup> E.g. involvement of industrial participants from other healthcare related sector, increased flexibility and transparency in terms of governance.

## ANNEX

**Innovative Medicines Joint Undertaking (Brussels)****Competences and activities**

<p><b>Areas of Union competence deriving from the Treaty</b></p> <p><i>Extracts from Articles 187 and 188 of the Treaty on the Functioning of the European Union</i></p>	<p>The Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes.</p> <p>The Council, on a proposal from the Commission and after consulting the European Parliament and the Economic and Social Committee, shall adopt the provisions referred to in Article 187.</p> <p>The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, shall adopt the provisions referred to in Articles 183, 184 and 185. Adoption of the supplementary programmes shall require the agreement of the Member States concerned.</p>
<p><b>Competences of the Joint Undertaking</b></p> <p><i>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)</i></p>	<p><b>Objectives</b></p> <p>According to Article 2 of Council Regulation 557/2014 the IMI2 Joint Undertaking shall have the following objectives:</p> <ul style="list-style-type: none"> <li>(a) to support, in accordance with Article 25 of Regulation (EU) No 1291/2013, the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership or to address specific societal challenges in particular as described in parts II and III of Annex I to Decision 2013/743/EU, and in particular the challenge to improve European citizens' health and well-being;</li> <li>(b) to contribute to the objectives of the Joint Technology Initiative on Innovative Medicines, in particular to: <ul style="list-style-type: none"> <li>(i) increase the success rate in clinical trials of priority medicines identified by the World Health Organisation;</li> <li>(ii) where possible, reduce the time to reach clinical proof of concept in medicine development, such as for cancer, immunological, respiratory, neurological and neurodegenerative diseases;</li> <li>(iii) develop new therapies for diseases for which there is a high unmet need, such as Alzheimer's disease and limited market incentives, such as antimicrobial resistance;</li> <li>(iv) develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators;</li> <li>(v) reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks;</li> <li>(vi) improve the current drug development process by providing support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products.</li> </ul> </li> </ul>

<b>Governance</b>	<p>Governance bodies of the IMI2 JU are (i) the Governing Board, (ii) the Executive Director, (iii) the Scientific Committee, (iv) the States Representatives Group, and (v) the Stakeholder Forum. Other advisory groups may be set up by the Governing Board.</p> <p>The Governing Board is composed of 10 Board members representing equally the two Members of the Joint Undertaking: the European Union (represented by the European Commission) and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The Governing Board has overall responsibility for the strategic orientation and the operations of the IMI2 Joint Undertaking and supervises the implementation of its activities.</p> <p>The Executive Director is the chief executive responsible for the day-to-day management of the IMI2 JU in accordance with the decisions of the Governing Board and is supported by a Programme Office. The Executive Director is the legal representative of the IMI2 JU and shall implement the budget of the JU.</p> <p>The Scientific Committee, the States Representatives Group and the Stakeholder Forum are advisory bodies of the IMI2 JU.</p> <p>A Strategic Governing Group set up by the Governing Board ensures the coordination of IMI2 JU's work in certain strategic areas and work to make the development of new topics more transparent and effective.</p>
<b>Resources available to the Joint Undertaking in 2014</b>	<p><b>Budget</b></p> <p>223 294 603 euro for commitments</p> <p>170 801 250 euro for payments</p> <p>The amounts include appropriations carried over from 2013 as well as the revision following the establishment of the IMI2 JU as from 27/6/2014.</p> <p><b>Staff as at 31 December 2014</b></p> <p>34 out of 37 posts provided for in the establishment plan (29 Temporary staff and 8 Contract staff) were occupied. 80 % of these resources are directly assigned to support operational activities.</p>
<b>Activities and services provided in 2014</b>	See Annual Activity Report 2014 of the IMI JU at <a href="http://www.imi.europa.eu">www.imi.europa.eu</a>

Source: Information supplied by IMI2 JU.

## THE JOINT UNDERTAKING'S REPLIES

### **Basis for a clean opinion on the reliability of accounts**

#### **Basis for a clean opinion on the legality and regularity of the transactions underlying the accounts**

*Paragraphs 11 and 12*

IMI welcomes the positive conclusion of the Court on the reliability of its accounts as well as on the legality and regularity of all transactions underlying the annual accounts.

IMI remains committed to managing its funding under the principle of sound financial management and through a trust-based approach with the participants in the projects whilst ensuring sufficient control and accountability. This balanced approach will also contribute towards ensuring a successful outcome of the IMI projects as many of them are already starting to generate impressive or promising results, in the interest of patients and society at large.

### **Implementation of the budget**

*Paragraph 15*

The 8 Grant Agreements corresponding to Call 2 of IMI2 JU were all signed in the first quarter of 2015.

### **Key controls and supervisory systems**

*Paragraph 17*

Ex-ante controls on payments of project costs will be reinforced, in line with the recommendations and action plan agreed with the Commission's Internal Audit Service (IAS).

### **Internal audit and the Commission's Internal Audit Service**

*Paragraph 20*

An action plan has been developed and communicated to IAS on 06/03/2015. The IAS has considered the proposed action adequate. The action plan is being implemented by IMI.

### **Follow-up on previous observations**

*Paragraph 22*

IMI Calls and projects data have been exported and have been available in CORDA since September 2013. On the basis of the Delegation Agreement between the European Commission and the IMI2 JU, further integration of IMI2 call and project management IT system is currently under preparation with target date for completion by early 2016.

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