

REPORT

on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2010, together with the replies of the Joint Undertaking

(2011/C 368/03)

INTRODUCTION

1. The European 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 ⁽¹⁾ for a period of 10 years.

2. The objective of the IMI Joint Undertaking is 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 ⁽²⁾.

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). Any legal entity directly or indirectly supporting research and development in a Member State or in a country associated with the Seventh Framework Programme ⁽³⁾ may apply to become a Member of the IMI Joint Undertaking.

4. The maximum EU contribution to the IMI Joint Undertaking to cover running costs and research activities is 1 billion euro, to be paid from the budget of the Seventh Framework Programme. The EU and EFPIA, as Founding Members, are to contribute equally to the running costs, each with an amount not exceeding 4 % of the total EU contribution. Other Members are to contribute to running costs in proportion to their contribution to research activities. The research companies which are members of EFPIA are to contribute to the funding of research activities through in-kind ⁽⁴⁾ contributions at least equal to the EU financial contribution ⁽⁵⁾.

⁽¹⁾ 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).

⁽²⁾ The *Annex* summarises the Joint Undertaking's competences, activities and available resources. It is presented for information purposes.

⁽³⁾ The Seventh Framework Programme, adopted by Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006, 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. It is also a key pillar for the European Research Area.

⁽⁴⁾ According to Article 11(4) of the Annex to the Council Regulation setting up the Joint Undertaking, the in-kind contributions are 'non-monetary contributions by the research based pharmaceutical companies that are members of EFPIA with resources such as personnel, equipment, consumables, etc.'

⁽⁵⁾ According to Article 11(5) of the Annex to the Council Regulation setting up the Joint Undertaking, 'the participating research based pharmaceutical companies that are members of EFPIA shall not be eligible to receive any financial support from the IMI Joint Undertaking for any activity'.

5. The Joint Undertaking started to work autonomously on 16 November 2009.

STATEMENT OF ASSURANCE

6. Pursuant to the provisions of Article 287(1) of the Treaty on the Functioning of the European Union the Court has audited the annual accounts ⁽⁶⁾ of the Innovative Medicines Initiative Joint Undertaking, which comprise the 'financial statements' ⁽⁷⁾ and the 'reports on the implementation of the budget' ⁽⁸⁾ for the financial year ended 31 December 2010 and the legality and regularity of the transactions underlying those accounts.

7. This Statement of Assurance is addressed to the European Parliament and to the Council in accordance with Article 185(2) of Council Regulation (EC, Euratom) No 1605/2002 ⁽⁹⁾.

The Director's responsibility

8. As authorising officer, the Director implements the revenue and expenditure of the budget in accordance with the Joint Undertaking's financial rules, under his own responsibility and within the limits of the authorised appropriations ⁽¹⁰⁾. The Director is responsible for putting in place ⁽¹¹⁾ the organisational structure and the internal management and control systems and procedures relevant for drawing up final accounts ⁽¹²⁾ that are free from material misstatement, whether due to fraud or error, and for ensuring that the transactions underlying those accounts are legal and regular.

⁽⁶⁾ These accounts are accompanied by a report on the budgetary and financial management during the year which gives, inter alia, an account of the rate of implementation of the appropriations with summary information on the transfers of appropriations among the various budget items.

⁽⁷⁾ The financial statements include the balance sheet and the economic outturn account, the cash flow table, the statement of changes in net assets and the annex to the financial statements, which includes a description of the main accounting policies and other explanatory information.

⁽⁸⁾ The budget implementation reports comprise the budget outturn account and its annex.

⁽⁹⁾ OJ L 248, 16.9.2002, p. 1.

⁽¹⁰⁾ Article 33 of Commission Regulation (EC, Euratom) No 2343/2002 (OJ L 357, 31.12.2002, p. 72).

⁽¹¹⁾ Article 38 of Regulation (EC, Euratom) No 2343/2002.

⁽¹²⁾ The rules concerning the presentation of the accounts and accounting by EU bodies are laid down in Chapter 1 of Title VII of Regulation (EC, Euratom) No 2343/2002, as last amended by Regulation (EC, Euratom) No 652/2008 (OJ L 181, 10.7.2008, p. 23), and are integrated as such in the financial rules of the Joint Undertaking.

The Court's responsibility

9. The Court's responsibility is to provide, on the basis of its audit, a statement of assurance as to the reliability of the annual accounts of the Joint Undertaking and the legality and regularity of the transactions underlying them.

10. The Court conducted its audit in accordance with the IFAC and ISSAI⁽¹³⁾ International Auditing Standards and Codes of Ethics. Those standards require the Court to comply with ethical requirements and to plan and perform the audit so as to obtain reasonable assurance as to whether the accounts are free of material misstatement and whether the underlying transactions are legal and regular.

11. The Court's audit involves performing procedures to obtain audit evidence of the amounts and disclosures in the accounts and of the legality and the regularity of the transactions underlying them. The procedures selected, including its assessment of the risks of material misstatement of the accounts or of illegal or irregular transactions, whether due to fraud or error, depend on its audit judgement. In making those risk assessments, internal controls relevant to the entity's preparation and presentation of accounts are considered in order to design audit procedures that are appropriate in the circumstances. The Court's audit also includes evaluating the appropriateness of the accounting policies used and the reasonableness of the accounting estimates made by management, as well as evaluating the overall presentation of the accounts.

12. The Court considers that the audit evidence obtained is sufficient and appropriate to provide a basis for the opinions set out below.

Opinion on the reliability of the accounts

13. In the Court's opinion, the annual accounts of the Joint Undertaking fairly present, in all material respects, its financial position as of 31 December 2010, the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its financial rules.

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

14. In the Court's opinion, the transactions underlying the annual accounts of the Joint Undertaking for the

financial year ended 31 December 2010 are, in all material respects, legal and regular.

15. The comments which follow in paragraphs 16-24 do not call the Court's opinions into question.

COMMENTS ON THE BUDGETARY AND FINANCIAL MANAGEMENT

Implementation of the budget

16. The 2010 annual budget and implementation plan were not adopted by the Governing Board until 16 March 2010⁽¹⁴⁾. The late adoption was due to the Members of the Joint Undertaking taking a long time to establish and agree on the scientific priorities to be included in the annual implementation plan. This delayed the launch of the call for proposals. During the year, the Joint Undertaking launched the third call for proposals⁽¹⁵⁾, finalised the negotiation process for the second call for proposals⁽¹⁶⁾ and started to receive and pay cost claims from the beneficiaries participating in the projects funded under the first call for proposals⁽¹⁷⁾.

17. The final budget included commitment appropriations of 107 million euro and payment appropriations of 29 million euro. Additionally, 3 million euro in commitment appropriations and 78,6 million euro in payment appropriations were carried over from 2009. The utilisation rates for available commitment and payment appropriations were 6 % and 35 % respectively, 98,6 million euro in commitment appropriations were carried over to 2011 and 64 million euro of payment appropriations carried over from 2009 were cancelled at the end of the year. The low implementation of the budget is also reflected in the cash balance, which stood at 71 million euro at the end of the year (65 % of the available payment appropriations in 2010).

Internal control systems

18. The Joint Undertaking has not completely implemented its internal controls and financial information systems during 2010. In particular, further work is needed in establishing and documenting the accounting procedures and controls relating to the closure of the accounts and the recognition and measurement of the operational expenditure. These are important elements of the Joint Undertaking's system of internal control.

⁽¹⁴⁾ The budget rule 1/12 was used to make payments until budget adoption.

⁽¹⁵⁾ The third call for proposals was launched on 22 October 2010.

⁽¹⁶⁾ The second call for proposals was launched on 27 November 2009.

⁽¹⁷⁾ The first call for proposals was launched on 30 April 2008 and was managed by the Commission.

⁽¹³⁾ International Federation of Accountants (IFAC) and International Standards of Supreme Audit Institutions (ISSAI).

19. Furthermore, at the end of 2010 the underlying business processes had not yet been formalised and had not been validated by the Accounting Officer as required by the Joint Undertaking's financial rules.

20. The limited review of the IT controls showed that the Joint Undertaking has an adequate level of IT governance and practice for its size and mission, but the formalisation of policies and procedures, however, is lagging behind in certain areas⁽¹⁸⁾.

21. The *ex-post* audit strategy⁽¹⁹⁾ of the Joint Undertaking was adopted by a Governing Board decision on 14 December 2010 and is a key control for assessing the legality and regularity of the underlying transactions. This strategy envisages that the audit population⁽²⁰⁾ will increase progressively as from 2011 when projects relating to several calls will be running in parallel and cost claims for these projects will be submitted.

Methodology for evaluating contributions in kind

22. The methodology for evaluating contributions in-kind has not yet been approved by the Governing Board⁽²¹⁾ as it proved difficult for an agreement to be reached. As a

consequence, the EFPIA members were unable to report on the costs incurred during the first reporting period as established in the grant agreements.

OTHER MATTERS

Internal audit function and the Commission's Internal Audit Service

23. In its previous report, the Court pointed out the need to clarify the provision in the Statutes of the Joint Undertaking on the role of the Commission's internal auditor. Although the Joint Undertaking's financial rules have not yet been amended to include the provision referring to the powers of the Commission's internal auditor, the Commission and the Joint Undertaking have taken action to ensure that the respective operational roles of the Commission's Internal Audit Service and the Joint Undertaking's internal auditing function are clearly defined.

Lack of host State agreement

24. As previously reported by the Court, according to the Council Regulation setting up the Joint Undertaking, a host agreement should be concluded between the Joint Undertaking and Belgium concerning office accommodation, privileges and immunities and other support to be provided by Belgium. However, as at the end of 2010, no such agreement had been signed.

This Report was adopted by Chamber IV, headed by Mr Igors LUDBORŽS, Member of the Court of Auditors, in Luxembourg at its meeting of 25 October 2011.

For the Court of Auditors

Vitor Manuel da SILVA CALDEIRA

President

⁽¹⁸⁾ Namely: (a) incomplete strategic IT planning and monitoring cycle; (b) lack of formal security policies and rules; (c) incomplete IT Risk management; and (d) lack of formal Business Continuity Plan (BCP) and complete and tested Disaster Recovery Plan (DRP).

⁽¹⁹⁾ Article 12(4) of the Council Regulation setting up the Joint Undertaking states that 'the IMI Joint Undertaking shall carry out on-the-spot checks and financial audits among the participants of the Research Activities funded by the IMI Joint Undertaking'.

⁽²⁰⁾ The audit population is represented by cost claims received from project beneficiaries based on eligible costs and from EFPIA members based on in-kind contributions. The value of the cost claims corresponding to 2010 is estimated at 24,6 million euro.

⁽²¹⁾ Article 11(4) of the Annex to the Council Regulation setting up the Joint Undertaking stipulates that 'the methodology for evaluating contributions in-kind shall be defined in the internal rules and procedures of the Joint Undertaking, in compliance with its financial rules and based on the rules of participation of the Seventh Framework Programme'.

ANNEX

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

<p>Areas of Union competence deriving from the Treaty</p> <p><i>(Extracts from Articles 187 and 188 of the Treaty on the Functioning of the European Union)</i></p>	<p>Article 187:</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>Article 188:</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>Competences of the Joint Undertaking</p>	<p>Objectives</p> <p><i>(Article 2 of Council Regulation (EC) No 73/2008 setting up the Joint Undertaking)</i></p> <p>The IMI Joint Undertaking shall contribute to the implementation of the Seventh Framework Programme and in particular the Theme 'Health' of the Specific Programme Cooperation implementing the Seventh Framework Programme. It shall have the objective of significantly improving 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. In particular it shall:</p> <ul style="list-style-type: none"> (a) support 'pre-competitive pharmaceutical research and development' in the Member States and countries associated with the Seventh Framework Programme via a coordinated approach to overcome the identified research bottlenecks in the drug development process; (b) support the implementation of the research priorities as set out by the Research Agenda of the Joint Technology Initiative on Innovative Medicines (hereinafter referred to as 'Research Activities'), notably by awarding grants following competitive calls for proposals; (c) ensure complementarity with other activities of the Seventh Framework Programme; (d) be a public-private partnership aiming at increasing the research investment in the biopharmaceutical sector in the Members States and countries associated with the Seventh Framework Programme by pooling resources and fostering collaboration between the public and private sectors; (e) promote the involvement of small and medium-sized enterprises (SME) in its activities, in line with the objectives of the Seventh Framework Programme. <p>Tasks</p> <p><i>(Article 1 of the Annex – Statutes of the Joint Undertaking for the Implementation of the Joint Technology Initiative on Innovative Medicines)</i></p> <p>The main tasks and activities of the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines (hereinafter referred to as 'IMI Joint Undertaking') shall be the following:</p> <ul style="list-style-type: none"> (a) to ensure the establishment and sustainable management of the Joint Technology Initiative on 'Innovative Medicines'; (b) to define and carry out the annual implementation plan referred to in Article 18 via calls for projects; (c) to regularly review and make any necessary adjustments to the Research Agenda of the Joint Technology Initiative on Innovative Medicines in the light of scientific developments occurring during its implementation;

	<p>(d) to mobilise the public and private sector resources needed;</p> <p>(e) to establish and develop close and long-term cooperation between the Union, industry and the other stakeholders such as regulatory bodies, patients' organisations, academia and clinical centres, as well as cooperation between industry and academia;</p> <p>(f) to facilitate coordination with national and international activities in this area;</p> <p>(g) to undertake communication and dissemination activities;</p> <p>(h) to communicate and interact with the Member States and the countries associated with the Seventh Framework Programme via a group specifically established for this purpose (hereinafter referred to as the 'IMI States Representatives Group');</p> <p>(i) to organise at least an annual meeting (hereinafter referred to as a 'Stakeholder Forum') with interest groups to ensure openness and transparency of the Research Activities of the IMI Joint Undertaking with its stakeholders;</p> <p>(j) to notify legal entities that have concluded a grant agreement (hereinafter referred to as 'Grant Agreement') with the IMI Joint Undertaking of the potential borrowing opportunities from the European Investment Bank, in particular the Risk Sharing Finance Facility set up under the Seventh Framework Programme;</p> <p>(k) to publish information on the projects, including the name of the participants and the amount of the financial contribution of the IMI Joint Undertaking per participant;</p> <p>(l) to ensure the efficiency of the Joint Technology Initiative on 'Innovative Medicines';</p> <p>(m) to carry out any other activity needed to achieve the objectives referred to in Article 2 of the Regulation.</p>
<p>Governance</p>	<p><i>(Article 4 of the Annex to Council Regulation (EC) No 73/2008 – Statutes of the Joint Undertaking for the Implementation of the Joint Technology Initiative on Innovative Medicines)</i></p> <p>1 — The Governing Board</p> <p>2 — The Executive Director</p> <p>3 — The Scientific Committee</p> <p>4 — Two Advisory Bodies</p> <p>The IMI States Representatives Group and the Stakeholder Forum.</p> <p>5 — Internal audit</p> <p>— the Internal Auditor of the European Commission,</p> <p><i>(Article 10 of the Annex to Council Regulation (EC) No 73/2008 – Statutes of the Joint Undertaking for the Implementation of the Joint Technology Initiative on Innovative Medicines)</i></p> <p>— internal audit capability within the IMI JU.</p> <p><i>(Article 6 of Council Regulation (EC) No 73/2008)</i></p> <p>6 — External audit</p> <p>The European Court of Auditors.</p> <p><i>(Article 17(5) of the Statutes annexed to Council Regulation (EC) No 73/2008 and Article 126 of the IMI's financial rules).</i></p> <p>7 — Discharge authority</p> <p>The European Parliament, acting on a recommendation from the Council.</p> <p><i>(Article 11(4) of Council Regulation (EC) No 73/2008 and Article 129 of the IMI's financial rules)</i></p>

<p>Resources available to the Joint Undertaking in 2010</p>	<p>Budget</p> <p><i>(Article 7(4) of Council Regulation (EC) No 73/2008 on staff resources)</i></p> <p>The final budget included commitment appropriations of 107 million euro and payment appropriations of 29 million euro. Additionally, 3 million euro in commitment appropriations and 78,6 million euro in payment appropriations were carried over from 2009.</p> <p>Staff at 31 December 2010</p> <p>29 posts provided for in the establishment plan, of which, 18 posts were occupied.</p> <p>Other staff:</p> <ul style="list-style-type: none"> — Seconded National Experts: 0, — contract staff: 4, — local staff: 0, <p>total staff employed: 22.</p> <p>Allocated to:</p> <ul style="list-style-type: none"> — operational activities: 4, — administrative tasks: 7 ⁽¹⁾, — mixed tasks: 11.
<p>Activities and services provided in 2010</p>	<p>Launched or prepared for new calls for proposals, evaluation, negotiation, grant management, ongoing contact, support and guidance to beneficiaries and other participants, communication and organisation of meetings and events with key stakeholders, as well as consultations and support to the Founding Members on the innovative medicine research strategy and associated activities.</p>

Source: Information supplied by the IMI JU.

⁽¹⁾ The number refers to administrative assistants with administrative tasks.

REPLIES OF THE JOINT UNDERTAKING

Implementation of the budget

Paragraphs 16 and 17

IMI JU has taken several initiatives to facilitate and expedite the implementation of the budget, including the revision of the Scientific Research Agenda, the launch of the third and fourth calls for proposals, the conclusion of negotiations and the signature of grant agreements for new projects funded under the second call, as well as the receipt and payment of cost claims from the beneficiaries participating in projects funded under the first call. In collaboration with the Founding Members, the Executive Office is also exploring ways of how it can simplify and streamline its call management processes and shorten time lines.

Internal Control Systems

Paragraphs 18 and 21

IMI JU's internal control system is being further consolidated through the systematic review, strengthening and formalisation of internal processes, including IT policies and procedures. *Ex-post* audits of first cost claims received from project beneficiaries will also be launched by the end of 2011.

In parallel, the creation of a new senior management position responsible for Administration and Finance as well as the establishment of the internal control and the internal audit functions further enhances the overall management and oversight of IMI JU's implementation of the internal control framework.

The validation of the underlying business processes supporting the accounting system by the Accounting Officer was concluded in June 2011. The implementation of the recommendations resulting from this exercise will lead to further strengthening of internal controls.

Methodology for evaluating in-kind contributions

Paragraph 22

There are ongoing consultations on the methodology to be used for the evaluation of in-kind contributions by member companies of the European Foundation of Pharmaceutical Industries and Associations (EFPIA) in IMI JU projects. Individual reports on the in-kind contributions will be submitted following the approval by the Governing Board of the revised model grant agreement.

Internal Audit Function and the Commission's Internal Audit Service

Paragraph 23

The roles of the IMI JU's Internal Audit Manager (IAC) and the Internal Audit Service of the European Commission (IAS) were clarified and formalised through the approval, in March 2011, of the IAS and IAC Audit Charters. A coordinated strategic audit plan for the period 2012-14 is also being prepared to ensure that the impact of planned audits is optimised and any duplication of audit work between the IAS and IAC is minimised.

The need to further clarify the role of the IAS in IMI JU's financial rules will be assessed after the finalisation of the ongoing revision of the European Commission's Framework Financial Regulation.

Lack of host State Agreement

Paragraph 24

There are ongoing proceedings with the Belgian authorities for the signature of the Host Agreement. It is expected to be signed by the end of 2011.
