

REPORT**on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2012, together with the Joint Undertaking's replies**

(2013/C 369/04)

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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 produce more effective and safer innovative medicines ⁽²⁾.

3. The founding members of the Joint Undertaking are the European Union, represented by the 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 the 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 contributions ⁽⁴⁾ at least equal to the EU financial contribution ⁽⁵⁾.

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

⁽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 (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. It is also a key pillar for the European Research Area.

⁽⁴⁾ According to Article 11(4) of the Annex to Regulation (EC) No 73/2008 setting up the Joint Undertaking, 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.)'. The contribution from research companies must at least match the financial contribution of the Union.

⁽⁵⁾ According to Article 11(5) of the Annex to Regulation (EC) No 73/2008, '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'.

INFORMATION IN SUPPORT OF THE STATEMENT OF ASSURANCE

6. 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

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

- (a) the annual accounts of the IMI Joint Undertaking, which comprise the financial statements ⁽⁶⁾ and the reports on the implementation of the budget ⁽⁷⁾ for the financial year ended 31 December 2012; and
- (b) the legality and regularity of the transactions underlying those accounts.

The management's responsibility

8. In accordance with Articles 33 and 43 of Commission Regulation (EC, Euratom) No 2343/2002 ⁽⁸⁾, 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 ⁽⁹⁾, 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.

⁽⁶⁾ These include the balance sheet and the economic outturn account, the cash-flow table, the statement of changes in net assets, a summary of the significant accounting policies and other explanatory notes.

⁽⁷⁾ These comprise the reports on implementation of the budget, a summary of budgetary principles and other explanatory notes.

⁽⁸⁾ OJ L 357, 31.12.2002, p. 72.

⁽⁹⁾ 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.

- (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

9. The Court's responsibility is, on the basis of its audit, to provide the European Parliament and the Council⁽¹⁰⁾ 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.

10. 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.

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

Opinion on the reliability of the accounts

12. In the Court's opinion, the Joint Undertaking's annual accounts present fairly, in all material respects, its financial

position as at 31 December 2012 and the results of its operations and 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.

Basis for a qualified opinion on the legality and regularity of the underlying transactions

13. The Joint Undertaking's *ex post* audit strategy⁽¹¹⁾ was adopted by a Governing Board decision on 14 December 2010 and is a key tool for assessing the legality and regularity of the underlying transactions. 56 *ex post* audits had been completed as of June 2013, covering 4,4 million euro (37,3 % of the accepted IMI JU's contribution for the first call validated by June 2011)⁽¹²⁾. The detected error rate resulting from these audits was 5,82 %.

Qualified opinion on the legality and regularity of the transactions underlying the accounts

14. In the Court's opinion, except for the possible effects of the matter described in paragraph 13, the transactions underlying the annual accounts of the Joint Undertaking for the year ended 31 December 2012 are, in all material respects, legal and regular.

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

COMMENTS ON BUDGETARY AND FINANCIAL MANAGEMENT

Implementation of the budget

16. The 2012 annual budget and implementation plan were adopted by the Governing Board on 22 December 2011. For 2012, where operational activities are concerned, IMI achieved a 96 % execution rate for commitment appropriations (351 million euro) and a rate of 100 % for payment appropriations (103 million euro). Despite this high level of budgetary execution, a significant amount in commitment appropriations (162 million euro) is still no more than a global figure, meaning that, while calls have been launched, no corresponding grant agreements have been signed. IMI's financial statements show 543 million euro of carried-forward contractual obligations, which indicates a significant need for funding until 2017.

⁽¹¹⁾ Article 12(4) of Regulation (EC) No 73/2008 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'. *Ex post* audits may identify ineligible expenditure claimed by beneficiaries which is then subject to recovery procedures.

⁽¹²⁾ The *ex post* audits completed correspond to the first representative sample of 60 audits launched at the end of 2011 and finalised in 2013. *Ex post* audits for the second representative sample, based on IMI JU's funding related to cost claims validated between July 2011 and November 2012, are ongoing and therefore no definitive results are available.

⁽¹⁰⁾ Article 185(2) of Council Regulation (EC, Euratom) No 1605/2002 (OJ L 248, 16.9.2002, p. 1).

17. A high level of payment and commitment appropriations for administrative expenditure in 2012 were still unused at year's end (26,81 % of commitment appropriations and 39,8 % of payment appropriations).

Calls for proposals

18. In 2012, the Joint Undertaking launched four calls for proposals and signed 11 grant agreements. In 2012 it committed 351 million euro, or almost 37 % of its total available budget (960 million euro maximum funding stipulated in Regulation (EC) No 73/2008), for research activities. The time needed to sign agreements decreased in 2012, from 413 days for the final grant agreements under the fourth call to 161 days for the sixth call.

19. At the end of 2012, the cumulative total of approved commitments for research costs was 736 million euro. IMI needs in principle to commit a further 224 million euro for research activities (23 % of the 960 million euro maximum) by the end of 2013, and EFPIA members need to commit an equivalent amount in kind. By the end of 2012 EFPIA had committed 706 million euro, and it now needs to commit 254 million euro more to match IMI's 960 million euro contribution.

Comments on key controls of the Joint Undertaking's supervisory and control systems

20. In 2012 the Joint Undertaking has continued developing adequate and comprehensive internal control systems. Nevertheless, further work is needed in documenting and updating operational and administrative procedures (especially for *ex post* and accounting closure activities), which will mitigate the risks of error and inconsistent practices.

OTHER MATTERS

Internal audit function and the Commission's Internal Audit Service

21. In 2011, the Commission's Internal Audit Service carried out a risk assessment exercise, and on 3 November 2011 the strategic audit plan for 2012-2014 was approved by the Governing Board.

22. The mission charter of the Commission's Internal Audit Service was adopted by the Governing Board on 8 March 2011. However, the Joint Undertaking's financial rules have not yet been amended to include the provisions of the framework Regulation ⁽¹³⁾.

23. In 2012 the Commission's Internal Audit Service carried out an assurance review of IMI's negotiation, grant agreement preparation and pre-financing processes. The IAS concluded that the existing internal controls provided reasonable assurance as to whether, with the exception of specific issues related to the management of conflicts of interests, documentation of the negotiation process and the related controls, and

an IT application used during the negotiation process, the business objectives had been achieved. The Joint Undertaking's action plan to address the IAS recommendations was validated by the IAS on 29 October 2012.

Monitoring and reporting of research results

24. The Seventh Framework Programme (FP7) establishes a monitoring and reporting system covering the protection, dissemination and transfer of research results ⁽¹⁴⁾.

25. In the grant agreements signed with members and other beneficiaries, the Joint Undertaking has included specific provisions governing intellectual property rights and the dissemination of research activities and results, in accordance with Article 15 of the Council Regulation setting up the Joint Undertaking. Implementation of these provisions is monitored by the Joint Undertaking at different stages of the funded projects.

26. The Joint Undertaking regularly presents specific reports on ongoing projects ⁽¹⁵⁾. However, as part of its objective to contribute to the implementation of the Seventh Framework Programme, which is stated in Article 2 of Regulation (EC) No 73/2008, the Joint Undertaking should also determine, together with the two Founding Members (the Commission and EFPIA), which information is to be made available for the general monitoring report that is regularly produced on FP7, and for other reporting tools of the Commission.

Follow-up of previous observations

27. In 2012 the business continuity plan and disaster recovery plan were finalised.

28. The accounting officer has reported on the validation of the accounting system on 27 September 2012 and most of the weaknesses identified were addressed by the end of the year. However, the validation of the accounting system does not yet cover *ex post* audit results.

29. The methodology for evaluating in-kind contributions ⁽¹⁶⁾ was approved by the Governing Board on 11 November 2011. These contributions are validated by way of *ex-ante* certification and *ex post* audits. In 2012, the first 14 certified methodologies for in-kind contributions were accepted and the first three *ex post* audits covering in-kind contributions were launched.

⁽¹³⁾ 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.

⁽¹⁴⁾ FP7 Monitoring reports: http://ec.europa.eu/research/evaluations/index_en.cfm?pg=fp7-monitoring.

⁽¹⁵⁾ In October 2012 and March 2013 IMI provided information on its research outputs through bibliometric analyses of ongoing projects.

⁽¹⁶⁾ In-kind contributions are eligible costs incurred by the legal entities participating in activities but not reimbursed by the Joint Undertaking.

30. Article 12(5) of the Council Regulation setting up the Joint Undertaking does not recognise the right of the Court of Auditors to audit the in-kind contributions of EFPIA companies, although they are recorded in IMI's financial statements. It is estimated that these contributions will represent approximately 1 billion euro over IMI's lifetime.

This Report was adopted by Chamber IV, headed by Dr Louis GALEA, Member of the Court of Auditors, in Luxembourg at its meeting of 22 October 2013.

For the Court of Auditors

Vítor Manuel da SILVA CALDEIRA

President

ANNEX

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

<p>Areas of Union competence deriving from the Treaty</p> <p><i>(Articles 187 and 188 of the Treaty on the Functioning of the European Union)</i></p>	<p>Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme provides for a Community contribution to the establishment of long-term public-private partnerships in the form of Joint Technology Initiatives which could be implemented through Joint Undertakings within the meaning of Article 187 of the Treaty.</p> <p>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.</p>
<p>Competences of the Joint Undertaking</p> <p><i>(Council Regulation (EC) No 73/2008)</i></p>	<p>Objectives</p> <p>The Innovative Medicines Joint Undertaking (IMI JU) shall contribute to the implementation of the Seventh Framework Programme (FP7) and in particular the theme 'Health' of the 'Cooperation' specific programme. It has the objective of significantly improving 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. In particular it shall:</p> <ul style="list-style-type: none"> — support 'pre-competitive pharmaceutical research and development' in the Member States and countries associated with FP7 via a coordinated approach to overcome the identified research bottlenecks in the drug development process, — support the implementation of the research priorities as set out by the research agenda of IMI JY, notably by awarding grants following competitive calls for proposals, — ensure complementarity with other activities of FP7, — be a public-private partnership aiming at increasing research investment in the biopharmaceutical sector in the Member States and countries associated with FP7 by pooling resources and fostering collaboration between the public and private sectors, — promote the involvement of small and medium-sized enterprises in its activities, in line with the objectives of FP7.
<p>Governance</p>	<p>The bodies of IMI JU are the Governing Board, the Executive Director and the Scientific Committee. The Governing Board is composed of ten Board members representing equally the two founding members of IMI: the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The Executive Director, the chief executive responsible for the day-to-day management of IMI JU in accordance with the decisions of the Governing Board, is supported by an executive office. The Scientific Committee is an advisory body to the Governing Board. The Joint Undertaking is also supported by two external advisory bodies: the IMI States Representatives Group and the Stakeholder Forum.</p>

Resources available to the Joint Undertaking in 2012	Budget ⁽¹⁾ 373 763 361 euro for commitments 113 209 163 euro for payments Staff at 31 December 2012 36 posts provided for in the establishment plan (29 temporary staff and 7 contract staff), of which 35 posts were occupied. 80 % of these resources are directly assigned to support operational activities.
Activities and services provided in 2012	See the IMI JU annual activity report for 2012, to be published at www.imi.europa.eu

⁽¹⁾ Including appropriations carried over from 2011.
Source: Information supplied by IMI JU.

THE JOINT UNDERTAKING'S REPLIES

13. IMI JU welcomes the positive conclusion of the Court on the legality and regularity of all transactions underlying the annual accounts of the Joint Undertaking with the only exception of material errors detected by IMI JU through its first *ex post* audits in relation to interim payments for first call claims made prior to the financial year under review.

The estimated representative and residual error rates of 5,82 % and 3,64 % respectively that are used as the basis of the Court's qualified opinion reflect the outcome of 56 audits covering 65 first call cost claims that were accepted in 2010 and 2011 when IMI JU was still in its start-up phase. In addition,

- (a) The vast majority of financial errors identified in these audits of the 2010 and 2011 claims were relatively small in amounts to be adjusted (less than EUR 5 000 in favour of IMI JU) and clearly arose from misunderstandings of the rules or a lack of attention to the detail of the provisions of the grant agreements. The audits were also, by design, focused in most cases on new or unaudited beneficiaries under the EU research programmes. For such audits a higher rate of error can be expected.
- (b) The estimated error rate does not reflect the outcome of audits of interim payments made to beneficiaries in 2012 for which a new representative sample of 40 *ex post* audits is being conducted in 2013 and the first preliminary results are expected at the end of the year. These new audits cover a broader population of claims and beneficiaries, including the first claims of the second call projects as well as the second and third reporting periods of first call projects.
- (c) IMI has since taken a series of concrete preventive and monitoring measures to help reduce the common types of errors and minimise the inherent underlying risks related to grant management. These measures have included:
 - (i) the review and strengthening of internal *ex ante* control policies and procedures to be carried out by staff for interim payments after the experience of the first 2 years of operation;
 - (ii) timely revisions of the IMI model grant agreement that have led to more clarity on the legal conditions and requirements of the grant;
 - (iii) the introduction of IMI specific financial guidelines in January 2012 and the issue of an updated version in June 2013, providing participants and their appointed independent auditors for the certificates of financial statements with comprehensive information and guidance on the provisions of the IMI model grant agreement;

- (iv) the organisation of frequent financial workshops for participants which focus on recurrent causes of errors and prevention; and
- (v) the introduction in 2012 of integrated business solutions through IMI JU's dedicated submission and project management Information Technology tool SOFIA (Submission OF Information Application) allowing electronic submission and checking of cost claims, thereby reducing the margin of error.

In parallel, the appropriate controls have been taken by IMI JU to ensure that errors in favour of the Joint Undertaking that were detected from the first finalised *ex post* audits are duly corrected. This is being systematically achieved either through a recovery order or as a set-off against a future payment. In addition, errors that are considered as systematic are also being extended to non-audited claims submitted to the same audited beneficiary.

Moreover, IMI JU has continued to implement an intensive annual programme of *ex post* audits covering 40 % of the total value of interim payments made in the previous year in line with the Ex-Post Audit Strategy approved by the Governing Board. These audits have been highly effective and reliable basis for assessing and monitoring the overall regularity and legality of interim payments on a multiannual basis, and as a basis for detecting and correcting errors found in the audited claims. The Joint Undertaking also maintains close coordination with the European Commission and its agencies involved in the Seventh Framework Programme and shares information on common beneficiaries in order to optimise its audit coverage and effectively mitigate risks of non-compliance.

IMI JU remains committed to managing its funding through a trust-based approach with the participants in the projects whilst ensuring sufficient control and accountability. The risk-based preventive and corrective actions already taken by the Joint Undertaking provide a sufficient basis for sound financial management and the gradual reduction of the risk of error in interim payments to beneficiaries on a multiannual basis. 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.

With many projects only starting to generate expenditure, particularly in the case of projects from Calls 3 to 8, the full impact of IMI's actions can only be seen in the longer term, once more projects submit cost claims and *ex post* audits cover a greater part of the total population of beneficiaries.

17. The budget was based on the adopted Legislative Financial Statements and its execution followed the principles of sound financial management. Moreover, none of the funds budgeted for running costs were lost and unutilised funds from the European Commission were transferred to research activities. It is also important to keep in view that 50 % of the budget for running costs is financed through EFPIA.

19. Effective measures have been in place in 2013 to increase and accelerate the commitment of EU funding and the matching in-kind contributions from EFPIA members through the launch of several Calls for proposals throughout the year.

20. IMI JU agrees with the Court's assessment on internal control systems. The Joint Undertaking has established a mature, effective and reliable internal control system. This includes a systematic review and updating of policies and procedures in line with the internal control priorities set by management before the start of the year. The observations of the Court reflect IMI's set priorities for 2013 which will be duly implemented by the end of the year.

22. This issue has been superseded with the publication on 30 September 2013 of the Delegated Act of the European Commission 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. IMI JU's financial rules will be duly amended to reflect this development.

23. In the final audit report of the Internal Audit Service of the European Commission, the IAS proposed 11 recommendations on how IMI can address each of these issues. All of these were transformed into concrete actions and implemented by IMI JU during the course of the fieldwork of the European Court of Auditors between August 2012 and July 2013. During this period the IAS also verified and closed 10 of the 11 recommendations, with the remaining one to be closed after an on-the-spot verification of IMI JU's actions.

26. IMI JU has already taken action on the Court's observation. The requirements for the general monitoring report have in fact been defined and the data was given to the European Commission in September 2013 for integration in CORDA.

28. With regard to the Court's comments on the scope of the validation of the accounting system, IMI JU highlights the fact that the *ex post* audit results were implemented in 2013 and will be first reflected in the 2013 Accounts.
