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COVER NOTE

from: Mr Vítor CALDEIRA, President of the Court of Auditors
date of receipt: 10 December 2012
to: Mrs Erato KOZAKOU-MARCOULLIS, President of the Council of the
European Union

Subject: Report on the annual accounts of the Innovative Medicines Initiative Joint
Undertaking for the financial year 2011 together with the replies of the Joint
Undertaking

Madam,

I enclose in all the official languages of the European Union a copy of the Court of Auditors' report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2011.

This report is accompanied by the Joint Undertaking's replies and will shortly be published in the Official Journal of the European Union.

(Complimentary close).

(s.) Vítor CALDEIRA

Encl.: Report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2011 together with the replies of the Joint Undertaking.

Report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking
for the financial year 2011

together with the replies of the Joint Undertaking

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 2007¹ 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 medicines².
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 Programme³ 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 one 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

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 achieving the goals of growth, competitiveness and employment. It is also a key pillar for the European Research Area.

activities. The research companies which are members of EFPIA are to contribute to the funding of research activities through in-kind⁴ contributions at least equal to the EU financial contribution⁵.

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

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(1) of the Treaty on the Functioning of the European Union the Court has audited the annual accounts⁶ of the Innovative Medicines Initiative Joint Undertaking, which comprise the

⁴ According to article 11(4) of the Annex to Regulation (EC) No 73/2008 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)”. The contribution from the research companies shall at least match the financial contribution of the Union.

⁵ According to article 11(5) of the Annex to Regulation (EC) No 73/2008 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”.

⁶ The Court received the annual accounts on 1 July 2012 and a corrigendum to these accounts on 12 October 2012. 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.

“financial statements”⁷ and the “reports on the implementation of the budget”⁸ for the financial year ended 31 December 2011 and the legality and regularity of the transactions underlying those accounts.

8. This Statement of Assurance is addressed to the European Parliament and the Council in accordance with Article 185(2) of Council Regulation (EC, Euratom) No 1605/2002⁹.

The Management's responsibility

9. 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 appropriations¹⁰. The Director is responsible for putting in place¹¹ the organisational structure and the internal management and control systems and procedures relevant for drawing up final accounts¹² that are free from material misstatement, whether due to fraud or errors and for ensuring that the transactions underlying those accounts are legal and regular.

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 Auditor's responsibility

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

11. The Court conducted its audit in accordance with the IFAC and ISSAI¹³ International Auditing Standards and Codes of Ethics. Those standards require the Court to comply with ethical and professional requirements and to plan and perform the audit so as to obtain reasonable assurance as to whether the accounts are free from material misstatement and whether the underlying transactions are legal and regular.

12. 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.

13. 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 accounts

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

14. 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 2011 and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its financial rules.

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

15. The ex-post audit strategy 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 transactions¹⁴. The ex-post audits that were completed as of September 2012 covered 2,2 million euro (18,8 % of accepted IMI JU contribution for the first call validated by the IMI Joint Undertaking by June 2011). The error rate resulting from these ex-post audits was 6,84 %¹⁵.

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

16. In the Court's opinion, except for the effects of the matters described in paragraph 15, the transactions underlying the annual accounts of the Joint Undertaking for the year end 31 December 2011, are in all material respects, legal and regular.

17. The comments which follow in paragraphs 18-32 do not call the Court's opinions into question.

¹⁴ 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 expenditures claimed by the beneficiaries which are then subject to recovery procedures.

¹⁵ The error rate is calculated using an average of the overdeclarations found in the different cost claims weighted by their amount.

COMMENTS ON THE BUDGETARY AND FINANCIAL MANAGEMENT

Implementation of the budget

18. The 2011 annual budget and implementation plan were adopted by the Governing Board on 4 April 2011¹⁶ due to the time taken 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 fourth call for proposals, signed five grant agreements for the third call for proposals and eight grant agreements for the second call for proposals.

19. The implementation rate for the 159 million euro commitment appropriations available for research activities was 66 % and it was implemented through a global commitment covering the fourth call for proposals. The high level of unused appropriations of the administrative budget (44 %) indicates that it was not based on realistic estimates.

20. Commitment appropriations amounting to 117 million euro and payment appropriations amounting to 65 million euro not used in the financial year 2010 were carried over to 2011 and commitment appropriations amounting to 62 million euro and payment appropriations amounting to 11 million euro not used during the financial year 2011 were carried over to 2012.

Calls for proposals

21. The calls for proposals organised in 2008, 2009 and 2010 resulted in signed grant agreements amounting to 269 million euro at the end of 2011. In 2011 the fourth call for proposals was launched with an indicative budgeted EU contribution of 105 million euro. In 2012 the fifth call for proposals was launched with an indicative budgeted EU contribution of 80 million euro.

¹⁶ On the basis of Article 14 of the IMI's financial rules, budget rule 1/12 was used to make payments until the budget was adopted.

Consequently, if calls for proposals remain at the current level, it is highly likely that the total available EU contribution will not be used.

Inconsistencies between the Governing Board Decisions and the report on budgetary and financial management

22. In the report on budgetary and financial management, the total amount of chapter 30-C2 “Research agenda” (117 million euro) is lower than the budget line B03000-C2 (141 million euro) which is part of the aforementioned chapter. In addition, the Governing Board Decision of 28 January 2011 only authorises the carry-over of 115 million euro of commitment appropriations, while the report on budgetary and financial management discloses a carry-over of 117 million euro.

COMMENTS ON KEY CONTROLS OF THE JOINT UNDERTAKING’S SUPERVISORY AND CONTROL SYSTEMS

23. During 2011 significant progress regarding internal control systems was noted. However, further work is needed to establish and document the budget and accounting procedures and related controls. In addition, no formal assessment of the internal control system was carried out during 2011.

24. The Accounting Officer reported on the validation of the accounting system on 27 September 2012 and underlined significant weaknesses which need to be addressed¹⁷.

¹⁷ Major observations reported by the accounting officer: (a) no use of an accurate and established methodology for the calculation of accruals at the end of the financial year (b) improve treasury management and archiving practices (c) formalize the approval of the updated draft manual of financial procedures (d) ensure a complete supporting documentation in payment files (e) introduce an IT-tool in order to better register and manage contracts and agreements.

Methodology for evaluating in kind contributions

25. The methodology for evaluating in-kind contributions¹⁸ was approved by the Governing Board on 11 November 2011. The in-kind contributions are validated by way of an ex-ante certification and ex-post audits. In 2011 no ex-ante certification and no ex-post audit were carried out.

OTHER MATTERS***Internal audit function and the Commission's Internal Audit Service***

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

27. The mission charter of the Commission's Internal Audit Service was adopted by the Governing Board on 8 March 2011. However, the financial rules of the Joint Undertaking have not yet been amended to include the provision of the Framework Regulation¹⁹.

28. The Joint Undertaking obtained its autonomy in November 2009, but no internal assurance audit work was performed until March 2012 either by the Internal Audit Service of the Commission or the internal audit manager. The internal audit manager has been directly involved in operational activities (implementation of ex-post strategy, KPI framework, review of ex-ante certificate on in-kind contributions) and other consultancy engagements.

¹⁸ In-kind contributions are the eligible costs incurred by the legal entities participating in the activities which are not reimbursed by the Joint Undertaking.

¹⁹ Regulation (EC, Euratom) No 2343/2002.

Audit rights of the European Court of Auditors

29. The provisions of the grant agreement do 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 one billion euro over IMI's lifetime.

Follow up of previous observations

30. A host agreement was concluded on 02 February 2012 between the Joint Undertaking and Belgium concerning the office accommodation, privileges and immunities and other support to be provided by Belgium.

31. During 2011 the Joint Undertaking made progress on the formalisation of IT security policies. However, the business continuity plan and disaster recovery plan were not finalised.

Annual activity report

32. According to Article 6.4 of the Statutes of the Joint Undertaking and Article 41 of the IMI Joint Undertaking's financial rules, the Executive Director is required to draw up an annual activity report including a declaration of assurance stating that the information contained in the report presents a true and fair view except as otherwise specified in any reservation. The declaration of assurance was issued in February 2012 without reservation despite the lack of information on the effectiveness of the ex-post audit strategy, which is the key control for operational expenditure.

This Report was adopted by Chamber IV, headed by Dr Louis GALEA, Member of the Court of Auditors, in Luxembourg at its meeting of 13 November 2012.

For the Court of Auditors

Vítor Manuel da SILVA CALDEIRA
President

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: 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: 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 (Article 2 of <i>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 produce 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 (Article 1 of the Annex – <i>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; (d) to mobilise the public and private sector resources needed; (e) to establish and develop close and long-term cooperation between the Community,

	<p>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>
Governance	<p><i>(Article 4 of the Annex to Regulation (EC) No 73/2008 – Statutes of the Joint Undertaking for the Implementation of the Joint Technology Initiative on Innovative Medicines)</i></p> <p><u>1 - The Governing Board</u></p> <p><u>2 - The Executive Director</u></p> <p><u>3 - The Scientific Committee</u></p> <p><u>4 - Two Advisory Bodies:</u> the IMI States Representatives Group and the Stakeholder Forum</p> <p><u>5 - Internal audit:</u></p> <ul style="list-style-type: none"> – The Internal Auditor of the European Commission <p><i>(Article 10 of the Annex to Regulation (EC) No 73/2008 – Statutes of the Joint Undertaking for the Implementation of the Joint Technology Initiative on Innovative Medicines)</i></p> <ul style="list-style-type: none"> – Internal audit capability within the IMI JU <p><i>(Article 6 of Regulation (EC) No 73/2008)</i></p> <p><u>6 - External audit:</u> The European Court of Auditors</p> <p><i>(Article 17(5) of the Statutes annexed to Regulation (EC) No 73/2008 and Article 126 of the IMI's financial rules)</i></p> <p><u>7 - Discharge authority</u> The European Parliament, acting on a recommendation from the Council.</p> <p><i>(Article 11(4) of Regulation (EC) No 73/2008 and Article 129 of the IMI's financial rules)</i></p>
Resources available to the Joint Undertaking in 2011	<p>Budget The final budget consisted of commitment appropriations of 285 379 570 euro and payment appropriations of 88 898 250 euro. These amounts included appropriations carried over from 2010 of 116 862 090 euro in commitment appropriations and of 64 506 677 euro in payment appropriations.</p> <p>Staff as at 31 December 2011 31 posts provided for in the establishment plan (26 Temporary Agents + 5 Contract Agents), of which, 31 posts were occupied. Staff:</p> <ul style="list-style-type: none"> - Temporary Agents: 26 - Contract staff: 6 (one CA was recruited in anticipation in order to cover the maternity leave of one TA) - Seconded National Experts: 0

	<ul style="list-style-type: none">- Local staff: 0 Allocated to: <ul style="list-style-type: none">- Operational activities: 6- Administrative tasks: 8*- Horizontal tasks: 17 <p>* the number refers to administrative assistants with administrative tasks.</p>
Activities and services provided in 2011	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.

Source: Information supplied by the IMI JU.



**IMI Joint Undertaking's reply to the European Court of Auditors
on the Report on the annual accounts of the
Innovative Medicines Initiative Joint Undertaking
for the financial year 2011**

19 November 2012

Paragraph 15

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 in relation to interim payments for first call claims. Interim payments in 2011 accounted for 20 % (15,2 million euro) of the total payments paid out by IMI JU in 2011 (74,3 million euro) and 22 % of the total payments made by IMI JU to beneficiaries (69,0 million euro).

In addition, without questioning the Court's own calculation of the error rate based on IMI JU's first audits, the detected and residual error rate resulting from these finalised ex-post audits, applying the methodology established in IMI JU's ex-post audit strategy, were 4,58 % and 3,72 % respectively as at September 2012. This result is based on a relatively limited number of concluded audits, and concentrated on new or unaudited beneficiaries from the first IMI projects, where a higher rate of error can be expected.

2011 was the first complete year of ex-ante and ex-post control with audits being launched as soon as the first costs claims related to Call 1 projects were validated and paid. The errors reported by the Court as the basis for a qualified opinion were detected by IMI JU's own internal control system and this in itself demonstrates the effectiveness of this process. Moreover, the multi-annual basis of IMI JU's strategy and operations also means that additional time is needed before a full assessment can be made on the impact of such controls.

IMI JU, nonetheless, acknowledges the risks related to grant management and is taking the appropriate measures both at ex-ante and ex-post level to follow-up and correct the errors detected from the finalised ex-post audits. In addition, new initiatives are being introduced with the aim of preventing the occurrence of such errors among existing and new participants of IMI JU projects. These have included the further strengthening of ex-ante controls in order to allow higher detection and correction of errors before validation of cost claims, the organisation of financial workshops and the development of guidance aimed at increasing the awareness and the understanding of participants on key issues such as the eligibility of costs and the importance of keeping adequate supporting documentation linked to the submitted claims. This is all the more important as a large portion of participants are small and medium size enterprises and other entities are unfamiliar with EU research programmes.

Paragraph 19

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.

Paragraph 21

Effective measures were put in place in 2012 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. To date in 2012, three Calls for Proposals have been launched with another one foreseen by the end of 2012, thus marking significant progress in the execution of IMI programme.

Paragraph 22

The total amount of chapter 30-C2 “Research Agenda” (117 million euro) is the correct amount with the difference being due to a technical problem in the ABAC system which is now being addressed. With regard to the authorised carry-over, this is duly clarified in the preamble of the Governing Board Decision whereby it is stated that IMI JU had operational commitments and payment appropriations which had not been used at the end of the financial year 2010 and that it was considered necessary to use the cancelled appropriation during 2011. Nonetheless, IMI JU will clarify the text of the decision for the future carry-overs.

Paragraph 23

Work related to the formal assessment of the internal control system was carried out by the Internal Control Coordinator in the last quarter of 2011 and finalised through the approval of the report to the Executive Director on 13 February 2012. This is in line with what is foreseen in Internal Control Standard 15 and in preparation of the Annual Activity Report of 2011. During 2011, the implementation of the internal control systems was also periodically reviewed, in a formal manner, through the preparation and approval of the 2011 Action Plan in February 2011 and through its updating in May and October 2011.

Paragraph 24

An Action Plan is being drawn up to address the recommendations of the Accounting Officer of 27 September 2012.

Paragraph 25

EFPIA members participating in IMI JU projects submitted their first declarations on in-kind contributions in February 2012 following the approval of the methodology by the Governing Board on 11 November 2011. Apart from ex-ante checks of these declarations and the respective certified methodologies, the first ex-post audit of in-kind contributions will be carried out in 2012.

Paragraphs 26 to 28

The Coordinated IAS-IAC Strategic Audit Plan for 2012-2014 was approved by the Governing Board on 3 November 2011. This was based on a comprehensive risk assessment exercise carried out jointly by the IAS and IMI JU's Internal Audit Capability and finalised in September 2011. Throughout 2011, the Internal Audit Capability within IMI JU also carried out a number of internal audit consultancy engagements in relation to the development and strengthening of IMI JU's governance, internal control and risk management systems and processes.

The first internal audit by the Internal Audit Service of the European Commission was carried out during the second quarter of 2012 with the final report being issued and submitted to the Executive Director and the Governing Board in July. This comprehensive internal audit exercise focused on the negotiations, grant agreement preparations and pre-financing sub-processes of IMI JU.

The role of internal audit in IMI JU's financial rules will also be duly amended to reflect the requirements of the model financial regulation for Public Private Partnerships expected to be introduced by the European Commission in 2013.

Paragraph 29

The provisions set out in the revised model Grant Agreement approved by the Governing Board on 11 November 2011 with regard to the audit of EFPIA companies' in-kind contributions are in line with the parameters set out in Articles 12(4) and 12(5) of the Council Regulation (EC) No 73/2008 setting up IMI JU.

Nevertheless, as this is fundamentally a question of principle, the advice of the European Commission is now being sought on the rights of the European Court of Auditors to audit in-kind contributions of EFPIA companies who are not recipients of IMI JU funding.

Paragraph 31

Considerable progress was done in 2011 in preparation for IMI JU's business continuity and disaster recovery plans. Both have since been finalised and were in place by the first quarter of 2012.

Paragraph 32

Ex-post audits were launched in November 2011 and as at February 2012 there was no indication from the on-going audits that would have reasonably justified a reservation.