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| From: | Mr Vítor CALDEIRA, President of the European Court of Auditors |
| date of receipt: | 19 November 2014 |
| To: | Mr Linas LINKEVICIUS, 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 2013 together with the Joint Undertaking's replies |

Delegations will find attached the European Court of Auditors' report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2013.

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

Encl.: Report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2013 together with the Joint Undertaking's replies.¹

¹ In English only. The other languages of this report are available on the European Court of Auditors' website: <http://eca.europa.eu/>.

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EUROPEAN COURT OF AUDITORS
COUR DES COMPTES EUROPÉENNE
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Report on the annual accounts of the
Innovative Medicines Initiative Joint Undertaking
for the financial year 2013

together with the Joint Undertaking's replies

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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 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 produce 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 the 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 reaching 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-kind contributions⁴ 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 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 statements⁶ and the reports on the implementation of the budget⁷ for the financial year ended 31 December 2013, and

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”.

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.

(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 2343/2002⁸, 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 officer⁹, 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

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.

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 Council¹⁰ 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

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

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 2013 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.

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

13. The Joint Undertaking's *ex-post* audit strategy¹¹ 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. As of June 2014, 14 out of 40 *ex-post* audits of the second representative sample had been finalised, covering 3 million euro (11,8 % of the audited population). The detected error rate resulting from these audits is 2,3 %¹².

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 detected error rate resulting from the 56 concluded audits of the first representative sample was 5,8 % (see paragraph 13 of the Court's Specific Annual Report for 2012).

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

14. In the Court's opinion, except for the effects of the matter described in paragraph 13, the transactions underlying the annual accounts of the Joint Undertaking for the year ended 31 December 2013 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 initial 2013 budget included commitment appropriations amounting to 226 million euro and payment appropriations amounting to 135 million euro. At the end of the year the Governing Board adopted an amending budget that increased commitment appropriations to 255,7 million euro and decreased payment appropriations to 130,6 million euro. The overall implementation rate was 99,5 % for commitment appropriations and 97,5 % for payment appropriations.

17. In the case of operational activities, the implementation rate was 100 % for commitment appropriations and 99 % for payment appropriations¹³. However, the total amount of commitment appropriations was committed at level one, meaning that, while calls for proposals have been launched, no corresponding grant agreements have yet been signed.

¹³ As regards administrative expenditure, the appropriations available for 2013 amounted to 8,4 million euro, the IMI Joint Undertaking achieved an implementation rate of 85 % for commitment appropriations (7 million euro) and 70 % for payment appropriations (6 million euro).

Calls for proposals

18. 2013 was the last year in which calls for proposals could be launched under the FP7 programme. The entire budget for research was committed (970 million euro), along with the requisite matching in-kind contributions from the EFPIA companies (982 million euro).

OTHER MATTERS

Legal framework

19. The new Financial Regulation applicable to the general budget of the Union was adopted on 25 October 2012 and took effect on 1 January 2013¹⁴. However the model financial regulation for public-private partnership bodies referred to in Article 209 of Regulation No 966/2012 of the European Parliament and of the Council¹⁵ did not enter into force until 8 February 2014. The financial rules of the Joint Undertaking were amended on 7 July 2014 to reflect these changes.

Internal audit function and the Commission's Internal Audit Service

20. In accordance with the strategic audit plan for 2012-2014 approved by the Governing Board on 3 November 2011, the Commission's Internal Audit Service (IAS) carried out an assurance engagement of project management and reporting on operational performance¹⁶.

¹⁴ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

¹⁵ OJ L 38, 7.2.2014, p. 2.

¹⁶ The final report dated 30 January 2014 included the following recommendations, in the context of IMI's continuous "efforts to further improve the effectiveness and efficiency of systems that are set up to monitor projects and report on operational performance": (a) review the design and reporting of objectives and KPIs; (b) strengthen project monitoring and improve IT systems to enhance reporting.

21. Additionally, the IAS performed an IT risk assessment of both the IMI Joint Undertaking's specific IT systems¹⁷ and the common IT infrastructure¹⁸ that the IMI Joint Undertaking shares with the FCH, Cleansky, Eniac and ARTEMIS Joint Undertakings.

Monitoring and reporting of research results

22. The Seventh Framework Programme (FP7) Decision¹⁹ establishes a monitoring and reporting system related to the protection, dissemination and transfer of the research results. The Joint Undertaking has developed procedures to monitor the protection and dissemination of research results at different stages of the projects. The requirements regarding the general monitoring report on FP7 have been defined, and the data related to the IMI Joint Undertaking's projects were transferred to the Commission in September

The action plan proposed by the IMI Joint Undertaking to implement these improvements in the course of 2014 was accepted and considered adequate by the IAS on 24 February 2014.

- ¹⁷ The final report dated 22 November 2013 noted the need for more formal instructions on project management and on change control processes in the contracts in order to mitigate contract-management risks. This recommendation was implemented by the IMI Joint Undertaking in January 2014.
- ¹⁸ The final report dated 22 November 2013 noted the need to formalise IT security policy and include detailed procedures/controls in future contracts with IT service providers.
- ¹⁹ Article 7 of Decision No 1982/2006 of the European Parliament and the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) states that the Commission shall continually and systematically monitor the implementation of the Seventh Framework Programme and its specific programmes and regularly report and disseminate the results of this monitoring.

2013 for integration in CORDA²⁰. However, this monitoring requires further development in order to comply fully with the provisions of the Decision²¹.

Conflicts of interest

23. The IMI Joint Undertaking has put in place specific measures to prevent conflicts of interest in respect to its Governing Board members, experts and employees. These are included in the rules of procedure of both the Governing Board and the Scientific Committee, and in the documentation on the code of conduct and conflicts of interest in the case of independent experts during evaluation. Furthermore, in April 2013 the Joint Undertaking adopted an updated and comprehensive policy on conflicts of interest for both management and staff.

The Commission's Second Interim Evaluation

24. The Commission's Second Interim Evaluation was carried out from March to July 2013, assessing the IMI Joint Undertaking in terms of relevance, effectiveness, efficiency and research quality.

25. The report, issued on 31 July 2013, was positive about the success of the IMI Joint Undertaking in achieving its objectives. It also highlighted areas where further improvements could be made, in particular as regards communication strategy, the development of additional key performance indicators to quantitatively demonstrate the Joint Undertaking's impact and socio-economic benefits, optimisation of the organisational structure, and a more flexible funding mechanism.

²⁰ Common Research Data Warehouse.

²¹ See the observation made in the 2012 Annual Progress Report from the Commission to the European Parliament and the Council on the activities of the Joint Technology Initiative Joint Undertakings (SWD (2013) 539 final) with regard to the integration of results achieved in research projects in the Commission's communication and dissemination system.

Follow-up of previous observations

26. The ex-post audit corrections resulting from the first audits of the representative sample were implemented and reflected in the 2013 accounts. However, the validation of the accounting system does not yet cover the implementation of ex-post audit results.

27. The methodology for evaluating in-kind contributions²² 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 2013, the remaining eight certified methodologies for in-kind contributions were accepted, bringing the total number of EFPIA companies with certified methodologies to 22. The first three *ex-post* audits covering in-kind contributions were completed during the course of the year²³, a further ex-post audit was initiated and two were in the process of being initiated at the year-end.

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 21 October 2014.

For the Court of Auditors

Vítor Manuel da SILVA CALDEIRA
President

²² In-kind contributions are eligible costs incurred by the legal entities participating in research activities but are not reimbursed by the Joint Undertaking (see also footnote 4).

²³ In one case the auditors found errors of a systematic nature, resulting in a significant increase (1 million euro) in the allowable amount that could be declared by the EFPIA company. As a consequence, the certificate on in-kind methodology was updated and re-submitted for the IMI Joint Undertaking's approval. As for the other two companies, the auditors identified isolated non-systematic errors with minor impact on the total contributions declared. All findings were accepted by all three companies.

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

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| <p>Areas of Union competence deriving from the Treaty</p> <p><i>(Extracts from Articles 171 and 172 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 171 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 (OJ L 30, 4.2.2008, p. 38)</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 specific programme 'Cooperation'. 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"> – 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 the IMI JU, 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 Members 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 the IMI JU are the Governing Board, the Executive Director and the Scientific Committee. The Governing Board is composed of 10 Board members representing equally the two Founding Members of the IMI Joint Undertaking: the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The Executive Director is the chief executive responsible for the day-to-day management of the IMI JU in accordance with the decisions of the Governing Board and 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> |
| <p>Resources available to the Joint Undertaking in 2013</p> | <p>Budget*</p> <p>255 715 919 € for commitments</p> <p>130 558 622 € for payments</p> <p>* The amounts include appropriations carried over from 2012.</p> <p>Staff as at 31 December 2013</p> <p>All 36 posts provided for in the establishment plan (29 temporary staff and seven contract staff) were occupied. 80 % of these resources are directly assigned to support operational activities.</p> |
| <p>Activities and services</p> | <p>See Annual Activity Report 2013 of the IMI JU at www.imi.europa.eu</p> |

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Source: Information supplied by IMI JU.
