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COVER NOTE

From:	Mr Klaus-Heiner LEHNE, President of the European Court of Auditors
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To:	Mr Märt KIVINE, 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 2016 together with the Joint Undertaking's reply

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 2016.

This report is accompanied by the Joint Undertaking's reply 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 2016 together with the Joint Undertaking's reply.¹

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



EUROPEAN
COURT
OF AUDITORS

Report on the annual accounts of the
Innovative Medicines Initiative Joint Undertaking
for the financial year 2016

together with the Joint Undertaking's reply

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INTRODUCTION

Establishment of the IMI Joint Undertaking

1. The Initiative on Innovative Medicines (IMI) Joint Undertaking, located in Brussels, was set up in December 2007¹ for a period of ten years and started working autonomously on 16 November 2009. In May 2014, the Council adopted a new founding Regulation and extended the lifetime of the Joint Undertaking to 31 December 2024².

2. The IMI Joint Undertaking is a public-private partnership for health research and innovation. The founding members of the Joint Undertaking are the European Union (EU), represented by the Commission, and the pharmaceutical sector, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Governance

3. The governance structure of the IMI Joint Undertaking includes the Governing Board, the Executive Director, the Scientific Committee, the States Representatives Group, the Strategic Governing Groups and the Stakeholder Forum.

4. The Governing Board is the main decision-making body and is responsible for the operations of the Joint Undertaking and oversight of its activities. The Board is composed of ten members representing the two founding members equally. The Executive Director is responsible for the day-to-day management of the Joint Undertaking.

5. The Scientific Committee, the States Representatives Group, the Strategic Governing Groups and the Stakeholder Forum are advisory bodies. The Scientific Committee is made up of scientific experts from diverse fields and provides recommendations to the Governing Board. The States Representatives Group, consisting of representatives of the EU Member

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 Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (OJ L 169, 7.6.2014, p. 54).

States and the countries associated with the EU's research programmes, provides strategic opinions to the Governing Board. The Strategic Governing Groups, which comprise representatives of pharmaceutical companies, the European Commission and the Scientific Committee, coordinate IMI projects among themselves and with the EU's wider research programmes. The Stakeholder Forum is an annual event, where IMI stakeholders discuss the IMI's latest activities and plans.

Objectives

6. The objective of the IMI is to improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need. The IMI seeks to facilitate collaboration between the key players in healthcare research, including universities, the pharmaceutical and other industries, small- and medium-sized enterprises (SMEs), patient organisations and medicine regulators.

Resources

7. The maximum EU contribution to the activities of the IMI1 programme (2008-2013) is one billion euro, funded from the Seventh Research Framework Programme (FP7)³. Contributions from pharmaceutical sector members must be equal to the EU contribution.

8. The maximum EU contribution to the activities of the IMI2 programme (2014-2024) is 1 638 million euro, to be paid from the Horizon 2020 programme. Of this amount, a maximum of 1 425 million euro can be used to match the contribution of EFPIA, and up to 213 million euro can be used to match contributions from other companies and universities that decide to join the IMI Joint Undertaking as members or associated partners⁴.

9. EFPIA is to contribute resources of at least 1 425 million euro. Other members or associated partners of the IMI2 programme are to contribute resources corresponding to the amounts they committed when becoming a member or an associated partner.

³ Article 5(1) of Regulation (EC) No 73/2008.

⁴ Article 3(1) of Regulation (EU) No 557/2014.

10. The administrative costs of the Joint Undertaking are limited to 85,2 million euro, to be covered by the cash contributions of the members, divided equally on an annual basis between the EU and the industry members⁵.

11. In 2016, the payment budget for the IMI Joint Undertaking was 263,4 million euro (2015: 195 million euro). At 31 December 2016, the Joint Undertaking employed 41 staff (2015: 35)⁶.

OPINION

12. We have audited:

- (a) the accounts of the Joint Undertaking which comprise the financial statements⁷ and the reports on the implementation of the budget⁸ for the financial year ended 31 December 2016, and
- (b) the legality and regularity of the transactions underlying those accounts, as required by Article 287 of the Treaty on the Functioning of the European Union (TFEU).

Opinion on the reliability of the accounts

13. In our opinion, the accounts of the Joint Undertaking for the year ended 31 December 2016 present fairly, in all material respects, the financial position of the Joint Undertaking at 31 December 2016, the results of its operations, its cash flows, and the changes in net assets for the year then ended, in accordance with its Financial Regulation

⁵ Article 13(2) of the Statutes of the IMI 2 Joint Undertaking (Annex I of Regulation (EU) No 557/2014).

⁶ Further information on the Joint Undertaking's activities is available on its website: <https://www.imi.europa.eu>.

⁷ The financial statements comprise the balance sheet, the statement of financial performance, the cash flow statement, the statement of changes in net assets and a summary of significant accounting policies and other explanatory notes.

⁸ The reports on implementation of the budget comprise the reports which aggregate all budgetary operations and the explanatory notes.

and with accounting rules adopted by the Commission's accounting officer. These are based on internationally-accepted accounting standards for the public sector.

Opinion on the legality and regularity of revenue underlying the accounts

14. In our opinion, revenue underlying the accounts for the year ended 31 December 2016 is legal and regular in all material respects.

Opinion on the legality and regularity of payments underlying the accounts

15. In our opinion, payments underlying the accounts for the year ended 31 December 2016 are legal and regular in all material respects.

Responsibilities of management and those in charge of governance

16. In accordance with Articles 310 to 325 of the TFEU and the Joint Undertaking's Financial Regulation, management is responsible for the preparation and presentation of the accounts on the basis of internationally-accepted accounting standards for the public sector and for the legality and regularity of the transactions underlying them. This responsibility includes the design, implementation and maintenance of internal control relevant to the preparation and presentation of financial statements that are free from material misstatement, whether due to fraud or error. Management is also responsible for ensuring that the activities, financial transactions and information reflected in the financial statements are in compliance with the authorities which govern them. The Joint Undertaking's management bears the ultimate responsibility for the legality and regularity of the transactions underlying the accounts.

17. In preparing the accounts, management is responsible for assessing the Joint Undertaking's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting.

18. Those in charge of governance are responsible for overseeing the entity's financial reporting process.

Auditor's responsibilities for the audit of the accounts and underlying transactions

19. Our objectives are to obtain reasonable assurance about whether the accounts of the Joint Undertaking are free from material misstatement and the transactions underlying them are legal and regular and, on the basis of our audit, to provide the European Parliament and the Council or other respective discharge authorities with a statement of assurance as to the reliability of the accounts and the legality and regularity of the transactions underlying them. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit will always detect a material misstatement or non-compliance when it exists. These can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these accounts.

20. An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the accounts and the legality and the regularity of the transactions underlying them. The procedures selected depend on the auditor's judgment, including an assessment of the risks of material misstatement of the accounts and of material non-compliance of the underlying transactions with the requirements of the legal framework of the European Union, whether due to fraud or error. In making those risk assessments, internal control relevant to the preparation and fair presentation of the accounts and legality and regularity of underlying transactions is considered in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of internal control. An audit also includes evaluating the appropriateness of accounting policies used, the reasonableness of accounting estimates made by the management and the overall presentation of the accounts.

21. For revenue, we verify the subsidy received from the Commission and assess the Joint Undertaking's procedures for collecting fees and other income.

22. For expenditure, we examine payment transactions when expenditure has been incurred, recorded and accepted. This examination covers all categories of payments (including those made for the purchase of assets) other than advances at the point they are made. Advance payments are examined when the recipient of funds provides justification

for their proper use and the Joint Undertaking accepts the justification by clearing the advance payment, whether in the same year or later.

23. In preparing this report and opinion, we considered the audit work of the independent external auditor performed on the Joint Undertaking's accounts as stipulated in Article 208(4) of the EU Financial Regulation⁹.

24. The comments which follow do not call the ECA's opinions into question.

BUDGETARY AND FINANCIAL MANAGEMENT

Implementation of the 2016 budget

25. Taking into account unused appropriations from previous years (54,1 million euro), the final 2016 budget available for FP7 and Horizon 2020 programme implementation included commitment appropriations of 307 million euro and payment appropriations of 263,4 million euro. The utilisation rates for commitment and payment appropriations were 94,1 % and 69,6 %, respectively. The low implementation rate for payment appropriations was mainly due to a reduction in spending on the Ebola+ programme and to delays in concluding grant agreements for calls under Horizon 2020.

Multiannual budget implementation under FP7

26. Out of the 1 billion euro of FP7 funds allocated to the IMI Joint Undertaking, by the end of 2016 the Joint Undertaking had made commitments of 966 million euro and payments of 648 million euro. The high level of outstanding payments of 318 million euro (32 %) was mainly due to the delayed start of FP7 activities during the first years of the IMI Joint Undertaking.

27. Out of the 1 billion euro of contributions to be made by the industry members to the activities of the IMI Joint Undertaking, by the end of 2016 the Joint Undertaking had

⁹ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council (OJ L 298, 26.10.2012, p. 1).

validated in-kind and cash contributions of 403 million euro. A further 103 million euro of in-kind contributions had been reported by the members to the IMI Joint Undertaking.

28. Consequently, at the end of 2016, the in-kind and cash contributions of the industry members totalled 506 million euro, compared to the EU's cash contributions to the FP7 activities of the IMI Joint Undertaking, which amounted to 728 million euro.

Multiannual budget implementation under Horizon 2020

29. Out of the 1 638 million euro of Horizon 2020 funds allocated to the IMI Joint Undertaking, by the end of 2016 the Joint Undertaking had made commitments of 515 million euro (31 %) and payments of 111 million euro (7 % of the allocated funds) for the implementation of its first wave of projects. The low level of payments is mainly due to delays in concluding Horizon 2020 grant agreements with the industry partners.

30. Out of the 1 638 million euro of in-kind and cash contributions to be made by the industry members to the activities of the Joint Undertaking, by the end of 2016 the industry partners had reported 83,8 million euro of in-kind contributions, of which 47,2 million euro had been validated by the Executive Director.

31. Consequently, at the end of 2016, the total contributions of the industry members to the Horizon 2020 activities of the Joint Undertaking amounted to 83,8 million euro, compared to the EU's cash contribution of 135 million euro.

INTERNAL CONTROLS

Internal control framework

32. The Joint Undertaking has set up effective ex-ante control procedures based on financial and operational desk reviews, and performs ex-post audits of grant cost claims under FP7. These checks are key tools for assessing the legality and regularity of the underlying transactions, including other members' cash and in-kind contributions to the Joint

Undertaking. The residual rate for the ex-post audits reported by the Joint Undertaking at the end of 2016 was 1,67 %¹⁰.

Management of Horizon 2020 grants

33. At the end of 2016 – the third year of Horizon 2020 implementation – the Joint Undertaking had only partially completed the integration of its control systems with the Commission’s common Horizon 2020 grant management and monitoring tools.

Ex-ante checks and monitoring of cost claims

34. The Joint Undertaking experienced some delays in making payments to beneficiaries (universities, research organisations and SMEs). This indicates weaknesses in the internal control and monitoring procedures for project reports and related cost claims, adversely affecting the efficiency of project implementation.

This Report was adopted by Chamber IV, headed by Mr Baudilio TOMÉ MUGURUZA, Member of the Court of Auditors, in Luxembourg at its meeting of 19 September 2017.

For the Court of Auditors

Klaus-Heiner LEHNE

President

¹⁰ IMI Joint Undertaking 2016 annual activity report, p. 102.

Follow-up of previous years' comments

Year	The ECA's comment	Status of corrective action (Completed / Ongoing / Outstanding)
2014	<p>Key controls and supervisory systems</p> <p>The performance of operational ex-ante controls on the payment of project costs was insufficiently documented in the following critical areas:</p> <ul style="list-style-type: none"> (a) the ex-ante control form used by the IMI Scientific Project Officers (SPOs) focused on administrative compliance rather than on operational compliance as it did not clearly identify and comment upon the status of the project (ongoing, ongoing subject to deficiencies, suspended/cancelled) and its deliverables (no reservations, reservations requiring clarification, major reservations); (b) payment was made without an official listing of deliverables accepted by the SPO and without any reference to the assessment of deliverables by the SPO. 	Completed
2015	<p>Conflicts of interest</p> <p>In July 2015, the Commission issued guidelines to the Joint Undertakings related to rules on conflicts of interest, including a common template for the declaration of absence of a conflict of interest, which should be incorporated by the Joint Undertaking into its procedures.</p>	Completed

THE JU'S REPLY

29. The relatively low level of operational payments is linked to delays of the successful consortium members in concluding consortium agreements which are required for signing H2020 grant agreements with the IMI2 Joint Undertaking.

Moreover, projects in Ebola and Antimicrobial resistance programmes have claimed less funds than foreseen in the initial project budgets, which was mainly due to the decline of the epidemic.

31. At this stage of programme implementation, it is important to know that commitments of 275,8 million euro of EU funds and 249,1 million euro of industry in-kind contributions are allocated to 25 Horizon 2020 projects. While the EU contributions are transferred on an annual basis to cover the advance payments and costs claimed by the project beneficiaries, costs incurred by industry are reported as in-kind contributions in line with the established project reporting timelines, which start at the earliest 12 months after the signature of a grant agreement.

33. The IMI2 Joint Undertaking is dedicated to completing the transition to the common Horizon 2020 management tools by the end of 2017, including the migration of project data from the first eight IMI2 Calls which were temporarily hosted in the local SOFIA system.

34. The IMI2 Joint Undertaking has experienced some delays in receiving the periodic reports of the beneficiaries as set in the relevant grant agreement. Often the first versions of the periodic reports sent by the beneficiaries were incomplete as they lacked some of the required supporting documents. Those delays affected the effectiveness of the first part of the payment control process (report submission, receipt of the report, completeness check). In 2016, the average time to pay for interim cost claims was 95 days, while the target was 90 days.