Basic information

2012/2219(DEC) DEC - Discharge procedure	Procedure completed
2011 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines **Subject** 8.70.03.07 Previous discharges	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	GERBRANDY Gerben-Jan (ALDE)	29/02/2012
	Shadow rapporteur RÜBIG Paul (PPE) AYALA SENDER Inés (S&D) STAES Bart (Verts/ALE) BRADBOURN Philip (ECR) SØNDERGAARD Søren Bo (GUE/NGL) ANDREASEN Marta (EFD) EHRENHAUSER Martin (NI)	

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	

European Commission

Commission DG	Commissioner
Budget	ŠEMETA Algirdas

Key events

Date	Event	Reference	Summary
25/07/2012	Non-legislative basic document published	COM(2012)0436	Summary
13/09/2012	Committee referral announced in Parliament		
19/03/2013	Vote in committee		
21/03/2013	Committee report tabled for plenary	A7-0088/2013	Summary
16/04/2013	Debate in Parliament		
17/04/2013	Decision by Parliament	T7-0169/2013	Summary
17/04/2013	Results of vote in Parliament		
17/04/2013	End of procedure in Parliament		
16/11/2013	Final act published in Official Journal		

Technical information

Procedure reference	2012/2219(DEC)
Procedure type	DEC - Discharge procedure
Stage reached in procedure	Procedure completed
Committee dossier	CONT/7/10581

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE497.955	29/01/2013	
Amendments tabled in committee		PE506.006	27/02/2013	
Committee report tabled for plenary, single reading		A7-0088/2013	21/03/2013	Summary
Text adopted by Parliament, single reading		T7-0169/2013	17/04/2013	Summary

Council of the EU

Document type	Reference	Date	Summary
Document attached to the procedure	05755/2013	01/02/2013	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2012)0436	25/07/2012	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
CofA	Court of Auditors: opinion, report	N7-0040/2013 OJ C 006 10.01.2013, p. 0027	13/11/2012	Summary

Additional information		
Source	**Document**	**Date**
European Commission	EUR-Lex	

Final act	
Decision 2013/0622 OJ L 308 16.11.2013, p. 0357	Summary

2011 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

2012/2219(DEC) - 13/11/2012 - Court of Auditors: opinion, report

PURPOSE: presentation of the EU Court of Auditors' report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2011, together with the Joint Undertaking's replies.

CONTENT: in accordance with the tasks conferred on the Court of Auditors by the Treaty on the Functioning of the European Union, the Court presents to the European Parliament and to the Council, in the context of the discharge procedure, a Statement of Assurance as to the reliability of the annual accounts of each institution, body or agency of the EU, and the legality and regularity of the transactions underlying them, on the basis of an independent external audit.

This audit concerned, amongst others, the annual accounts of the Innovative Medicines Initiative (IMI) Joint Undertaking.

In the Court's opinion, the IMI Joint Undertaking's Annual Accounts 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 Regulation.

The Court also considers that the **transactions underlying the annual accounts** of the IMI Joint Undertaking for the financial year ended 31 December 2011 are, in all material respects, **partially legal and regular and gives a qualified opinion.** As of September 2012 covered EUR 2.2 million (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%.**

The report confirms that the IMI Joint Undertaking's budget for 2011 amounted to EUR 285 379 570 million in commitment appropriations and 88 898 250 million in payment appropriations. Staff totalled 31 at the end of 2011.

Court's comments:

- calls for proposals: the calls for proposals organised in 2008, 2009 and 2010 resulted in signed grant agreements amounting to EUR 269 million at the end of 2011. In 2011 the fourth call for proposals was launched with an indicative budgeted EU contribution of EUR 105 million. In 2012 the fifth call for proposals was launched with an indicative budgeted EU contribution of EUR 80 million. Consequently, if calls for proposals remain at the current level, it is highly likely that the total available EU contribution will not be used;
- budgetary and financial management: the Governing Board Decision of 28 January 2011 only authorises the carry-over of EUR 115 million of commitment appropriations, while the report on budgetary and financial management discloses a carry-over of EUR 117 million;
- accounting system: the Accounting Officer reported on the validation of the accounting system on 27 September 2012 and underlined significant weaknesses which need to be addressed;
- internal audit: 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. 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.

Joint Undertaking's replies:

- **qualified opinion**: 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.** 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, none the less, 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;
- calls for proposals: the IMI JU states that 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;
- as regards internal controls, 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.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.

Lastly, the Court of Auditors' report contains a summary of the Joint Undertaking's activities in 2011. The main task of the IMI Joint Undertaking was to launch new calls for proposals, evaluation, negotiation, grant management, 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.

2011 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

2012/2219(DEC) - 01/02/2013

Having examined the revenue and expenditure accounts for the financial year 2011 and the balance sheet at 31 December 2011 of the Innovative Medicines Initiative Joint Undertaking, and the report by the Court of Auditors on the annual accounts of the Joint Undertaking for the financial year 2011, accompanied by the Joint Undertaking's replies to the Court's observations, the Council recommends the European Parliament to give a discharge to the Executive Director of the Joint Undertaking in respect of the implementation of the budget for the financial year 2011.

The observations in the Court of Auditors' report in relation to the financial year 2011 call for some comments by the Council, which may be summarised as follows:

- the Council welcomes the Court's opinion that, in all material respects, the Joint Undertaking's annual accounts present fairly its financial position as at 31 December 2011 and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of the Joint Undertaking's Financial Rules, and that the underlying transactions for that financial year are legal and regular, with the exception of the matter described below;
- however, **it regrets the Court's qualified opinion on the legality and regularity of the transactions underlying the accounts**, due to the high error rate resulting from the ex-post audits carried out for the first time, on the basis of a risk-based and not representative sample selected by external auditors. The Council urges the Joint Undertaking to take the **necessary corrective action to recover the amounts unduly paid**;
- the Council calls on the Joint Undertaking to pay due attention to the proper implementation of commitment and payment appropriations in the course of the budgetary year, in line with the budgetary principle of annuality, thus **avoiding excessive carry-overs**. It invites the Joint Undertaking, in cooperation with the Commission, to adapt, if necessary, its financial programming to real needs with the intention of limiting the risk of over-budgeting;
- moreover, the Council asks the Joint Undertaking to: (i) remedy the inconsistencies identified by the Court between decisions of its Governing Board and the Joint Undertaking's report on budgetary and financial management; (ii) establish functioning and validated budgeting, accounting and internal control systems; (iii) include the provision of the framework Financial Regulation for bodies set up under the TFEU having a legal personality and receiving contributions charged to the EU budget, referring to the powers of the Commission's internal auditor.

2011 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

2012/2219(DEC) - 21/03/2013 - Committee report tabled for plenary, single reading

The Committee on Budgetary Control adopted the report by Gerben-Jan GERBRANDY (ADLE, NL) on discharge to be granted to the Executive Director of the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines in respect of the implementation of the budget of the Joint Undertaking for the financial year 2011.

Noting that the Court of Auditors stated that it has obtained reasonable assurances that the annual accounts of the Joint Undertaking for the financial year 2011 are reliable but has **delivered a qualified opinion on the legality and the regularity of the transactions underlying the Joint Undertaking's accounts**, Members approve the closure of the Joint Undertaking's accounts. However, they make a number of recommendations that need to be taken into account when the discharge is granted, in addition to the general recommendations that appear in the draft resolution on performance, financial management and control of EU agencies:

- **Financing, budget and financial management**: the maximum contribution for the period of 10 years from the Union to the Joint Undertaking is EUR 1 billion to be paid from the budget of the Seventh Research Framework Programme. Members note that the budget of the Joint Undertaking for the financial year 2011 and the implementation plan were adopted by the Governing Board very late and that this delayed the launch of the call for proposals and, for the entire first quarter of the year, the Joint Undertaking was obliged to use provisional twelfths budget rule to make payments;

- **Implementation rate of appropriations and carryovers:** Members reiterate their concern about the low implementation rate of the commitment appropriations available for research activities and express, once again, their concern about the low implementation rate of the Joint Undertaking's budget. They call for a detailed progress report on those shortcomings.
- **Qualified opinion of the Court of Auditors:** Members are concerned that the Joint Undertaking annual accounts received a qualified opinion from the Court of Auditors on the legality and the regularity of the transactions underlying those accounts on the grounds that the error rate resulting from the *ex-post* audits was 6.84%. They await the agreement between the Court and the Joint Undertaking on an audit methodology that for the same *ex-post* audits delivers the same results.

Lastly, Members made a series of observations as regards the Joint Undertaking's procurement system, its control system and its internal audit system, the weaknesses in its annual activity report and other questions linked to the management of this Joint Undertaking. They reiterate their invitation for the Court of Auditors to provide, within a reasonable deadline, a special report to Parliament on common issues due to the nature of the joint undertakings in order to **ensure their added value** and efficient execution of Union research, technological development and demonstration programmes. They call for that report should include **an assessment of the effectiveness of the joint undertakings' establishment and structure**.

2011 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

2012/2219(DEC) - 17/04/2013 - Text adopted by Parliament, single reading

The European Parliament adopted a decision on discharge to be granted to the Executive Director of the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines (IMI) for the financial year 2011. The vote on the decision to grant discharge covers the closure of the accounts (in accordance with Annex VI, Article 5(1) of the European Parliament's Rules of Procedure).

Noting that the Court of Auditors stated that it has obtained reasonable assurances that the annual accounts of the Joint Undertaking for the financial year 2011 are reliable but that it had delivered **a qualified opinion on the legality and the regularity of the transactions underlying the Undertaking's accounts,** Parliament approved the closure of the accounts. It, however, adopted a series of recommendations that need to be taken into account when the discharge is granted, in addition to the general recommendations that appear in the draft resolution on performance, financial management and control of EU agencies.

- **Financing, budget and financial management:** the maximum contribution for the period of 10 years from the Union to the Joint Undertaking is EUR 1 billion to be paid from the budget of the Seventh Research Framework Programme. Parliament notes that the budget of the Joint Undertaking for the financial year 2011 and the implementation plan were adopted by the Governing Board very late and that this delayed the launch of the call for proposals and, for the entire first quarter of the year, the Joint Undertaking was obliged to use provisional twelfths budget rule to make payments;
- **Implementation rate of appropriations and carryovers:** Parliament reiterates its concern about the low implementation rate of the commitment appropriations available for research activities and express, once again, their concern about the low implementation rate of the Joint Undertaking's budget. It calls for a detailed progress report on those shortcomings.
- **Qualified opinion of the Court of Auditors:** Parliament is concerned that the Joint Undertaking annual accounts received a qualified opinion from the Court of Auditors on the legality and the regularity of the transactions underlying those accounts on the grounds that the error rate resulting from the *ex-post* audits was 6.84%. It awaits the agreement between the Court and the Joint Undertaking on an audit methodology that for the same *ex-post* audits delivers the same results.
- **EFPIA:** Parliament is surprised to learn that 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 the financial statements of the Joint Undertaking and are estimated at EUR 1 000 million over the lifetime of the Joint Undertaking.

Lastly, Parliament also makes a series of observations as regards the Joint Undertaking's procedures for calls for proposals, its internal control systems, its annual activity report, as well as other management matters.

Parliament invites the Court of Auditors to provide, within a reasonable deadline, a special report to Parliament on common issues which occur due to the nature of the joint undertakings in order to ensure their **added value and efficient execution of Union research, technological development and demonstration programmes.** It further notes that the same report should include **an assessment of the effectiveness of the joint undertakings' establishment and structure**.

2011 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

2012/2219(DEC) - 17/04/2013 - Final act

PURPOSE: to grant discharge to the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines for the financial year 2011.

NON-LEGISLATIVE ACT: Decision 2013/622/EU of the European Parliament on discharge in respect of the implementation of the budget of the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines for the financial year 2011.

CONTENT: with the present decision, and in accordance with Article 319 of the Treaty on the Functioning of the European Union (TFEU), the European Parliament grants discharge to the Executive Director of the IMI Joint Undertaking in respect of its budget for the financial year 2011.

This decision is in line with the European Parliament's resolution adopted on 17 April 2013 and comprises a series of observations that form an integral part of the discharge decision (please refer to the summary of the opinion of 17 April 2013).

A parallel decision, 2013/623/EU, adopted on the same day, approves the closure of the Undertaking’s accounts for the 2011 financial year.

2011 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

2012/2219(DEC) - 25/07/2012 - Non-legislative basic document

PURPOSE: presentation by the Commission of the consolidated annual accounts of the European Union for the financial year 2011, as part of the 2011 discharge procedure.

Analysis of the accounts of the **Innovative Medicines Initiative Joint Undertaking (IMI).**

CONTENT: this Commission document sets out the consolidated annual accounts of the European Union for the financial year 2011 as prepared on the basis of the information presented by the institutions, organisations and bodies of the EU, in accordance with Article 129 (2) of the Financial Regulation applicable to the EU's General Budget, including the Innovative Medicines Initiative Joint Undertaking (IMI).

In 2011, the tasks and budget of this agency were as follows:

- **description of the tasks of the Joint Undertaking:** the IMI Joint undertaking, which is located in Brussels, was set up in 2007 by Council Regulation (EC) No 73/2008 for a period of 10 years. Its main task is to improve significantly the efficiency, effectiveness and safety of the drug development process;
- **budget of the Joint Undertaking for the 2011 financial year:** the maximum EU contribution to the IMI Joint Undertaking to cover running costs and research activities is EUR 1 billion to be paid from the budget of the Seventh Research Framework Programme.

The complete version of the Agency's final accounts for 2011 may be found at the following address: http://www.imi.europa.eu/content/budget-0