



# Procedure file

Basic information		
DEC - Discharge procedure	<a href="#">2011/2241(DEC)</a>	Procedure completed
2010 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
	<b>CONT</b> Budgetary Control		03/03/2011
		PPE <a href="#">MACOVEI Monica</a>	
		Shadow rapporteur	
		S&D <a href="#">HERCZOG Edit</a>	
		ALDE <a href="#">GERBRANDY Gerben-Jan</a>	
		Verts/ALE <a href="#">STAES Bart</a>	
		ECR <a href="#">CZARNECKI Ryszard</a>	
		EFD <a href="#">ANDREASEN Marta</a>	
		NI <a href="#">EHRENHAUSER Martin</a>	
	Committee for opinion	Rapporteur for opinion	Appointed
	<b>ITRE</b> Industry, Research and Energy	The committee decided not to give an opinion.	
European Commission	Commission DG	Commissioner	
	<a href="#">Budget</a>	ŠEMETA Algirdas	

Key events			
25/07/2011	Non-legislative basic document published	<a href="#">COM(2011)0473</a>	Summary
12/10/2011	Committee referral announced in Parliament		
27/03/2012	Vote in committee		
04/04/2012	Committee report tabled for plenary	<a href="#">A7-0108/2012</a>	Summary
10/05/2012	Results of vote in Parliament		
10/05/2012	Debate in Parliament		
10/05/2012	Decision by Parliament	<a href="#">T7-0193/2012</a>	Summary
10/05/2012	End of procedure in Parliament		
17/10/2012	Final act published in Official Journal		

Technical information

Procedure reference	2011/2241(DEC)
Procedure type	DEC - Discharge procedure
Other legal basis	Rules of Procedure EP 159
Stage reached in procedure	Procedure completed
Committee dossier	CONT/7/07279

### Documentation gateway

Non-legislative basic document	<a href="#">COM(2011)0473</a>	26/07/2011	EC	Summary
Court of Auditors: opinion, report	<a href="#">N7-0031/2012</a> <a href="#">OJ C 368 16.12.2011, p. 0017</a>	25/10/2011	CofA	Summary
Committee draft report	<a href="#">PE474.055</a>	06/02/2012	EP	
Document attached to the procedure	<a href="#">06086/2012</a>	08/02/2012	CSL	Summary
Amendments tabled in committee	<a href="#">PE483.673</a>	07/03/2012	EP	
Committee report tabled for plenary, single reading	<a href="#">A7-0108/2012</a>	04/04/2012	EP	Summary
Text adopted by Parliament, single reading	<a href="#">T7-0193/2012</a>	10/05/2012	EP	Summary

### Final act

[Decision 2012/612](#)  
[OJ L 286 17.10.2012, p. 0334](#) Summary

## 2010 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

**PURPOSE:** presentation by the Commission of the consolidated annual accounts of the European Union for the financial year 2010, as part of the 2010 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 2010 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 2010, 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 and effectiveness of the drug development process;
- budget of the Joint Undertaking for the 2010 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. In 2010, the EU's contribution amounted to EUR 107 million in commitment appropriations and EUR 29 million in payment appropriations.

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

## 2010 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

**PURPOSE:** presentation of the EU Court of Auditors report on the annual accounts of the Innovative Medicines Initiative Joint Undertaking for the financial year 2010, together with the Joint Undertakings 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 Courts opinion, the IMI Joint Undertakings Annual Accounts fairly present, in all material respects, its financial position as of 31 December 2010 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 2010 are, in all material respects, legal and regular.

The report confirms that 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 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 activities. The research companies which are members of EFPIA are to contribute to the funding of research activities through in-kind contributions at least equal to the EU financial contribution.

The report also makes a series of observations on the budgetary and financial management of the Joint Undertaking, accompanied by the latter's response. The main observations may be summarised as follows:

The Courts observations:

- implementation of the budget: the final budget included commitment appropriations of EUR 107 million and payment appropriations of EUR 29 million. Additionally, EUR 3 million in commitment appropriations and EUR 78.6 million in payment appropriations were carried over from 2009. The utilisation rates for available commitment and payment appropriations were 6 % and 35 % respectively, EUR 98.6 million in commitment appropriations were carried over to 2011 and EUR 64 million of payment appropriations carried over from 2009 were cancelled at the end of the year;
- internal control systems: the Joint Undertaking has not fully implemented its internal controls and financial information systems during 2010. Furthermore, at the end of 2010 the underlying business processes had not yet been formalised and had not been validated by the Accounting Officer as required by the Joint Undertaking's financial rules. The methodology for evaluating contributions in-kind has not yet been approved by the Governing Board as it proved difficult for an agreement to be reached. Consequently, the EFPIA members were unable to report on the costs incurred during the first reporting period as established in the grant agreements;
- lack of host agreement: according to the Council Regulation setting up the Joint Undertaking, a host agreement should be concluded between the Joint Undertaking and Belgium concerning office accommodation, privileges and immunities and other support to be provided by Belgium. However, as at the end of 2010, no such agreement had been signed.

The Joint Undertakings response:

- implementation of the budget: IMI Joint Undertaking has taken several initiatives to facilitate and expedite the implementation of the budget, including the revision of the Scientific Research Agenda, the launch of the third and fourth calls for proposals, the conclusion of negotiations and the signature of grant agreements for new projects funded under the second call, as well as the receipt and payment of cost claims from the beneficiaries participating in projects funded under the first call. In collaboration with the Founding Members, the Executive Office is also exploring ways of how it can simplify and streamline its call management processes and shorten time lines;
- internal control systems: IMI Joint Undertakings internal control system is being further consolidated through the systematic review, strengthening and formalisation of internal processes, including IT policies and procedures. In parallel, the creation of a new senior management position responsible for Administration and Finance as well as the establishment of the internal control and the internal audit functions further enhances the overall management and oversight of IMI Joint Undertakings implementation of the internal control framework;
- host state: there are ongoing proceedings with the Belgian authorities for the signature of the Host Agreement. It is expected to be signed by the end of 2011.

Lastly, the Court of Auditors report contains a summary of the Joint Undertakings activities in 2010. 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.

## 2010 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

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The Committee on Budgetary Control adopted the report by Monica Luisa MACOVEI (EPP, RO) on discharge in respect of the implementation of the budget of the Innovative Medicines Initiative Joint Undertaking and called on the European Parliament to grant the Executive Director of the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines discharge in respect of the implementation of the Joint Undertaking's budget for the financial year 2010.

Noting that the Court of Auditors stated that it has obtained reasonable assurances that the annual accounts for the financial year 2010 are reliable and that the underlying transactions are legal and regular, Members approve the closure of the Joint Undertakings accounts. However, they make a number of recommendations that need to be taken into account when the discharge is granted.

- Budget and Financial Management: Members note with concern that the budget of the Joint Undertaking for the financial year 2010 and the implementation plan were adopted by the Governing Board only on 16 March 2010 and therefore, for almost the entire first quarter of the year, the Joint Undertaking was obliged to use provisional twelfths budget rule to make payments. They regret that the members of the Joint Undertaking could not establish and agree in due time the scientific priorities to be included in the annual implementation plan which delayed the launch of the 2010 annual call for proposals. Members are also concerned about the low

implementation rate of the budget and, moreover, about the underlying activities of the Joint Undertaking. They call on the Joint Undertaking and its members to take appropriate actions to ensure a timely definition of the scientific priorities and call topics and to enable the budget to be balanced in future financial years;

- Evaluation of contributions in kind: Members recall that the Joint Undertaking was set up in December 2007 and started to work autonomously in November 2009. They express grave concern that the methodology for evaluating contributions in-kind to be defined in the Joint Undertakings internal rules and procedures in compliance with its financial rules has not yet been approved by the Governing Board and therefore the European Federation of Pharmaceutical Industries and Associations (EFPIA) members of the Joint Undertaking were unable to report on the costs incurred during the first reporting period as established in the grant agreements. Even though ongoing consultations are underway, the Joint Undertaking is urged to update the discharge authority about this matter;
- Procurement Procedures: Members find the Joint Undertakings' initiative to issue joint procurement procedures interesting and believe that it would enable the Joint Undertakings to realise economies of scale and to save taxpayers' money. They encourage the Joint Undertakings, therefore, to resort as often as possible to joint procurement procedures;
- Call for Proposals and Projects Negotiations: Members note that, in the framework of the second call for proposals, independent experts participated in the evaluation panels except for final assessment and without voting rights and that in addition the Executive Office of the Joint Undertaking invited independent observers to the two-stage evaluation process. They call on the Joint Undertaking to inform the discharge authority about the verification mechanisms that it implements to ensure the full independence of experts and observers and therefore to mitigate the risks of conflict of interests during the evaluation of tenders;
- Internal control systems: Members urge the Joint Undertaking to complete its internal controls and financial information systems and to formalise and validate the underlying business processes in due time as required by the financial rules. They state that given its size and mission, the formalisation of policies and procedures in strategic IT planning and monitoring cycle, IT Risk management and Business Continuity Plan and Disaster Recovery Plan is lagging behind. This situation should be remedied;
- Internal Audit: Members note that the Commission and the Joint Undertaking have taken action to ensure that the respective operational roles of the Commissions Internal Audit Service (IAS) and the Joint Undertakings internal auditing function are clearly defined;
- Performance: Members note that the Commission commissioned an interim review which focused on the quality, efficiency and contribution of the Joint Undertaking towards the achievement of set objectives. The review identified certain weaknesses to which the Joint Undertaking should rapidly respond;
- Lack of host State agreement: Members reiterate that the Joint Undertaking should rapidly conclude a host agreement with Belgium concerning office accommodation, privileges and immunities and other support to be provided by Belgium to it.

Horizontal observations on the Joint Undertakings: Members underline that seven Joint Undertakings have so far been established by the European Commission under Article 187 of the Treaty on the Functioning of the European Union, and notes that the total Union contribution deemed necessary for the Joint Undertakings for their period of existence amounts to EUR 11.5 billion (for the financial year 2010 alone, the overall Union contribution amounted to EUR 505 million). Members call on the Commission to provide the discharge authority annually with consolidated information on the total annual funding per Joint Undertaking made from the general budget of the Union in order to ensure transparency and clarity on the use of the Union's funds and restore trust among the European taxpayers. They recall that Joint Undertakings are public-private partnerships and that as a consequence public and private interests are intertwined. The committee is of the opinion that under the circumstances the likelihood of conflicts of interest should not be dismissed but addressed properly. It calls therefore on the Joint Undertakings to inform the discharge authority on the verification mechanisms which exist in their respective structures to enable a proper management and prevention of conflicts of interest.

Lastly, the Court of auditors is asked to provide, within a reasonable deadline, a special report to Parliament, on the added value of the establishment of the Joint Undertakings.

## 2010 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

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**PURPOSE:** to grant discharge to the Initiative on Innovative Medicines (IMI) Joint Undertaking in respect of the implementation of its budget for the financial year 2010.

**NON-LEGISLATIVE ACT:** Decision 2012/612/EU of the European Parliament on discharge in respect of the implementation of the budget of the IMI Joint Undertaking for the financial year 2010.

**CONTENT:** with the present decision, and in accordance with Article 319 of the Treaty on the Functioning of the European Union, the European Parliament grants discharge to the Executive Director of the IMI Joint Undertaking in respect of the implementation of its budget for the financial year 2010.

This decision is in line with the European Parliament's resolution adopted on 10 May 2012 and comprises a series of observations that form an integral part of the discharge decision (please refer to the summary of the opinion of 10/05/2012).

A parallel decision, 2012/613/EU, adopted on the same day, approves the closure of this Joint Undertaking's accounts for the 2010 financial year.

## 2010 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

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The European Parliament adopted a decision to grant discharge to the Executive Director of the Innovative Medicines Initiative Joint Undertaking in respect of the implementation of the Joint Undertaking's budget for the financial year 2010. This decision also approves the closure of the Agency's accounts.

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 2010 are reliable and that the underlying transactions are legal and regular, Parliament adopted a resolution containing 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.

These recommendations may be summarised as follows:

- **Budget and Financial Management:** Parliament is concerned about the low implementation rate of the budget and, moreover, about the underlying activities of the Joint Undertaking. It underlines that the cash balance at year-end stood at EUR 70 731 612,03 representing 65 % of the available payment appropriations in 2010. It notes with concern that the budget of the Joint Undertaking for the financial year 2010 and the implementation plan were adopted by the Governing Board only on 16 March 2010 and therefore, for almost the entire first quarter of the year, the Joint Undertaking was obliged to use provisional twelfths budget rule to make payments. Members regret that the members of the Joint Undertaking could not establish and agree in due time the scientific priorities to be included in the annual implementation plan which delayed the launch of the 2010 annual call for proposals. They are also concerned about the low implementation rate of the budget and, moreover, about the underlying activities of the Joint Undertaking. They call on the Joint Undertaking and its members to take appropriate actions to ensure a timely definition of the scientific priorities and call topics and to enable the budget to be balanced in future financial years;
- **Evaluation of contributions in kind:** Parliament recalls that the Joint Undertaking was set up in December 2007 and started to work autonomously in November 2009. It expresses grave concern that the methodology for evaluating contributions in-kind to be defined in the Joint Undertakings internal rules and procedures in compliance with its financial rules has not yet been approved by the Governing Board and therefore the European Federation of Pharmaceutical Industries and Associations (EFPIA) members of the Joint Undertaking were unable to report on the costs incurred during the first reporting period as established in the grant agreements. Even though ongoing consultations are underway, the Joint Undertaking is urged to update the discharge authority about this matter;
- **Procurement Procedures:** Members find the Joint Undertakings' initiative to issue joint procurement procedures interesting and believe that it would enable the Joint Undertakings to realise economies of scale and to save taxpayers' money. They encourage the Joint Undertakings, therefore, to resort as often as possible to joint procurement procedures;
- **Call for Proposals and Projects Negotiations:** Parliament notes that, in the framework of the second call for proposals, independent experts participated in the evaluation panels except for final assessment and without voting rights and that in addition the Executive Office of the Joint Undertaking invited independent observers to the two-stage evaluation process. It calls on the Joint Undertaking to inform the discharge authority about the verification mechanisms that it implements to ensure the full independence of experts and observers and therefore to mitigate the risks of conflict of interests during the evaluation of tenders;
- **Internal control systems:** Parliament urges the Joint Undertaking to complete its internal controls and financial information systems and to formalise and validate the underlying business processes in due time as required by the financial rules. It states that given its size and mission, the formalisation of policies and procedures in strategic IT planning and monitoring cycle, IT Risk management and Business Continuity Plan and Disaster Recovery Plan is lagging behind. This situation should be remedied;
- **Internal Audit:** Parliament notes that the Commission and the Joint Undertaking have taken action to ensure that the respective operational roles of the Commissions Internal Audit Service (IAS) and the Joint Undertakings internal auditing function are clearly defined;
- **Performance:** it notes that the Commission commissioned an interim review which focused on the quality, efficiency and contribution of the Joint Undertaking towards the achievement of set objectives. The review identified certain weaknesses to which the Joint Undertaking should rapidly respond;
- **Lack of host State agreement:** Members reiterate that the Joint Undertaking should rapidly conclude a host agreement with Belgium concerning office accommodation, privileges and immunities and other support to be provided by Belgium to it.

Horizontal observations on the Joint Undertakings: Members underline that seven Joint Undertakings have so far been established by the European Commission under Article 187 of the Treaty on the Functioning of the European Union and that the total Union contribution deemed necessary for the Joint Undertakings for their period of existence amounts to EUR 11.5 billion (for the financial year 2010 alone, the overall Union contribution amounted to EUR 505 million). They note that six Joint Undertakings (IMI, ARTEMIS, ENIAC, CLEAN SKY, FCH and ITER-F4E) are in the research area under the Commissions DGs RTD and INFSO and one is charged with developing the new air traffic management system (SESAR) in the transport domain whose activities are supervised by DG MOVE.

In this context, Parliament calls on the Commission to provide the discharge authority annually with consolidated information on the total annual funding per Joint Undertaking made from the general budget of the Union in order to ensure transparency and clarity on the use of the Union's funds and restore trust among the European taxpayers. It recalls that Joint Undertakings are public-private partnerships and that as a consequence public and private interests are intertwined. Members consider that the likelihood of conflicts of interest should not be dismissed but addressed properly. They call therefore on the Joint Undertakings to inform the discharge authority on the verification mechanisms which exist in their respective structures to enable a proper management and prevention of conflicts of interest.

Parliament notes, with the notable exception of the Joint Undertaking for ITER and the Development of Fusion Energy, that Joint Undertakings are relatively small structures and geographically-concentrated and that they should pool their resources where possible.

Lastly, the Court of Auditors is invited to provide, within a reasonable deadline, a special report to Parliament, on the added value of the establishment of the Joint Undertakings.