### Procedure file

Basic information		
DEC - Discharge procedure	2013/2251(DEC)	Procedure completed
2012 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines		
Subject 8.70.03.07 Previous discharges		

Key players			
uropean Parliament	Committee responsible	Rapporteur	Appointed
	CONT Budgetary Control		10/10/2013
		PPE RÜBIG Paul	
		Shadow rapporteur	
		S&D STAVRAKAKIS Georgios	3
		ALDE GERBRANDY Gerben-Jan	
		Verts/ALE STAES Bart	
		ECR ANDREASEN Marta	
		EFD VANHECKE Frank	
		NI EHRENHAUSER Martin	
	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			
26/07/2013	Non-legislative basic document published	COM(2013)0570	
22/10/2013	Committee referral announced in Parliament		
18/03/2014	Vote in committee		
20/03/2014	Committee report tabled for plenary	A7-0200/2014	Summary
02/04/2014	Debate in Parliament	-	
03/04/2014	Results of vote in Parliament	<u> </u>	

03/04/2014	Decision by Parliament	<u>T7-0335/2014</u>	Summary
03/04/2014	End of procedure in Parliament		
05/09/2014	Final act published in Official Journal		

Technical information		
Procedure reference	2013/2251(DEC)	
Procedure type	DEC - Discharge procedure	
Other legal basis	Rules of Procedure EP 159	
Stage reached in procedure	Procedure completed	
Committee dossier	CONT/7/14238	

Documentation gateway				
Non-legislative basic document	COM(2013)0570	26/07/2013	EC	
Court of Auditors: opinion, report	N7-0008/2014 OJ C 369 17.12.2013, p. 0025	22/10/2013	CofA	Summary
Committee draft report	PE521.710	28/01/2014	EP	
Document attached to the procedure	05851/2014	05/02/2014	CSL	Summary
Amendments tabled in committee	PE528.209	26/02/2014	EP	
Committee report tabled for plenary, single reading	A7-0200/2014	20/03/2014	EP	Summary
Text adopted by Parliament, single reading	T7-0335/2014	03/04/2014	EP	Summary

### Final act

Budget 2014/629

OJ L 266 05.09.2014, p. 0335 Summary

# 2012 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 2012, as part of the 2012 discharge procedure.

Analysis of the accounts of the Joint Technology Initiative on Innovative Medicines(IMI).

CONTENT: this Commission document sets out the consolidated annual accounts of the European Union for the financial year 2012 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 IMI Joint Undertaking.

In 2012, the tasks and budget of the Joint Undertaking 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 of the drug development, so that in the long-term, the pharmaceutical sector might produce safe and effective innovative medicine;
- budget of the Joint Undertaking for the 2012 financial year: the maximum indicative contribution of the Commission to cover running costs and research activities is EUR 1 billion to be paid from the budget of the Seventh Research Framework Programme. At 31 December 2012, the Commission held 78.58% of the ownership participation in IMI.

Please also consult the final accounts of IMI Joint Undertaking.

2012 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 2012, 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 2012 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 Commissions accounting officer.

The Court also considers that the transactions underlying the annual accounts of the IMI Joint Undertaking for the financial year ended 31 December 2012 are, in all material respects, partially legal and regular and gives a qualified opinion. The basis for this opinion concerns the JUs ex post audit strategy. 56 ex post audits had been completed as of June 2013, covering EUR 4.4 million (37.3% of the accepted IMI JUs contribution for the first call validated by June 2011). The detected error rate resulting from these audits was 5.82%.

The report confirms that the IMI Joint Undertakings budget for 2012 amounted to EUR 373 763 361 million in commitment appropriations and EUR 113 209 163 million in payment appropriations.

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

#### Courts comments:

- implementation of the budget: a high level of payment and commitment appropriations for administrative expenditure in 2012 were still unused at years end (26.81% of commitment appropriations and 39.8% of payment appropriations);
- internal audit procedure: in 2012, the Commissions Internal Audit Service carried out an assurance review of IMIs negotiation, grant agreement preparation and pre-financing processes. The IAS concluded that the existing internal controls provided reasonable assurance as to whether, with the exception of specific issues related to the management of conflicts of interests, documentation of the negotiation process and the related controls, and an IT application used during the negotiation process, the business objectives had been achieved. The Joint Undertakings action plan to address the IAS recommendations was validated by the IAS on 29 October 2012.

#### Joint Undertakings replies:

- qualified opinion: the JU states that the Courts qualified opinion reflects the outcome of 56 audits covering 65 first call cost claims that
  were accepted in 2010 and 2011 when IMI JU was still in its start-up phase. For the IMI, the vast majority of financial errors were
  relatively small in amounts to be adjusted (less than EUR 5 000 in favour of IMI JU) and clearly arose from misunderstandings of the
  rules or a lack of attention to the detail of the provisions of the grant agreements.
- The estimated error rate does not reflect the outcome of audits of interim payments made to beneficiaries in 2012 for which a new representative sample of 40 ex post audits is being conducted in 2013 and the first preliminary results are expected at the end of the year. These new audits cover a broader population of claims and beneficiaries, including the first claims of the second call projects as well as the second and third reporting periods of first call projects. IMI has since taken a series of concrete preventive and monitoring measures to help reduce the common types of errors and minimise the inherent underlying risks related to grant management;
- the IMI states that it has transformed 11 recommendations proposed by the IAS into concrete actions. During August 2012 and July 2013, the IAS also verified and closed 10 of the 11 recommendations.

As regards the activities of the Joint Undertaking in 2012, the report refers to the Annual Activity Report 2012 which can be found at <a href="https://www.imi.europa.eu">www.imi.europa.eu</a>.

On an operation level, the Courts report states that in 2012, the Joint Undertaking launched four calls for proposals and signed 11 grant agreements. During this period, it committed EUR 351 million, or almost 37% of its total available budget for research activities. At the end of 2012, the cumulative total of approved commitments for research costs was EUR 736 million.

## 2012 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

The Committee on Budgetary Control adopted the report by Paul RÜBIG (EPP, AT) on discharge in respect of the implementation of the budget of the Innovative Medicines Initiative (IMI) Joint Undertaking for the financial year 2012 and called on the European Parliament to grant the Executive Director of the IMI Joint Undertaking discharge in respect of the implementation of the Office's budget for the financial year 2012.

Noting that the Court of Auditors stated that it has obtained reasonable assurances that the annual accounts of the IMI for the financial year 2012 are reliable and that the underlying transactions are legal and regular, Members made 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 <u>draft resolution on performance</u>, financial management and control of EU agencies:

• Qualified opinion of Court of Auditors: Members were concerned that the error rate resulting from the ex post audits, performed by or on behalf of the Joint Undertaking was 5.82 %. They recognised that most of these errors were relatively small in amounts to be adjusted (less than EUR 5 000 in favour of the Joint Undertaking) and noted that steps had been taken to recover or offset these amounts from subsequent claims. The report pointed out that actions taken by the Joint Undertaking to prevent and correct these

errors had a bearing on the residual error rate. However, Members took note that the Court of Auditors issued a qualified opinion on the legality and the regularity of the transactions on that basis, underlying the annual accounts of the Joint Undertaking for the second consecutive year.

Rate of utilisation and carryovers: Members were concerned that a high level of payment and commitment appropriations for administrative expenditure in 2012 were still unused at year end (26.81 % of commitment appropriations and 39.8 % of payment appropriations). They noted that the high level of unused appropriations of the administrative budget indicated that it was not based on realistic estimates defined through the Legislative Financial Statement.

Members went on to make a series of observations on calls for proposals, internal control systems, internal audits, and horizontal aspects of European Research Joint Undertakings.

JTI: the committee invited the Court of Auditors to comprehensively analyse the Joint Technology Initiatives (JTIs) and the other joint undertakings in a separate report in light of the substantial amounts involved and the risks- notably reputational presented. It noted that the Joint Undertakings total 2012 forecasted budgeted income amounted to some EUR 2.5 billion or about 1.8 % of the 2012 Union general budget while approximately EUR 618 million came from the general budget (cash contribution from the Commission) and approximately EUR 134 million came from the industrial partners and members of the Joint Undertakings.

Members recalled that Parliament had previously requested that the Court of Auditors draw up a special report on the capacity of the joint undertakings, together with their private partners, to ensure added value and efficient execution of Union research, technological development and demonstration programmes.

They agreed with the Court of Auditors conclusion that the JTIs had been set up to support long-term industrial investment in particular research areas, but noted that it had taken on average two years to grant financial autonomy to a JTI, with the Commission usually remaining responsible for one third of the expected operational lifetime of the JTIs.

### 2012 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

PURPOSE: to grant discharge to the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines for the financial year 2012.

NON-LEGISLATIVE ACT: Decision 2014/629/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 2012.

CONTENT: with the present decision, the European Parliament grants discharge to the Executive Director of the IMI Joint Undertaking in respect of its budget for the financial year 2012.

This decision is in line with the European Parliament's resolution adopted on 3 April 2014 and comprises a series of observations that form an integral part of the discharge decision (please refer to the summary of the opinion of 3 April 2014).

Amongst the main observations made, Parliament made a number of cross-cutting comments as regards all the Joint Undertakings (JUs) and invited the Court of Auditors to conduct a detailed analysis of the JUs in a separate report in light of the substantial amounts involved and the risks - notably reputational - presented.

# 2012 discharge: IMI Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

The European Parliament adopted a decision concerning the discharge to be granted to the Executive Director of the IMI Joint Undertaking discharge in respect of the implementation of the Office's budget for the financial year 2012. The vote on the discharge decision approved the closure of the accounts (in accordance with Annex VI, Article 5(1) of the Rules of Procedure of the European Parliament.

Noting that in the Court of Auditors opinion, the Joint Undertakings annual accounts present fairly, in all material respects, its financial position as at 31 December 2012 and the results of its operations and cash flows for the year then ended, Parliament adopted by 485 votes to 62, with 15 abstentions, a resolution containing a series of recommendations that form an integral part of the discharge decision and as well as the general recommendations that appear in the draft resolution on performance, financial management and control of EU agencies.

These recommendations are summarised as follows:

- Qualified opinion of Court of Auditors: Parliament was concerned that the error rate resulting from the ex post audits, performed by or on behalf of the Joint Undertaking was 5.82 %. It recognised that most of these errors were relatively small in amounts to be adjusted (less than EUR 5 000 in favour of the Joint Undertaking) and noted that steps had been taken to recover or offset these amounts from subsequent claims. It pointed out that actions taken by the Joint Undertaking to prevent and correct these errors had a bearing on the residual error rate. However, Parliament took note that the Court of Auditors issued a qualified opinion on the legality and the regularity of the transactions on that basis, underlying the annual accounts of the Joint Undertaking for the second consecutive year.
- Rate of utilisation and carryovers: Parliament was concerned that a high level of payment and commitment appropriations for administrative expenditure in 2012 were still unused at year end (26.81 % of commitment appropriations and 39.8 % of payment appropriations). It noted that the high level of unused appropriations of the administrative budget indicated that it was not based on realistic estimates defined through the Legislative Financial Statement.
- Audit rights of the Court of Auditors: Parliament was surprised to learn that the provisions of the Council Regulation setting up the
  Joint Undertaking do not recognise the right of the Court of Auditors to audit the in-kind contributions of EFPIA (European Federation
  of Pharmaceutical Industries and Associations) companies, although they are recorded in the Joint Undertakings financial statements.

It emphasised that it is estimated that these contributions will represent approximately EUR 1 billion over the Joint Undertaking's lifetime and it invited the Court of Auditors to clarify the implications of that provision in the Court of Auditors annual opinion on the accounts of the Joint Undertaking.

Parliament went on to make a series of observations on calls for proposals, internal control systems, internal audits, and horizontal aspects of European Research Joint Undertakings. It also invited the Court of Auditors to monitor the Joint Undertaking's policies as regards the management and prevention of conflicts of interests by drafting a Special Report on the matter by the next discharge procedure.

JTI: Parliament invited the Court of Auditors to comprehensively analyse the Joint Technology Initiatives (JTIs) and the other joint undertakings in a separate report in light of the substantial amounts involved and the risks- notably reputational presented. It noted that the Joint Undertakings total 2012 forecasted budgeted income amounted to some EUR 2.5 billion or about 1.8 % of the 2012 Union general budget while approximately EUR 618 million came from the general budget (cash contribution from the Commission) and approximately EUR 134 million came from the industrial partners and members of the Joint Undertakings. It also recalled that the total Union contribution deemed necessary for the Joint Undertakings for their period of existence amounts to EUR 11.5 million.

Parliament recalled that it had previously requested that the Court of Auditors draw up a special report on the capacity of the joint undertakings, together with their private partners, to ensure added value and efficient execution of Union research, technological development and demonstration programmes. It agreed with the Court of Auditors conclusion that the JTIs had been set up to support long-term industrial investment in particular research areas, but noted that it had taken on average two years to grant financial autonomy to a JTI, with the Commission usually remaining responsible for one third of the expected operational lifetime of the JTIs.