Procedure file

Basic information

NLE - Non-legislative enactments	2013/0240(NLE)	Procedure completed
Innovative Medicines Initiative 2 Joint Undertaking (IMI2 Joint Undertaking) Repealing Regulation (EC) No 73/2008 2007/0089(CNS) Subject 3.50.01.05 Research specific areas 3.50.20 Scientific and technological cooperation and agreements 4.20.04 Pharmaceutical products and industry		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ITRE Industry, Research and Energy		08/10/2013
		S&D RIERA MADURELL Teresa	
		Shadow rapporteur	
		PPE GROSSETÊTE Françoise	
		ALDE HALL Fiona	
		Verts/ALE RIVASI Michèle	
		ECR FORD Vicky	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	
	BUDG Budgets	The committee decided not to give an opinion.	
	JURI Legal Affairs	The committee decided not to give an opinion.	
	Committee for opinion on the legal basis	Rapporteur for opinion	Appointed
	JURI Legal Affairs		12/12/2013
		PPE VOSS Axel	
Council of the European Union	Council configuration	Meeting	Date
	General Affairs	3306	18/03/2014
	Competitiveness (Internal Market, Industry, Research and Space)	3276	03/12/2013
	Competitiveness (Internal Market, Industry, Research and Space)	3258	26/09/2013
European Commission	Commission DG	Commissioner	
	Research and Innovation	GEOGHEGAN-QUINN Máire	

Key events

10/07/2013	Legislative proposal published	COM(2013)0495	Summary
10/09/2013	Committee referral announced in Parliament		
26/09/2013	Debate in Council	3258	

23/01/2014	Vote in committee		
13/02/2014	Committee report tabled for plenary, 1st reading/single reading	A7-0105/2014	Summary
15/04/2014	Results of vote in Parliament		
15/04/2014	Decision by Parliament	T7-0373/2014	Summary
06/05/2014	Act adopted by Council after consultation of Parliament		
06/05/2014	End of procedure in Parliament		
07/06/2014	Final act published in Official Journal		

Technical information

Procedure reference	2013/0240(NLE)
Procedure type	NLE - Non-legislative enactments
Procedure subtype	Consultation of Parliament
	Repealing Regulation (EC) No 73/2008 2007/0089(CNS)
Legal basis	Treaty on the Functioning of the EU TFEU 188 -a1; Treaty on the Functioning of the EU TFEU 187
Other legal basis	Rules of Procedure EP 159
Stage reached in procedure	Procedure completed
Committee dossier	ITRE/7/13392

Documentation gateway

Legislative proposal		COM(2013)0495	10/07/2013	EC	Summary
Document attached to the procedure		SWD(2013)0245	10/07/2013	EC	
Document attached to the procedure		SWD(2013)0246	10/07/2013	EC	
Committee draft report		PE523.015	12/11/2013	EP	
Amendments tabled in committee		PE524.772	06/12/2013	EP	
Specific opinion	JURI	PE526.132	06/01/2014	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0105/2014	13/02/2014	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0373/2014	15/04/2014	EP	Summary
Commission response to text adopted in plenary		SP(2014)471	09/07/2014	EC	
Follow-up document		SWD(2017)0338	06/10/2017	EC	
Follow-up document		SWD(2017)0339	06/10/2017	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2014/557
OJ L 169 07.06.2014, p. 0054 Summary

Innovative Medicines Initiative 2 Joint Undertaking (IMI2 Joint Undertaking)

PURPOSE: to prolong the IMI joint undertaking (JU) in the field of innovative medicines (Innovative Medicines Initiatives 2 J U).

PROPOSED ACT: Council Regulation.

ROLE OF THE EUROPEAN PARLIAMENT: the Council adopts the act after consulting the European Parliament but without being obliged to follow its opinion.

BACKGROUND: the framework programme for research and innovation Horizon 2020 encourages public-private partnerships (PPP) in research and innovation with a view to tackling the major challenges facing Europe, including in the field of public health.

The proposal for a public-private partnership builds on the previous IMI JU established under the 7th Research Framework Programme (FP7) covering the period 2007 2013. IMI JU is a public-private partnership between the European Commission and the biopharmaceutical industry. The IMI JU has (i) mobilised resources by bringing together partners from the pharmaceutical industry, academia, SMEs, patient organisations and regulators in focused projects; (ii) stepped up cooperation between stakeholders in the health research and innovation field by opening access to other partners expertise; (iii) increased the collaboration between the pharmaceutical industry and other stakeholders in Europe; and (iv) fostered the development of comprehensive research agendas, and horizontal policy coordination.

A Joint Undertaking in the area of innovative medicines is needed because: (i) the challenges it will tackle are vital for public health in Europe and for its citizens; (ii) it will help tackle a series of obstacles to effective research and innovation (e.g. expensive and complex development of diagnostics and treatments, decreasing productivity of the drug and vaccine development processes and the lack of economic incentives to develop such interventions); (iii) it will help the life-science industries to set a long-term research and innovation strategic agenda in a pan-European structure to obtain the necessary critical mass and reduce risk at lower costs.

IMPACT ASSESSMENT: the proposal is accompanied by a summary of the impact assessment.

LEGAL BASIS: Articles 187 and 188, first paragraph, of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the proposal seeks to create an Innovative Medicines Initiative 2 Joint Undertaking (IMI2) for a period running from 1 January 2014 to 31 December 2024. The IMI2 JU would replace the previous IMI JU launched under the 7th Framework Programme.

The objectives of the IMI2 JU include:

- improve the success rate in clinical trials in diseases identified in the Priority Medicines for Europe and the World WHO Report;
- reduce the time taken to reach clinical proof of concept in immunological, respiratory, neurological and neurodegenerative diseases;
- develop new therapies for diseases for which there is a high, unmet need (e.g. Alzheimers) or limited market incentives (e.g. antimicrobial resistance);
- develop diagnostic markers for diseases clearly linked to clinical relevance and approved by regulators;
- develop tested novel biomarkers to predict vaccine efficacy and safety early on in the process to improve multiple-candidate screening so as to achieve a reduction in the failure rate in phase III clinical trials.

The Horizon 2020 Rules for Participation and Dissemination would apply. However, given this initiatives specific operational needs, derogations from these Rules are necessary:

(1) one derogation will allow to limit the eligibility for funding to entities such as SMEs, secondary and higher education establishments, non-profit organizations, and companies encountering difficulties to access finance, such as mid-caps or medium-sized companies;

(2) in order to facilitate and speed up the delivery of innovative medicines to patients and to improve the drug research and development in Europe, IMI2 Joint Undertaking requires derogations from the intellectual property rules which concern relevant definitions, ownership, protection, exploitation, dissemination, transfer and licensing of results and access rights.

BUDGETARY IMPLICATION: the Union contribution shall be up to EUR 1.725 billion at current prices, including EFTA contribution. The maximum amount of Union contribution for administrative costs shall be EUR 44.85 million.

Innovative Medicines Initiative 2 Joint Undertaking (IMI2 Joint Undertaking)

The Committee on Industry, Research and Energy adopted the non-legislative report (consultation of Parliament) by Teresa Riera MADURELL (S&D, ES) on the proposal for a Council regulation on the Innovative Medicines Initiative 2 Joint Undertaking.

The committee recommended that Parliament made the following principal amendments to the Commission proposal:

Union contribution: the maximum Union contribution, including contributions from the members of the European Free Trade Association (EFTA), to the IMI2 Joint Undertaking to cover administrative costs and operational costs shall be EUR1 638 750 000 which shall consist of the following:

- up to EUR 1 425 000 000 to be added to the contribution of the European Federation of Pharmaceutical Industries and Associations (EFPIA);

- up to EUR 213 750 000 to be added to additional contributions from other Members Associated Partners

In order to respond to unforeseen situations or to new developments and needs the Commission may, following the interim evaluation of the Horizon 2020 Framework Programme, review the budget of the IMI2 Joint Undertaking within the annual budgetary procedure.

Members added that only the indispensable appropriations needed to cover the administrative costs derived from calls for proposals under Regulation (EC) No 73/2008 on IMI 1 shall be transferred from the unused appropriations under that Regulation to the IMI2 Joint Undertaking.

The committee considered that any IMI1 unused budget other than the indispensable administrative expenditure to wrap up IMI 1should be used to fund FP7 projects, e.g. for supporting projects in reserve list.

Tasks: the IMI2 Joint Undertaking shall carry out the following tasks: (i) leverage private investments and mobilise the public and private sector resources; (ii) ensure participation is as wide as possible; (iii) support pre-competitive research and innovation in health related life sciences including pre-competitive research related to pre-clinical phases of drug development and innovative clinical trials addressing public health needs where incentives for the private sector to invest alone are insufficiently met, as assessed by the IMI scientific committee; (iv) publish information on the projects, including the name of the participants and the amount of the financial contribution of the IMI2 Joint Undertaking per participant.

Alignment with Horizon 2020: the committee inserted several provisions in order to bring a greater alignment of the text with the provisions of Horizon 2020, including:

- higher involvement of SMEs;
- the need to take into consideration results of the reviews of the Horizon 2020 Scientific Panel for Health, including when adopting the annual work programme;
- full compliance with the general principles laid down in Horizon 2020, and in particular the principles on gender equality and open access.
- calls for proposals for collaborative R&D projects should be issued in the field of health research under Horizon 2020 in addition and in parallel to the activities of the IMI2 Joint Undertaking, particularly regarding research at Technology Readiness Levels 1 to 4;

Rules for participation and dissemination: Members specified that derogations provided in Regulation (EU) No 1290/2013 laying down rules for participation in Horizon 2020 should be consistently applied so as to guarantee legal and procedural certainty for all types of participants, allow the widest possible participation, and ensure an equitable and fair treatment of all participants regarding ownership of and access to the results generated within IMI2 projects. Derogations may not have deterrent effects towards participations of universities, non-for profit research organisations or SMEs.

Governance: Members added several amendments in order to strengthen the transparency and accountability of the IMI JU governance structure and decision-making processes in order to reaffirm its legitimacy. IMI 2 must publish information on the projects, including the name of the participants and the amount of the financial contribution of the IMI2 Joint Undertaking per participant.

Indicators: Members added a new clause to the Annex regarding the specific performance indicators related to the functioning of the IMI2 Joint Undertaking.

In addition, they felt that the provisions related to the leverage of private investment should be further enhanced so as to render them more visible. Accordingly, a new R&D intensity indicator for EFPIA companies, co-member of IMI JU, was introduced to the proposal.

Reports and evaluation: by 30 June 2017 the Commission shall organise an independent interim evaluation of the IMI2 Joint Undertaking, which shall take into consideration the general recommendations provided by the Scientific Panel on Health and also compare the interim achievements of IMI 2 against the specific indicators listed in the Annex to the Regulation. The results of this independent interim evaluation should be taken into account in the interim evaluation of the Horizon 2020 Framework Programme.

Innovative Medicines Initiative 2 Joint Undertaking (IMI2 Joint Undertaking)

The European Parliament adopted by 560 votes to 104, with 9 abstentions, a legislative resolution on the proposal for a Council regulation on the Innovative Medicines Initiative 2 Joint Undertaking (IMI2).

Parliament approved the Commission proposal subject to the following amendments:

Joint Undertaking: for the implementation of the Joint Technology Initiative on Innovative Medicines, the IMI2 Joint Undertaking should be established until 31 December 2024. In order to take into account the duration of the Horizon 2020 Framework Programme, calls for proposals under IMI2 should be launched at the latest by 31 December 2020. In duly justified cases calls for proposals may be launched until 31 December 2021.

IMI 2 Joint Undertaking should support the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership or to address specific societal challenges, and in particular to improving European citizens' health and well-being.

Members added that the Joint Undertaking should contribute to the objectives of the Joint Technology Initiative on Innovative Medicines, in particular to, where possible, reduce the time to reach clinical proof of concept in medicine development, such as for cancer.

It is stipulated that the Joint Undertaking should:

- contribute to the closing of the research and innovation divide within the Union by promoting synergies with the European Structural and Investment Funds (ESIF);
- seek to foster the capacity of smaller actors such as research organisations, universities and SMEs for participating in open innovation models and to promote the involvement of small and medium-sized enterprises (SME) in its activities.

Financial contributions: the maximum Union contribution, including EFTA appropriations, to the IMI2 Joint Undertaking to cover administrative

costs and operational costs shall be EUR 1 638 million which should consist of the following:

- up to EUR 1 425 million to match the contribution of EFPIA, or its constituent entities or their affiliated entities;
- up to EUR 213 million to match additional contributions from other Members, Associated Partners, or from their constituent or their affiliated entities.

In-kind contributions consisting of costs incurred in third countries other than countries associated to Horizon 2020 should be justified and relevant and should not exceed 30% at the level of the IMI2 programme of the eligible costs incurred by the Members other than the Union and the Associated Partners.

Openness and transparency: in order to facilitate participation, the calls for proposals launched by the Joint Undertaking should also be published on the single portal for participants as well as through other Horizon 2020 electronic means of dissemination managed by the Commission.

The IMI2 Joint Undertaking should operate in an open and transparent way providing all relevant information in a timely manner to its appropriate bodies as well as promoting its activities, including information and dissemination activities to the wider public.

Discharge: in view of the specific nature and the current status of the Joint Undertakings, and in order to ensure continuity with the 7th Framework Programme, the Joint Undertakings should continue to be subject to a separate discharge.

Simplification: for the purpose of simplification, administrative burdens should be reduced for all parties. Double audits and disproportionate documentation and reporting should be avoided.

Scientific Panel for Health: this Group has been set up by Horizon 2020 as a science-led stakeholder platform in order to elaborate scientific input, provide a coherent scientific focused analysis of research and innovation bottlenecks and opportunities related to the Horizon 2020 societal challenge on health, demographic change and well-being.

Members proposed that the IMI2 Joint Undertaking should, therefore, collaborate and exchange information with it, where appropriate.

Evaluation: by 30 June 2017, the Commission should carry out, with the assistance of independent experts, an interim evaluation of the IMI2 Joint Undertaking, and send a report to the European Parliament and to the Council by 31 December 2017. The results of the interim evaluation of the Joint Undertaking shall be taken into account in the interim evaluation of Horizon 2020.

Innovative Medicines Initiative 2 Joint Undertaking (IMI2 Joint Undertaking)

PURPOSE: to establish a new Joint Undertaking, IMI2, in order to strengthen industrial research and innovation across the Union.

NON-LEGISLATIVE ACT: Council Regulation (EU) n° 557/2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking.

CONTENT: the Framework Programme for Research and Innovation, Horizon 2020, supports public-private partnerships in research and innovation in order that the Union might tackle certain key challenges.

This Regulation aims to establish a new Joint Undertaking (JU) for the implementation of the Joint Technology Initiative on Innovative Medicines, for a period up to 31 December 2024.

The IMI2 Joint Undertaking replaces the IMI JU, set up under the Seventh Framework Programme.

IMI JU has demonstrated the effective mobilisation of resources by bringing together several partners from the pharmaceutical industry, academia, small and medium-sized enterprises (SMEs), patient organisations and regulators. It has also stepped up cooperation between stakeholders in the health research and innovation field.

The IMI2 JU is a body entrusted with the implementation of a public-private partnership. Its seat will be located in Brussels, Belgium.

In order to take into account the duration of Horizon 2020, calls for proposals under the ECSEL Joint Undertaking must be launched at the latest by 31 December 2020 (in duly justified cases, by 31 December 2021). Calls for proposals will be published on the single portal for participants as well as through other Horizon 2020 electronic means of dissemination managed by the Commission.

The rules for participation and dissemination of the Horizon 2020 programme will apply to the JU.

Objectives of the JU: this involves supporting, in accordance with Horizon 2020, the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Unions competitiveness and industrial leadership or to address specific societal challenges and in particular the challenge to improve European citizens health and well-being. The JU also aims to:

- increase the success rate in clinical trials of priority medicines identified by the World Health Organisation;
- where possible, reduce the time to reach clinical proof of concept in medicine development, such as for cancer, immunological, respiratory, neurological and neurodegenerative diseases;
- develop new therapies for diseases for which there is a high unmet need, such as Alzheimers disease and limited market incentives, such as antimicrobial resistance;
- develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators;
- reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks;
- improve the current drug development process.

IMI 2 should seek to develop close interactions with the European Structural and Investment Funds (ESIF).

Funding: the Union financial contribution to the JU shall come from Horizon 2020 and be up to 1 638 000 000 and shall consist of up to EUR 1 425 000 000 to match the contribution of European Federation of Pharmaceutical Industries and Associations (EFPIA). EFPIA shall make contributions of at least EUR 1 425 000 000. Other Members other than the Union and Associated Partners shall make the contributions

corresponding to the amounts they have committed when becoming a Member or an Associated Partner.

The Commission may terminate, proportionally reduce or suspend the Unions financial contribution to the JU or trigger the winding-up procedure if members other than the Union, including their constituent entities and affiliated entities, do not provide contributions.

The Regulation contains provisions that aim to ensure the protection of the financial interests of the Members.

The discharge for the implementation of the budget of the JU shall be given by the European Parliament, upon recommendation of the Council in accordance with the procedure provided for in the financial rules of the IMI 2 JU.

Evaluation: by 30 June 2017 the Commission shall carry out, with the assistance of independent experts, an interim evaluation of the JU. It shall send that report to the European Parliament and to the Council by 31 December 2017. The results of the interim evaluation shall be taken into account in the interim evaluation of Horizon 2020.

IMI2s mandate will end on 31 December 2024 and the JU will be wound up.

ENTRY INTO FORCE: 27.06.2014.