Basic information

2007/0089(CNS) CNS - Consultation procedure Regulation	Procedure completed
Establishment of the Innovative Medicines Initiative Joint Undertaking Repealed by 2013/0240(NLE) **Subject** 3.50.20 Scientific and technological cooperation and agreements 4.20.04 Pharmaceutical products and industry	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	GROSSETÊTE Françoise (PPE-DE)	25/06/2007

Committee for opinion	Rapporteur for opinion	Appointed
BUDG Budgets	HAUG Jutta (PSE)	20/09/2004
CONT Budgetary Control	The committee decided not to give an opinion.	04/06/2007
ENVI Environment, Climate and Food Safety	ROTH-BEHRENDT Dagmar (PSE)	19/09/2007
JURI Legal Affairs	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meetings	Date
Competitiveness (Internal Market, Industry, Research and Space)	2832	2007-11-22
Competitiveness (Internal Market, Industry, Research and Space)	2820	2007-09-28
Competitiveness (Internal Market, Industry, Research and Space)	2801	2007-05-21
Environment	2842	2007-12-20

European Commission

Commission DG	Commissioner
Research and Innovation	POTONIK Janez

Key events

Date	Event	Reference	Summary
15/05/2007	Legislative proposal published	COM(2007)0241	Summary
21/05/2007	Debate in Council		
19/06/2007	Committee referral announced in Parliament		
28/09/2007	Debate in Council		Summary
12/11/2007	Vote in committee		Summary
22/11/2007	Debate in Council		Summary
28/11/2007	Committee report tabled for plenary, 1st reading/single reading	A6-0479/2007	
11/12/2007	Decision by Parliament	T6-0590/2007	Summary
11/12/2007	Results of vote in Parliament		
20/12/2007	Act adopted by Council after consultation of Parliament		
20/12/2007	End of procedure in Parliament		
04/02/2008	Final act published in Official Journal		

Technical information

Procedure reference	2007/0089(CNS)
Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealed by 2013/0240(NLE)
Legal basis	EC Treaty (after Amsterdam) EC 172 EC Treaty (after Amsterdam) EC 171
Stage reached in procedure	Procedure completed
Committee dossier	ITRE/6/49941

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE393.972	11/09/2007	
Amendments tabled in committee		PE394.109	28/09/2007	
Committee opinion	ENVI	PE393.954	10/10/2007	
Amendments tabled in committee		PE396.465	12/10/2007	
Amendments tabled in committee		PE396.561	17/10/2007	
Committee opinion	BUDG	PE394.056	13/11/2007	
Committee report tabled for plenary, 1st reading/single reading		A6-0479/2007	28/11/2007	
Text adopted by Parliament, 1st reading/single reading		T6-0590/2007	11/12/2007	Summary

European Commission

Document type	Reference	Date	Summary
Document attached to the procedure	SEC(2007)0569	15/05/2007	
Legislative proposal	COM(2007)0241	15/05/2007	Summary
Document attached to the procedure	SEC(2007)0568	15/05/2007	
Commission response to text adopted in plenary	SP(2008)0411	23/01/2008	
Follow-up document	COM(2011)0557	14/09/2011	
Follow-up document	SEC(2011)1044	14/09/2011	
Follow-up document	SEC(2011)1072	21/09/2011	Summary
Follow-up document	SWD(2012)0105	27/04/2012	
Follow-up document	COM(2012)0190	27/04/2012	Summary
Follow-up document	SWD(2012)0430	14/12/2012	
Follow-up document	COM(2012)0758	14/12/2012	Summary
Follow-up document	COM(2013)0935	06/01/2014	Summary
Follow-up document	SWD(2013)0539	06/01/2014	
Follow-up document	COM(2014)0252	08/05/2014	Summary

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	PT_PARLIAMENT	COM(2012)0190	26/07/2012	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
ESC	Economic and Social Committee: opinion, report	CES1441/2007	24/10/2007	

Additional information

Source	Document	Date
National parliaments	IPEX	

European Commission	EUR-Lex	

Final act	
Regulation 2008/0073 OJ L 030 04.02.2008, p. 0038	Summary

Establishment of the Innovative Medicines Initiative Joint Undertaking

2007/0089(CNS) - 22/11/2007

The Council agreed on a "general approach" (substantial elements of the legal acts) on four proposals aimed at establishing joint technology initiatives (JTIs) in the following fields:

- Innovative medicines ("IMI")
- Embedded computing systems ("ARTEMIS
- Nanoelectronic technologies ("ENIAC")
- Aeronautics and air transport ("CLEAN SKY")

The agreement on the general approach paves the way for adopting the final Decisions as soon as possible after receiving the European Parliament's opinions, in order to enable a swift start to the four JTIs in early 2008.

According to the agreement reached today, the JTIs would have the following common features:

- The JTIs should be set up under Community law as Community bodies. They should receive Community funding in order to implement the research programmes, notably by awarding funding to selected projects, following publication of calls for proposals.
- They will take the form of real public / private partnerships with a shared responsibility of industry in the management of the joint undertakings. EU Member States and the Commission will exercise appropriate supervision over the use of public funds.
- They will have a limited duration of 10 years.
- JTIs will not have the status of international organisations.
- JTIs will have legal personality and will be established on the basis of Articles 171 and 172 of the EC Treaty.
- They will implement the research programmes by combining public and private funding.
- The Community will contribute to both the research activities and the running costs.

Establishment of the Innovative Medicines Initiative Joint Undertaking

2007/0089(CNS) - 15/05/2007 - Legislative proposal

PURPOSE: to set up a Joint Undertaking: “The Innovative Medicines Initiative”.

PROPOSED ACT: Council Regulation.

CONTENT: the 7th Framework Programme2007-2013 sets up four Specific Programmes: Co-operation, Ideas, People and Capacities. This proposal relates directly to the Specific Programme Co-operation and one of its core themes: health.

Joint Technology Initiatives (JTIs) were introduced for the first time under the Co-operation programme as a way of realising **public-private partnership** for large-scale research projects being developed at a European level. JTIs are born out of the “European Technology Platforms”, (ETPs), which already existed under the previous, 6th Framework Programme. In a small number of cases, ETPs have achieved such an ambitious scale and scope that they now require the mobilisation of greater public and private investments as well as substantial research resources.

JTIs are being proposed in the form of Joint Undertakings that have a legal structure. They are being proposed in a limited number of sectors only, including: hydrogen and fuel cells, aeronautics and air transport, embedded computing systems, nanoelectronics and global monitoring for environment and security.

The pharmaceutical industry is a research-intensive sector and contributes significantly to European innovation. The industry provides Europe with high-skill jobs and high-value products. However, where once Europe led the world in drug development, it now lags behind its global competitors in terms of both public and private research. The IMI JTI intends to improve this situation with a unique collaboration between the public sector (the Community) and the pharmaceutical industry (the EFPIA). The European Federation of Pharmaceutical Industries and Associations (EFPIA) has been instrumental in pushing for, and realising, the IMI Joint Undertaking.

The purpose of this proposal, is the implementation of a Joint Technology Initiative through the establishment of a Joint Undertaking entitled “The Innovative Medicine Initiative” or IMI JU. It will be based in Brussels and exist for a period ending on 31 December 2017. The financial impact on the EU budget will cease after 2013. Its main objective is to contribute towards the implementation of the 7th Framework Programme under the Specific Programme Co-operation: sub-heading “Health”. The IMI JU will be considered a Community body founded by the European Community and the European Federation of Pharmaceutical Industries and Associations, EFPIA.

The proposed funding for the IMI JU is EUR 2 billion. The maximum contribution from the European Community will be EUR 1 billion paid from the budget appropriation allocated to the Specific Programme Co-operation, theme “Heath”.

In particular, the IMI JU will seek:

- to support “pre-competitive” pharmaceutical research and development in the Member States and countries associated to the 7th Framework Programme via a co-ordinated approach in order to overcome the research bottlenecks that have been identified;

- to support the implementation of the research priorities as set out by the Research Agenda of the Joint Technology Initiative, by awarding grants following competitive calls for proposals;

- to be a public-private partnership aiming to increase the research investment in the biopharmaceutical sector by pooling resources and fostering collaboration between the public and private sectors;

- to conclude service and supply contracts needed to operate the IMI Joint Undertaking.

In short, the IMI JU will seek to foster collaboration between all stakeholders such as industry, public authorities (including regulators), patient organisations, academia, SME’s and clinical centres. In order to meet these objectives a common “Research Agenda” will be defined by the IMI JTI.

In setting up the IMI JU it is hoped that the following can be achieved:

- improved safety and efficacy for new drugs in the early development phases – before the costly clinical trials begin;

- reduced multiplication of research efforts – both in the private and public sector through the development of joint knowledge management systems; and

- improved professional training in order to ensure a more skilled workforce in the pharmaceutical sector.

The new collaborative partnership will provide for a legal and operational framework designed to be a win-win situation for all those involved: pharmaceutical companies who want to have access to new methods and results; SME’s who want to have their new techniques tested by users (i.e. pharmaceutical companies); universities who want their research results validated and recognised; clinicians who want to have rapid access to results and data; and patients who want more efficient medicines with less side effects. This proposal seeks to ensure the maximum utilisation of research results and data as well as a rapid uptake into industrial, clinical and regulatory practice.

In other measures the proposed Regulation states that:

- the Commission and EFPIA will share responsibility equally for costs and implementation;

- the IMI JU will consists of a Board, an Executive Office and a Scientific Committee. Member State Groups and a Stakeholder forum will also form part of the IMI JU;

- research activities will be conducted through collaborative projects organised between public and private organisations that will be selected through open calls for proposals and a peer review process;

- all participating “for-profit” organisations that are not considered SME’s will be expected to carry the costs of participation in the research activities and will not receive any financial support from the IMI JU; and

- grant agreements will govern the relationship between the selected consortia and the IMI JU.

On a final point, the proposed Regulation is consistent with the renewed Lisbon strategy and the objectives of the EU to invest 3% of its GDP in research and development by 2010, with two-thirds coming from the private sector.

Establishment of the Innovative Medicines Initiative Joint Undertaking

2007/0089(CNS) - 28/09/2007

The Council held an exchange of views on four proposals aimed at establishing joint technology initiatives (JTIs) in the following fields:

- innovative medicines ("**IMI**")
- aeronautics and air transport ("CLEAN SKY") (CNS/2007/0118)
- nano-electronics technologies ("ENIAC") (CNS/2007/0122)
- embedded computing systems ("ARTEMIS") (CNS/2007/0088)

The ministerial debate concentrated in horizontal issues with a view to adopting final decisions at the November Competitiveness Council meeting in order to enable a swift start to the four JTIs in 2008.

The Council underlined a number of important political elements which resulted from the

discussion:

- The JTIs should be set up under Community law as Community bodies. They should receive Community funding in order to implement the research programmes, notably by awarding funding to selected projects, following publication of calls for proposals.
- They will take the form of real public/private partnerships with a shared responsibility of industry in the management of the joint undertakings. EU member states and the Commission will exercise appropriate supervision over the use of public funds.
- They will have a limited duration of 10 years.
- They will not have the status of international organisations.
- They will have legal personality and will be established on the basis of articles 171 and 172 of the EC treaty.
- They will implement the research programmes by combining public and private funding.
- The Community will contribute to both the research activities and the running costs.
- The Council also tasked the preparatory bodies to continue further technical work based on the political guidelines agreed by the Council.

The IMI initiative will include: development of tools and methods to better predict the suitability, safety and efficacy of drugs, intelligent infrastructures for data integration and knowledge management through close cooperation between industry, academia and clinical centres. It will also address education and training gaps to ensure that Europe has the skills to translate research results into benefits for the patient.

The maximum of the Community contribution is estimated at EUR 1 billion (up to 2017).

Establishment of the Innovative Medicines Initiative Joint Undertaking

2007/0089(CNS) - 20/12/2007 - Final act

PURPOSE : to set up a Joint Undertaking: "The Innovative Medicines Initiative".

LEGISLATIVE ACT : Council Regulation (EC) No 73/2008.

CONTENT : this Regulation sets up a Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines for a period up to 31 December 2017. The JTI aims at increasing investments in the biopharmaceutical sector in Europe in the Members States and countries associated within the Seventh Framework Programme. It will provide socioeconomic benefits for European citizens, contribute to the health of European citizens, increase the competitiveness of Europe and help to establish Europe as the most attractive place for biopharmaceutical research and development. The JTI on Innovative Medicines will deliver new approaches and technologies, improve knowledge management of research results and data, and support the training of professionals. To this end, the IMI JU is set up. The latter will be a Community body and have legal personality. In terms of liability, the IMI Joint Undertaking will be solely responsible for meeting its obligations.

Objectives: the IMI Joint Undertaking will contribute to the implementation of the Seventh Framework Programme and in particular the Theme 'Health' of the Specific Programme Cooperation implementing the Seventh Framework Programme. It has the objective of significantly improving the effectiveness of the drug development process with the long-term aim that the pharmaceutical sector produces more effective and safer innovative medicines. In particular it shall:

(a) support 'pre-competitive pharmaceutical research and development' in the Member States and countries associated with the Seventh Framework Programme via a coordinated approach to overcome the identified research bottlenecks in the drug development process;

(b) support the implementation of the research priorities as set out by the Research Agenda of the Joint Technology Initiative on Innovative Medicines ('Research Activities'), notably by awarding grants following competitive calls for proposals;

(c) ensure complementarity with other activities of the 7th Framework Programme;

(d) be a public-private partnership aiming at increasing the research investment in the biopharmaceutical sector in the Members States and countries associated to the Seventh Framework Programme by pooling resources and fostering collaboration between the public and private sectors;

(e) promote the involvement of SMEs in its activities.

Tasks and activities: the main tasks are as follows:

(a) to ensure the establishment and sustainable management of the Joint Technology Initiative on 'Innovative Medicines';

(b) to define and carry out the annual implementation plan via calls for project;

(c) to regularly review and make any necessary adjustments to the Research Agenda of the JTI on Innovative Medicines in light of scientific developments;

(d) to mobilise the public and private sector resources needed;

(e) to establish long-term cooperation between the Community, industry and the other stakeholders such as regulatory bodies, patients organisations, academia and clinical centres, as well as cooperation between industry and academia;

(f) to facilitate coordination with national and international activities in this area;

(g) to undertake communication and dissemination activities;

(h) to communicate and interact with the Member States and the countries associated within the Seventh Framework Programme via a group specifically established for this purpose (IMI States Representatives Group);

(i) to organise at least an annual meeting (a Stakeholder Forum) with interest groups to ensure openness and transparency of the Research Activities of the IMI Joint Undertaking with its stakeholders;

(j) to notify legal entities that have concluded a grant agreement with the IMI Joint Undertaking of the potential borrowing opportunities from the European Investment Bank, in particular the Risk Sharing Finance Facility set up under the Seventh Framework Programme;

(k) to publish information on the projects, including the name of the participants and the amount of the financial contribution of the IMI Joint Undertaking per participant;

(l) to ensure the efficiency of the JTI on 'Innovative Medicines';

(m) to carry out any other activity needed to achieve the objectives.

Founding members are the Community and EFPIA. The latter is a non-profit organisation representing the research based pharmaceutical industry in Europe.

Community contribution: the maximum Community contribution to the IMI Joint Undertaking covering running costs and Research Activities will be EUR 1 000 million. It will be paid from the appropriation in the general budget of the EU allocated to the 'Health' theme of the Specific Programme Cooperation implementing the Seventh Framework Programme.

Seat: the seat will be located in Brussels, Belgium.

Bodies: these will be the Governing Board, the Executive Director, and the Scientific Committee. The JU will be supported by two external advisory bodies: the IMI States Representatives Group and Stakeholder Forum.

Report, evaluation and discharge: the Commission will present an annual report on the progress achieved by the IMI Joint Undertaking. By 31 December 2010, as well as by 31 December 2013, it will carry out interim evaluations with the assistance of independent experts, and carry out a final evaluation not later than six months after the end of the JU with the assistance of independent experts. Discharge for the implementation of the budget of the IMI JU will be given by the European Parliament, upon recommendation of the Council.

ENTRY INTO FORCE: 07/02/2008.

Establishment of the Innovative Medicines Initiative Joint Undertaking

2007/0089(CNS) - 11/12/2007 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Françoise **GROSSETÊTE** (EPP-ED, FR), and made some amendments to the proposal for a regulation setting up the Innovative Medicines Initiative Joint Undertaking (IMI JU).

The main amendments were as follows:

The creation of the Joint Undertaking: the Joint Undertaking is set up for a period ending on 31 December 2013. Work in progress may nonetheless continue until 31 December 2017. The IMI Joint Undertaking is a body as referred to in Article 185 of the Financial Regulation and Point 47 of the IIA of 17 May 2006.

Objectives: the Joint Undertaking must focus, above all, on the research to be carried out exclusively in the Member States and the countries associated with the Seventh Research Framework Programme. MEPs specified that the running costs of the Joint Undertaking shall not exceed 4% of the total budget.

SMEs: in pursuit of the objectives of the Specific Programme Cooperation, the IMI Joint Undertaking should make provision for boosting SME participation, inter alia by improving administrative procedures, taking their requirements more fully into account and deploying support measures.

Financial Regulation: the financial rules applicable to the IMI Joint Undertaking should not depart from Commission Regulation (EC, Euratom) No. 2343/2002 on the framework Financial Regulations for the Community bodies, unless their specific operating needs so require. The budgetary authority shall be informed of such derogations.

External auditor: the IMI Joint Undertaking shall appoint an external auditor in order to verify the fairness and accuracy of the annual accounts drawn up by the Joint Undertaking. The external auditor shall be responsible for ensuring satisfactory scrutiny of the annual accounts and the evaluation of the contributions made by the members and by the participants in the research projects. The IMI Joint Undertaking may make use of ad hoc external audits. The European Parliament shall be entitled to scrutinise the annual accounts of the IMI Joint Undertaking.

Personnel: the IMI Joint Undertaking shall recruit its staff in accordance with applicable regulations of the host country. The Commission may second to the IMI Joint Undertaking as many officials as may be needed. Parliament deleted references to the Staff Regulations of Officials of the European Communities being applicable to the IMI Joint Undertaking.

Report: no later than 31 December 2011, the Commission shall present to the European Parliament and to the Council an interim evaluation of the IMI Joint Undertaking. By 31 December 2013 or, if work in progress continues beyond that date, by 31 December 2017, the Commission shall conduct a final evaluation of the IMI Joint Undertaking.

Members also introduced the following amendments in the **annexes**:

- information on projects must be available on the Internet;

- the bodies of the IMI JU shall be the Board, the Executive Director and the Scientific Committee (it is inconsistent to create an Executive Office);

- the total number of votes held by new Members may not exceed the total number of votes held by the Founding Members;

- there should be no provision for proxy voting;

- three Members of the European Parliament shall attend meetings as observers and shall be invited by the Board. The European Parliament shall be consulted on any important changes to the JU's statutes;

- the evaluation of proposals shall establish whether the funds requested are commensurate with the work involved in carrying out the project;

- the Executive Director shall present the annual activity report to the European Parliament;

- Parliament deleted a clause stating that the members of the staff of the IMI Joint Undertaking shall be temporary agents and contract agents and shall have fixed term contracts extendable once up to a maximum total period of seven years;

- annual scientific and financial reports on the projects supported shall be submitted to the IMI Joint Undertaking by the participants. Such reports shall give details of the research activities carried out and the costs of such activities. Statements of expenditure shall be accompanied by an audit certificate. The external auditor shall examine the audit certificates and determine whether the in kind contributions match the contributions from public funds to the project;

- the European Parliament must be consulted on amendments to the Statutes;

- project participants should establish any cases of co-ownership of intellectual property arising from projects;

- lastly, a host agreement shall be concluded between the IMI Joint Undertaking and Belgium.

Establishment of the Innovative Medicines Initiative Joint Undertaking

2007/0089(CNS) - 21/09/2011

Joint Technology Initiatives (JTIs) were introduced by the Seventh Framework Programme. On the basis of Article 187 of the Treaty on the Functioning of the European Union, five JTIs have been set up under 7th Framework Programme (FP7):

Innovative Medicines initiatives (**IMI**);

Advanced Research and Technology for Embedded Intelligence and Systems (ARTEMIS);

Aeronautics and Air Transport (Clean Sky);

European Nanoelectronics Initiative Advisory Council (ENIAC);

Fuel Cells and Hydrogen (FCH).

In line with the request to the Commission under the various Council Regulations setting up the Joint Undertakings to implement the Joint Technology Initiatives, independent interim evaluations of the operation of the Joint Undertakings have recently been carried out. The Commission response to the interim evaluations of the ARTEMIS and ENIAC Joint Undertakings has already been presented.

This Staff Working Document presents the detailed Commission response to the interim evaluations of the IMI, Clean Sky and Fuel Cells and Hydrogen Joint Undertakings.

Establishment of the Innovative Medicines Initiative Joint Undertaking

2007/0089(CNS) - 14/12/2012

The Joint Technology Initiatives are public-private partnerships in industrial research at European level. They were set up as pilots in 2007-2008 under the Seventh Framework Programme in five strategic areas: aeronautics and air transport (the Clean Sky initiative), **public health (the Innovative Medicines Initiative (IMI))**, fuel cell and hydrogen technologies (the Fuel Cells and Hydrogen (FCH) initiative), embedded computing systems (the ARTEMIS initiative) and nanoelectronics (the ENIAC initiative). The SESAR (Single European Sky Air Traffic Management Research) programme should also be mentioned since it is funded under the Seventh Framework Programme.

An annual report on the progress achieved by the Joint Technology Initiatives Joint Undertakings ('JTI JUs') is required by Article 11(1) of the Council Regulations setting up the individual JTIs. This report contains details of implementation including number of proposals submitted, number of proposals selected for funding, type of participants, including SMEs, and country statistics. This **2011 annual report** follows the **first interim evaluations of the Joint Undertakings** carried out under Article 11(2) of the Council Regulations.

The European Commission, as a co-founding member, was responsible for starting up the JTI JUs. Once they had built up their legal and financial framework and demonstrated their capacity to manage their own budgets, ARTEMIS, IMI and Clean Sky were given autonomy in late 2009, followed by ENIAC in May and FCH in late 2010. Thus, 2011 was the first full year in which all the JTI JUs operated autonomously.

The first interim evaluation was performed on time and assessed their quality and efficiency and the progress achieved towards their objectives. All the reports concluded with a **favourable opinion**: the evaluation panels agreed that the **JUs should continue beyond 2013**. The evaluation panels supported the Sherpa Group's recommendations, in particular that **the current legal framework be streamlined to fit the purposes of setting up and implementing future JTIs**. In this respect, the current 'Community body' status of JTIs should be reviewed. They recommended **reinforcing and streamlining processes and decision-making**.

They also referred to the need (i) for more structured coordination and complementarity with FP7 and national programmes and funds; (ii) for improved communication, to enhance the visibility of JTI actions aimed at the general public and at international level; and (iii) for systematic data collection and a monitoring system for key performance indicators.

Progress achieved by the IMI JU: for the period 2008–2013, the Innovative Medicines Initiative (IMI) JU was allocated a total budget of EUR 2 billion. The European Commission contributes maximum EUR 1 billion from its Seventh Framework Programme budget, to be matched by in-kind contributions (consisting mostly of research activities) worth at least another EUR 1 billion from member companies of the European Federation of Pharmaceutical Industries and Associations (EFPIA). This makes the IMI Europe's largest public-private partnership overall, as well as the largest pharmaceutical-related PPP.

The IMI's main objectives are: (i) to build a more collaborative environment for pharmaceutical R&D in Europe; (ii) to speed up the development of more effective and safer medicines for patients and (iii) to increase the competitiveness of the EU pharmaceutical sector. The main challenges are: (i) industrial: insufficient R&D investment; (ii) scientific: technological complexity; and (iii) European: research is fragmented in Europe. Industrial partners are heavily involved in IMI; in particular, EFPIA companies participate much more in IMI projects than in FP7 Health Projects. Another feature of IMI is the two-stage process for calls for proposals: applicants send Expressions of Interest (EoIs) in stage one; then, in stage two, the best ranked participants and the EFPIA consortium are invited to form a full project consortium and draft a Full Project Proposal (FPP). In 2011, IMI completed the evaluation of call 3 and published a fourth call for proposals.

Calls 3 and 4 attracted wide interest and a high number of applicants: 1377. But because of the restricted number of topics, only 20 % (266) of the initial applicants were finally included in the projects selected for funding together with industry participants - about 50 teams from EFPIA companies joined the consortia. The total number of participants in the calls in 2011 is 316, resulting in an average success rate of 23 %.

The participants' typology of IMI is very specific. Industry is well represented (by EFPIA companies and SMEs) and there is also very high participation from universities. At the first stage, a good number of EoIs were submitted by SMEs, followed by other participants and patients' organisations. But academia accounted for most of the participants in the projects eventually funded (208) followed by the EFPIA (53) and SMEs (47), with the latter representing 17.7 % of total participation. SMEs received 13.56 % of the EU funding over the period from 2008 to 2011.

Regarding the geographical distribution of the applicants, in Call 3, participants in the winning projects (123, excluding EFPIA companies) came from 19 countries, mostly the United Kingdom, Germany, the Netherlands, France and Sweden. The Czech Republic and Hungary were the only EU-12

countries (recent EU members) represented, with a single participant each. Switzerland led the 'associated' countries, with six participants, followed by Israel and Iceland. As for international participation, the US had three participants (as many as Spain). For Call 4, IMI recorded 143 participations in the proposals selected for funding, but the geographical distribution is still unknown.

In 2011 the main research objectives evolved to reflect the latest progress in their fields of technology. The revision of the IMI's strategic research agenda will change the types of projects funded: calls will focus on **large-scale and game-changing projects**.

Establishment of the Innovative Medicines Initiative Joint Undertaking

2007/0089(CNS) - 06/01/2014

The Commission presented its annual progress report on the activities of the Joint Technology Initiative Joint Undertakings (JTI JUs) in 2012.

The Joint Technology Initiatives are public-private partnerships in industrial research at European level that are now well established and have reached cruising speed. They were set up in 2007-2008 under the Seventh Framework Programme in **five strategic areas**: (1) Aeronautics and Air Transport (Clean Sky); (2) **Public health** - Innovative Medicines Initiative (**IMI**) JU; (3) Fuel Cells and Hydrogen (FCH) JU; (4) Embedded Computing Systems (ARTEMIS) JU; (5) Nanoelectronics (ENIAC) JU.

Participation and geographical coverage: JUs are successful in funding highly specific, industry-driven research and that **stakeholders are getting more acquainted with the modus operandi of these new instruments**. Participation in terms of numbers of projects selected for funding remained stable in the last two years while the **overall success rate increased from 35.8 % in 2011 to 45 % in 2012**. Concerning industrial participation in 2012, large companies represented 31.1% of total participations and SMEs another 30%. **SMEs participation increased from 28% to 30%** in the last two years (2011 and 2012).

In terms of distribution of participation from Member States and Associated Countries, in 2012 as in the previous year the five JTI JUs involved, on average, **20 different countries** in the implementation of their research agendas.

First results and promising advances: the Innovative Medicines Initiative (**IMI)** is supporting a project, currently in patenting stage, which successfully developed a device and protocol related to the possibility to quickly diagnose (less than half an hour) what kind of infection and what treatment is needed for patients. The focus of this project has been put on the European Lead Factory and the antimicrobial resistance programme New Drugs for Bad Bugs.

Success stories are as follows:

- **the EUROPAIN project** has made important findings that contribute to a better understanding of the mechanisms of chronic pain;
- **the SUMMIT project** is developing methods to identify risk factors for chronic complications in diabetes patients, that lead to strokes or problems with the heart,
- kidneys or eyes, impose an immense burden on the patients' quality of life and account for more than 10% of health-care costs in Europe;
- **the MARCAR project** has developed and proved the effectiveness of methods that help identify chemical changes in the genetic material (chromosomes) that are related to cancer (non-genotoxic carcinogenesis).

Challenges and perspectives: for the future, a number of challenges remain open:

- **relatively small size of the JUs** and their relatively high running costs is still a major challenge;
- **maintaining the level of commitment from Industry and Members States**: certain difficulties have arisen in recent years in matching funds from industry and Member States and only in 2012 did the trend reverse;
- **effectively integrating results achieved in research projects into the Commission communication and dissemination system**: the JUs will probably be called upon under Horizon 2020 to adopt tools and working arrangements that will enable all parties involved to constantly assess results and to use them.

To summarise the **experience gained** in the first years of autonomy of all the Joint Undertakings, the following **successful results** can be highlighted:

- **JTIs are continuing at a steady pace** to reach their objectives in research and beyond;
- in terms of management, the JTI JUs have gained **speed**. In 2012, they generally reduced their Time to Grant (TtG), which is now 11.6 months on average;
- the **visibility** of JTI JU activities was also enhanced in 2012, among stakeholders and beyond;
- the JTI JUs' achievements started to be monitored and evaluated against a set of **key performance indicators** (KPIs);
- **SMEs are attracted to the JTI JUs' research topics**, especially because of the stability and continuity of the research and innovation environments, the funding arrangements and the involvement of larger value chains. Overall, SMEs have received about **EUR 170 million**, which accounts for roughly 27% of all EU funding available after evaluation;
- **industry commitment** to the achievement of general objectives remained stable and overall stakeholder participation continues to be well balanced following major updates in 2011;
- the JTI JUs **strategic research and innovation agendas** now include a **more ambitious approach towards innovation**, in line with Horizon 2020;
- lastly, respondents especially highlighted the clear **European added value** of PPPs in specific technological sectors.

Another interesting insight on progress achieved so far will be provided by the second interim evaluation, which will cover the period from setting up until 2013 and will be published as a separate report by November 2013.

Establishment of the Innovative Medicines Initiative Joint Undertaking

2007/0089(CNS) - 08/05/2014

The Commission presents its second interim evaluation of the Clean Sky; Fuel Cells and Hydrogen and **Innovative Medicines Initiative** Joint Technology Initiatives Joint Undertakings.

This report summarises the findings and main recommendations provided by the panels of independent experts (IEGs) who conducted the evaluations.

The overall conclusion is that the **Joint Undertakings have been successful in achieving their objectives**, that they are relevant to the challenges of Horizon 2020 and **they should be continued**. The second interim assessments show that the existing Joint Undertakings have successfully demonstrated the **viability of the Public Private Partnership** (PPP) concept for research in strategic technological areas. They have been effective in delivering on the main objectives and have been able to reinforce Europe's role in aeronautics, pharmaceutics and fuel cell and hydrogen R&D.

More specifically, the report presents the **Commission's observations and recommendations** and highlights the areas in which follow-up actions should be planned.

Implementation of the IMI initiative: according to the IEG, the Innovative Medicines Initiative8 has successfully demonstrated its effectiveness in reinforcing Europe's attractiveness for pharmaceutical R&D, in pooling resources and stimulating stronger engagement and involvement from various stakeholders, and stimulating new technologies and methodologies to accelerate medicines development. In

particular, the evaluation reports on the high quality and scientific excellence of the projects.

As regards **financing**, a maximum **EUR 1 billion** contribution was allocated from the FP7 budget. There have been 10 calls for proposals so far for an overall project portfolio of approximately 40 running projects. The 11th and final call was launched on 11 December 2013.

Commission's observations: the Commission acknowledges the IEG recommendations for further improvements in the organisational structure of the IMI Executive Office to ensure a suitable balance between administrative and scientific staff. Moreover, IMI should identify possible skills or competency gaps in the office with a view to improvements. The Commission supports the recommendation to continue planning and designing **new funding mechanisms** to ensure the sustainability of current and future projects, whenever appropriate and aligned with Horizon 2020 rules.

As regards **governance and participation**, the Commission welcomes the recommendation of encouraging the sharing of good practices. It also Commission has addressed this in its proposal for Innovative Medicines Initiative 2 under Horizon 2020. The IEG also observed that IMI projects could benefit from the participation of medium-sized pharmaceutical companies that are too big to be SMEs but are not EFPIA members.

The Commission takes note that the IEG suggested to **use the possibility to include non-EU in-kind contributions** as part of the total in-kind contribution. The Governing Board has already taken action by requesting that IMI '**scientific ambassadors'** be identified and appointed in each country. The Commission agrees that the **Key Performance Indicators** (KPIs) need further sharpening.

Perspectives: the Commission acknowledges the thorough and in-depth work carried out by the IEGs in undertaking the second interim evaluation of the three Joint Undertakings. It also notes that the IEGs recognised the validity of the PPP approach and expressed positive views about the future prospects for Joint Undertakings under Horizon 2020.

The IEG recommendations are considered valuable for removing or at least reducing the weaknesses identified in the current Joint Undertaking operations. The Commission undertakes to implement corrective measures when appropriate and within its powers of intervention whilst recalling that implementing the recommendations addressed to the next generation of joint undertakings requires the adoption of new Council Regulations.

Since 10 July 2013, when the Commission presented its proposed Regulations, the processes for continuing the JUs are fully underway.

Establishment of the Innovative Medicines Initiative Joint Undertaking

2007/0089(CNS) - 27/04/2012

The Commission presents its annual report on the progress achieved by the Joint Technology Initiatives Joint Undertakings in 2010. These were established as pilots in 2007-2008 under the Seventh Framework Programme in five strategic areas for a limited period up to 31 December 2017:

- Aeronautics and Air Transport (Clean Sky) JU increasing the competitiveness of the European aeronautics industry while reducing emissions and noise, established by Council Regulation (EC) 71/2008;
- **Innovative Medicines Initiative (IMI) JU fostering the development of better and safer medicines for patients, established by Council Regulation (EC) 73/2008;**
- Fuel Cells and Hydrogen (FCH) JU speeding up the development and deployment of hydrogen supply and fuel cell technologies, established by Council Regulation (EC) 521/2008;
- Embedded Computing Systems (ARTEMIS) JU helping the European industry to consolidate and reinforce its world leadership in embedded computing technologies, established by Council Regulation (EC) 74/2008;
- Nanoelectronics Technology 2020 (ENIAC) JU targeting to achieve a very high level of miniaturisation required for the next generation of nanoelectronics components, established by Council Regulation (EC) 72/2008.

ARTEMIS, IMI and Clean Sky gained officially their autonomy in October-November 2009, followed by ENIAC in May and FCH in November 2010. Thus, 2010 was the first full year of autonomous functioning of most of the JTI JUs.

The report starts with a brief introduction of the JTI JUs, summarises their key achievements in 2010 and outlines the fields for improvement in the future.

Key achievements in 2010: after the relatively slow operational start of the JTI JUs, to a certain extent due to the limitations of the existing legal and the regulatory framework for a "Community body", in 2010 the five Joint Undertakings revealed that the new business model between public and private sectors in research promises to be successful. The JTIs' activities that have been launched and already ongoing were recognised to be overall efficient and of a high quality according to the conclusions of first interim evaluations of the Joint Undertakings performed in 2010 (April 2011 for the FCH JU).

Operational activities: in 2010, the five JTI JUs concentrated efforts on the management of their calls for proposals – finalising negotiations, signature of grant agreements and kick-off of the projects coming out from the 2008 and 2009 calls, as well as launch of the 2010 calls, evaluation and selection of the winning proposals and, for some JTIs, start of the negotiation process. The Joint Undertakings worked also on the preparation of the 2011 calls for proposals: based on the lessons learned from the previous calls and consultations with the various stakeholders, they came out with a definition of the next calls' topics.

All JTI JUs were successful in attracting a wide variety of participation in their calls from Europe and FP7-associated countries. Overall, a large number of SMEs took part in the proposals. There were, however, some obstacles which the JTIs had to deal with to further strengthen the SME involvement in their research activities.

Administrative activities: after the initial start-up and preparatory phase before autonomy, the JTI JUs had to then work on their consolidation as a pre-requisite for sustainability and a factor for success. Although the establishment of the five public-private partnerships was a considerable achievement on its own, the Joint Undertakings needed to further develop their internal control frameworks, and introduce, if necessary, additional control mechanisms. This was also pointed out in the reports of the European Court of Auditors which found out that by the **end of 2010 none of the entities had completely implemented their internal controls** and financial information systems and/or had yet validated their underlying business processes as required by the Joint Undertakings' financial rules.

Moreover, implementation of key performance indicators in 2011 by all JTI JUs had to avoid making the output of the initiatives scattered and diffuse. Their task would be not only to assess and periodically monitor quality in order to maximise impact across research programmes, but also to be tracked by a sound monitoring and evaluation system. An important step towards this in 2011 had to be the implementation or adoption, where not done yet, of comprehensive internal audit plans and the performance of regular ex-ante verifications and ex-post audits. Moreover, as expressed by the European Court of Auditors, the JTI JUs had to clearly define the role of the Commission's IAS in their financial rules.

Concerning the IT and logistics matters, all Joint Undertakings needed to further consider the establishment of formal IT policies and procedures to ensure the proper functioning of the IT planning and monitoring cycle and provide for reliable risk management tools. Also, a host agreement had to be concluded with the Belgian authorities concerning the office accommodation, privileges and immunities, and other support provided by the State. Both comments were taken into consideration by the JTI JUs and actions are already underway.

Among the objectives of the Joint Undertakings in 2011 should have been the enhancement of their communication activities using a more proactive and target-oriented approach, especially within SMEs and the research community to increase their level of participation in the research projects. As recommended in the interim evaluation reports, the JTI JUs should develop and implement clear communication and dissemination plans, obtain a separate identity and work more on the synergy with national programmes and international cooperation with non-EU stakeholders.

Overall assessment: the first interim evaluations of the Joint Undertakings were carried out as planned by the end of 2010 (in April 2011 for the FCH JU) covering the quality and efficiency of their work and assessing the progress towards the set objectives. **The overall result of the evaluations is positive, affirming good prospects for achievement of the JTI JU's goals.**

As the Joint Undertakings are only now fully autonomous, **there needs to be a period of some years of consolidation before the real benefits can be assessed**. Nevertheless, the importance of cross-sectoral co-operation in key strategy setting is considered extremely important. In the case of the FCH JU, for example, where there are very specific market entry barriers, the industrial partners have been very effective in organising objective assessment of market potential in relation to other competing technologies. The stable allocation of funds has also underpinned the industry commitment – especially SMEs – at a time when the Framework Programme funds could easily have been diverted to competing technologies.

In 2011, the five Joint Undertakings had to follow up on the implementation of the ongoing activities and start the next waves of projects, as well as on the preparation and launch of the future calls. Calls topics needed to be defined on the grounds of the revised research agendas, considering the market forces and the quick pace of technology development in their industries.

As recommended by the European Court of Auditors and the experts in the first interim evaluation reports, the entities that experienced initial delays in starting their operations, such as Clean Sky, should have promptly recovered in order to achieve their objectives within the set timeframe. This would have also contributed to shorten the time for payments to beneficiaries and improve the implementation of the budget, which had been perceived overall as being low among all JTI JUs in 2010.

The JTI JUs had to further **encourage the wide participation of industrial and academic partners, and particularly of SMEs, in their research activities**. They needed to remove the obstacles for SMEs, where such existed. IMI had put on its agenda the development of a methodology for in-kind contribution and calculation of indirect costs, and FCH already initiated the process to adopt an increase in the funding rates, which were considerably lower than those in FP7. Clean Sky, ARTEMIS and ENIAC were challenged to keep the high interest of SMEs in the calls for proposals they were launching.

Taking into consideration that the report is looking at the JTI JUs' development in the first year of their autonomous operations, and at a point where none of their projects are completed, the prospects for the future remain to be considered. The results achieved by the five JTI JUs so far sets them as ambitious European initiatives with the potential to become a new affirmed model of a public-private partnership.