4.7.1 **Autonomy and a 'bottom-up' approach rather than standardisation**. This means that any efforts tending towards excessive standardisation should be rejected. Standardisation prevents best practice from first being empirically established through competition — which the 'bottom-up' principle basically allows — between different procedures, methods and cultural approaches, and thus also prevents the advantages of gradual progression from being tapped. This is the only way to identify which approach is particularly effective, deserves further funding and can serve as an example.

4.7.2 **Existing mechanisms are adequate**. Existing mechanisms at both the policymaking and programme and project levels already provide sufficient and reasonable scope in this regard. Further measures and rules can also be introduced or adapted later, if there is a well-founded specific need.

4.8 **Existing Community instruments for promoting and coordinating R&D**. On the other hand, the Committee recommends that general, clear and comprehensible rules should be developed to manage the wide range of Community instruments for promoting and coordinating R&D. It would be very helpful if the Commission listed and described (i.e. provided comprehensible instructions for use for) **all** the instruments and measures available to it for promoting and coordinating R&D objectives. This would also show whether, among the growing plethora of instruments, the purpose of each one is adequately defined and the instruments properly separated, and whether they can be easily understood by potential users and Commission staff or need to be overhauled to make them clearer.

Brussels, 24 October 2007.

The President
of the European Economic and Social Committee
Dimitris DIMITRIADIS

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## Opinion of the European Economic and Social Committee on the 'Proposal for a Council Regulation setting up the Innovative Medicines Initiative Joint Undertaking'

*COM(2007) 241 final — 2007/0089 (CNS)*

(2008/C 44/02)

On 11 June 2007 the Council decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the abovementioned proposal.

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 4 October 2007. The rapporteur was Mr Dantin.

At its 439th plenary session, held on 24 and 25 October 2007 (meeting of 24 October), the European Economic and Social Committee adopted the following opinion by 118 votes to two, with two abstentions.

### 1. **Conclusions and recommendations**

1.1 The pharmaceutical industry is quite rightly considered as a key strategic sector, and its products are crucial to the health and well-being of European citizens. It is also important from the point of view of employment.

1.2 In the light of this situation, and of the decline of pharmaceutical research in Europe, the decision to set up the IMI JU (Innovative Medicines Initiative Joint Undertaking) is very much justified. The Committee welcomes and supports this decision, in particular because it involves a genuine partnership between the public and private sectors.

1.3 The key aspects on which the role of the IMI JU should be focused include the following:

— improving the prediction of the safety and the efficacy of new drugs, especially in the early development phases before clinical trials begin;

— tackling the waste of resources caused by the current duplication of research efforts, both in the private and public sector, through the use of jointly developed knowledge management systems;

— bridging skills gaps by providing training to ensure that the skills of professionals match those required by the pharmaceutical research sector;

— providing a focal point for developing the required synergies by enabling cooperation between research initiated by the IMI JU and national and European activities, thus contributing to the establishment of the European Research Area in this sector.

1.4 The EESC welcomes the wide-ranging consultation that preceded the drafting of this regulation and supports the proposal that an annual report on the results of the IMI JU be submitted. However, the Committee regrets the absence of a detailed assessment of the operation and the results achieved by the former European Technology Platforms.

1.5 In the light of the multiple financing system that has been set up and of the significant volume of Community resources involved, the EESC believes that it would be appropriate to better define the use and allocation of the end products of the research in question, in particular as regards intellectual property and the issue of patents.

1.6 The EESC believes that it would be helpful to think about mechanisms conducive to returns on European investments. Similarly, it would be desirable to provide for the profits generated by research to be assigned to investments located within the EU.

## 2. **Introduction**

2.1 The purpose of the proposed regulation under review is to launch the very first public-private partnerships in the area of R&D. It defines one of the first two Joint Technology Initiatives (JTI). This involves innovative medicines ([1]).

2.2 The aim of JTIs is to allow industry, research organisations, Member States and the Commission to pool some or all of their resources into selected research programmes.

2.3 Unlike the traditional strategy, which involves providing public funding for projects on a case-by-case basis, JTIs involve large-scale research programmes with shared strategic research goals. This new approach is expected to create a critical mass for European research and innovation, consolidate the scientific community in key strategic areas, and harmonise the funding of projects so that research findings can be put to use more quickly. JTIs are aimed at key areas where the current instruments have neither the scale nor the speed to keep Europe ahead of global competition. These are areas where national, European and private funding of research could bring significant added value, inter alia by stimulating an increase in private R&D expenditure.

2.4 The JTI on the Innovative Medicines Initiative (IMI) seeks to support the development of new knowledge, new instruments and new methods that will facilitate the faster supply of safer and more effective medicines.

2.5 Thanks to an innovative financing method, the IMI should help to increase private investment in R&D, speed up the transfer of knowledge between universities and businesses, and facilitate the participation of SMEs in European research.

## 3. **Background**

3.1 Over the last ten to fifteen years, pharmaceutical research in Europe has gradually been falling behind. Whilst investment in R&D increased by a factor of 4,6 between 1990 and 2005 in the USA, the equivalent factor in Europe was just 2,8. Businesses are increasingly transferring their cutting-edge research units to countries outside the European Union, mainly the United States and, more recently, in Asia.

3.1.1 This situation could have grave consequences for European competitiveness, as innovation and cutting-edge technologies are among the keys to long-term economic growth. This was one of the main reasons behind the decision to create a JTI on innovative medicines.

3.2 Whereas governments draw up their plans at national level, industry has a global vision. Large countries such as the United States and China have a unified investment strategy that enables businesses to better plan and attract resources. In Europe, national governments do not coordinate their R&D investment and pharmaceutical companies must expend resources adapting their activities to local circumstances.

3.3 A Community legislative act could establish a targeted, coherent R&D programme that could draw on all the sources of R&D investment (public and private) at European level and thus create a more favourable environment for the European Union. This is the purpose of the regulation under review.

## 4. **The Commission's proposal**

4.1 The proposed regulation setting up the Innovative Medicines Initiative Joint Undertaking [COM(2007) 241] arises out of the provisions of the 7th Framework Programme (FP7) covered by Decision 1982/2006/EEC. This provides for a Community contribution towards the creation of long-term public-private partnerships at European level in the area of research.

4.2 These partnerships take the form of Joint Technology Initiatives (JTIs) and arise from the work of the former European Technology Platforms (ETPs).

([1]) Another JTI involves embedded computing systems. This is covered by opinion INT/364.

4.3 The Council, in its Decision No 971/2006/EEC on the Specific Programme 'Cooperation', emphasised the need to set up public-private partnerships and identified six areas in which the creation of joint technology initiatives is appropriate with a view to relaunching European research. These are:

— Hydrogen and fuel cells

— Aeronautics and air transport ([2])

— Innovative medicines

— Embedded computing systems ([3])

— Nanoelectronics ([4])

— GMES (global monitoring for environment and security).

4.4 Within the context of this general strategy, the regulation proposed by COM(2007) 241 under review provides for the implementation of the **Joint Technology Initiative on Innovative Medicines (IMI JTI)** by means of the establishment of an **Innovative Medicines Initiative Joint Undertaking (IMI JU)**.

4.5 In accordance with the Commission's aims, the establishment of an Innovative Medicines Initiative Joint Undertaking is expected to facilitate the involvement of stakeholders who are not currently able to carry out costly and complex research programmes (universities, SMEs, hospitals, public authorities, etc.).

4.6 The IMI JU will be founded as a joint undertaking, its founder members being the European Community represented by the Commission and the EFPIA (European Federation of Pharmaceutical Industries and Associations), and set up as a Community body by a Council Regulation under Treaty Article 171. The Member States and the countries involved in the 7th Framework Programme will be able to join it, as will any legal entity involved in R&D, provided that it makes a financial contribution.

4.7 This programme will benefit from a budget of EUR 2 billion, to be invested over a period of seven years, split equally between the Commission (resources from the 7th Framework Programme in accordance with the provisions of Article 54 of Council Regulation 1605/2002) and the businesses that belong to the EFPIA, who will provide most of the staff, equipment, consumables, etc.

4.8 The IMI JU will support research activities conducted in the Member States and in the countries associated with FP7. The entire Community contribution of one billion euro will be set aside for small and medium-sized enterprises and universities for applied pharmaceutical research. The participating large enterprises will invest an equal sum by bearing the costs of their part of the research and by involving SMEs and universities in this.

4.9 The IMI joint undertaking is to be considered as an international body with a legal personality within the meaning of Article 2 of Directive 2004/17/EEC and Article 15 of Directive 2004/18/EEC. Its seat will be in Brussels and its activities will cease in December 2017. This period may be extended by the Council.

## 5. **General comments**

5.1 The pharmaceutical industry is quite rightly considered, in the report entitled *Creating an innovative Europe*, as a key strategic sector, and its products are crucial to the health and well-being of European citizens. In essence, the effective and proper use of pharmaceutical products helps to improve quality of life.

5.2 The pharmaceutical industry also provides a lot of jobs in Europe. In 2004, this sector employed 612 000 people, 103 000 of whom were highly skilled in scientific research.

*Role of the IMI JU*

5.3 The main justification for the establishment of the IMI JU is the need to address Europe's decline in the area of pharmaceutical research and to reverse this trend, which was already observed in the Commission Communication dated 1 July 2003 entitled *A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient — A Call for Action*.

5.4 To achieve this, changes in the traditional methods of bilateral cooperation are necessary. A new approach at European level is now needed, bringing about direct cooperation between universities, relevant SMEs, public bodies and the pharmaceutical industry in connection with the financial provisions set out in the 7th Framework Programme.

5.5 The key aspects on which the role of the IMI JU should be focused are as follows:

— improving the prediction of the safety and the efficacy of new drugs, especially in the early development phases before clinical trials begin;

— tackling the waste of resources caused by the current duplication of research efforts, both in the private and public sector, through the use of jointly developed knowledge management systems;

— bridging skills gaps by providing training to ensure that the skills of professionals match those required by the pharmaceutical research sector;

— providing a focal point for developing the required synergies by enabling cooperation between research initiated by the IMI JU and national and European activities, thus contributing to the establishment of the European Research Area in this sector.

([2]) INT/369.
([3]) INT/364.
([4]) INT/370.

6. **Specific comments**

6.1 The EESC is pleased to note the wide-ranging consultation that preceded the drafting of this regulation and supports the implementation of appropriate training programmes aimed at providing the necessary skills in a sector that is crucial to the European economy and to citizens' quality of life.

6.2 As stated under point 4.2, JTIs arise out of the work of the former European Technology Platforms (ETPs). However, these latter rarely achieved their stated aim of strategically relaunching research in Europe. The creation of JTIs is based on this acknowledgement of partial failure regarding the role of the ETPs, which was essentially to make a key contribution to industry in the area of competitiveness.

6.2.1 In the light of this, the EESC regrets the absence from the Commission proposal of a more detailed outline of the work previously carried out by the European Technology Platforms (ETPs); there is no assessment, the results are not mentioned, and there are no bibliographical references.

6.2.2 For this reason, with regard to the JTIs, the EESC welcomes the proposal that an annual report, giving an assessment of the results and progress achieved, be submitted.

6.3 That said, the EESC welcomes the creation of the joint undertaking for the innovative medicines initiative. In general terms, it has the necessary features for relaunching pharmaceutical research in Europe thanks to a genuine partnership between the public and private sectors. This initiative is consistent with the aims of the Lisbon strategy, which provides for the investment of 3 % of GDP in R&D activities, two-thirds of which are to come from the private sector.

6.3.1 However, in the light of the multiple financing system that has been set up and of the significant volume of Community resources involved, the EESC believes that it would be appropriate to better define the use and allocation of the end products of the research in question. To this end, the issue of patents and intellectual property as defined in the regulation and its appendix, which limits itself to setting out principles, ought to be more precise and more explicit, lest it become a sticking point in the smooth implementation of the IMI JI.

6.3.2 Most of the large pharmaceutical companies that operate in Europe have a global dimension. Here too, because of the significant Community funding, it would be appropriate to think about mechanisms that promote a return on European investment. From this perspective, whilst taking care not to create barriers to the use of innovative medicines in non-EU countries, the regulation could contain provisions for all of the phases of research and the production of molecules based on such research to take place within the EU. Similarly, it would be desirable for these same provisions to state that the profits generated by research funded by the IMI JI should be assigned to investments located within the EU.

Brussels, 24 October 2007.

The President

of the European Economic and Social Committee

Dimitris DIMITRIADIS