

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 Programme](#) 2007-2013 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 “Health”.

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 consist 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.