

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 Member 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 Member 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.