

Innovative Medicines Initiative 2 Joint Undertaking (IMI2 Joint Undertaking)

2013/0240(NLE) - 10/07/2013 - Legislative proposal

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 initiative's 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.