Innovative Medicines Initiative 2 Joint Undertaking (IMI2 Joint Undertaking)

2013/0240(NLE) - 06/05/2014 - Final act

PURPOSE: to establish a new Joint Undertaking, IMI2, in order to strengthen industrial research and innovation across the Union.

NON-LEGISLATIVE ACT: Council Regulation (EU) n° 557/2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking.

CONTENT: the Framework Programme for Research and Innovation, Horizon 2020, supports public-private partnerships in research and innovation in order that the Union might tackle certain key challenges.

This Regulation aims to establish **a new Joint Undertaking** (JU) for the implementation of the Joint Technology Initiative on Innovative Medicines, for a period up to 31 December 2024.

The IMI2 Joint Undertaking replaces the IMI JU, set up under the Seventh Framework Programme.

IMI JU has demonstrated the effective mobilisation of resources by bringing together several partners from the pharmaceutical industry, academia, small and medium-sized enterprises ('SMEs'), patient organisations and regulators. It has also stepped up cooperation between stakeholders in the health research and innovation field.

The IMI2 JU is a body entrusted with the implementation of a public-private partnership. Its seat will be located in Brussels, Belgium.

In order to take into account the duration of Horizon 2020, calls for proposals under the ECSEL Joint Undertaking must be launched **at the latest by 31 December 2020** (in duly justified cases, by 31 December 2021). Calls for proposals will be published on the **single portal for participants** as well as through other Horizon 2020 electronic means of dissemination managed by the Commission.

The rules for **participation and dissemination** of the Horizon 2020 programme will apply to the JU.

Objectives of the JU: this involves supporting, in accordance with Horizon 2020, the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership or to address specific societal challenges and in particular the challenge to improve European citizens' health and well-being. The JU also aims to:

- €€€€€€€ increase the success rate in **clinical trials** of priority medicines identified by the World Health Organisation;

- €€€€€€€ where possible, **reduce the time** to reach clinical proof of concept in medicine development, such as for cancer, immunological, respiratory, neurological and neurodegenerative diseases;

- €€€€€€€ develop **new therapies** for diseases for which there is a high unmet need, such as Alzheimer' s disease and limited market incentives, such as antimicrobial resistance;

- €€€€€€€ develop diagnostic and treatment **biomarkers** for diseases clearly linked to clinical relevance and approved by regulators;

- €€€€€€€ reduce the failure rate of **vaccine candidates** in phase III clinical trials through new biomarkers for initial efficacy and safety checks;

- €€€€€€€ improve the **current drug development process**.

IMI 2 should seek to develop close interactions with the **European Structural and Investment Funds** (ESIF).

Funding: the Union financial contribution to the JU shall come from Horizon 2020 and be up **to 1 638 000 000** and shall consist of up to EUR 1 425 000 000 to match the contribution of European Federation of Pharmaceutical Industries and Associations ('EFPIA'). EFPIA shall make contributions of at least **EUR 1 425 000 000.** Other Members other than the Union and Associated Partners shall make the contributions corresponding to the amounts they have committed when becoming a Member or an Associated Partner.

The Commission **may terminate**, proportionally reduce or suspend the Union's financial contribution to the JU or trigger the winding-up procedure if members other than the Union, including their constituent entities and affiliated entities, do not provide contributions.

The Regulation contains provisions that aim to ensure the **protection of the financial interests of the Members.**

The **discharge** for the implementation of the budget of the JU shall be given by the European Parliament, upon recommendation of the Council in accordance with the procedure provided for in the financial rules of the IMI 2 JU.

Evaluation: by 30 June 2017 the Commission shall carry out, with the assistance of independent experts, an interim evaluation of the JU. It shall send that report to the European Parliament and to the Council by 31 December 2017. The results of the interim evaluation shall be taken into account in the interim evaluation of Horizon 2020.

IMI2's mandate will end on 31 December 2024 and the JU will be wound up.

ENTRY INTO FORCE: 27.06.2014.