

Innovative Medicines Initiative 2 Joint Undertaking (IMI2 Joint Undertaking)

2013/0240(NLE) - 13/02/2014 - Committee report tabled for plenary, 1st reading/single reading

The Committee on Industry, Research and Energy adopted the non-legislative report (consultation of Parliament) by Teresa Riera MADURELL (S&D, ES) on the proposal for a Council regulation on the Innovative Medicines Initiative 2 Joint Undertaking.

The committee recommended that Parliament made the following principal amendments to the Commission proposal:

Union contribution: the maximum Union contribution, including contributions from the members of the European Free Trade Association (EFTA), to the IMI2 Joint Undertaking to cover administrative costs and operational costs shall be EUR1 638 750 000 which shall consist of the following:

- up to **EUR 1 425 000 000** to be added to the contribution of the European Federation of Pharmaceutical Industries and Associations (EFPIA);
- up to **EUR 213 750 000** to be added to additional contributions from other Members Associated Partners

In order to respond to unforeseen situations or to new developments and needs the Commission may, following the interim evaluation of the Horizon 2020 Framework Programme, **review the budget** of the IMI2 Joint Undertaking within the annual budgetary procedure.

Members added that only the indispensable appropriations needed to **cover the administrative costs** derived from calls for proposals under Regulation (EC) No 73/2008 on IMI 1 shall be **transferred from the unused appropriations** under that Regulation to the IMI2 Joint Undertaking.

The committee considered that any IMI1 unused budget other than the indispensable administrative expenditure to wrap up IMI 1 should be used to fund FP7 projects, e.g. for supporting projects in reserve list.

Tasks: the IMI2 Joint Undertaking shall carry out the following tasks: (i) leverage private investments and mobilise the public and private sector resources; (ii) ensure participation is as wide as possible; (iii) support pre-competitive research and innovation in health related life sciences including pre-competitive research related to pre-clinical phases of drug development and innovative clinical trials addressing public health needs where incentives for the private sector to invest alone are insufficiently met, as assessed by the IMI scientific committee; (iv) publish information on the projects, including the name of the participants and the amount of the financial contribution of the IMI2 Joint Undertaking per participant.

Alignment with [Horizon 2020](#): the committee inserted several provisions in order to bring a greater alignment of the text with the provisions of Horizon 2020, including:

- higher involvement of SMEs;
- the need to take into consideration results of the reviews of the Horizon 2020 Scientific Panel for Health, including when adopting the annual work programme;

- full compliance with the general principles laid down in Horizon 2020, and in particular the principles on gender equality and open access.
- calls for proposals for collaborative R&D projects should be issued in the field of health research under Horizon 2020 in addition and in parallel to the activities of the IMI2 Joint Undertaking, particularly regarding research at Technology Readiness Levels 1 to 4;

Rules for participation and dissemination: Members specified that derogations provided in Regulation (EU) No 1290/2013 laying down rules for participation in Horizon 2020 should be **consistently applied** so as to guarantee legal and procedural certainty for all types of participants, allow the widest possible participation, and ensure an equitable and fair treatment of all participants **regarding ownership of and access to the results** generated within IMI2 projects. Derogations may not have deterrent effects towards participations of universities, non-for profit research organisations or SMEs.

Governance: Members added several amendments in order to strengthen the transparency and accountability of the IMI JU governance structure and decision-making processes in order to reaffirm its legitimacy. IMI 2 must publish information on the projects, including the name of the participants and the amount of the financial contribution of the IMI2 Joint Undertaking per participant.

Indicators: Members added a new clause to the Annex regarding the specific performance indicators related to the functioning of the IMI2 Joint Undertaking.

In addition, they felt that the provisions related to the leverage of private investment should be further enhanced so as to render them more visible. Accordingly, a new R&D intensity indicator for EFPIA companies, co-member of IMI JU, was introduced to the proposal.

Reports and evaluation: by 30 June 2017 the Commission shall organise an independent interim evaluation of the IMI2 Joint Undertaking, which shall take into consideration the **general recommendations provided by the Scientific Panel on Health** and also compare the interim achievements of IMI 2 **against the specific indicators** listed in the Annex to the Regulation. The results of this independent interim evaluation should be taken into account in the interim evaluation of the Horizon 2020 Framework Programme.