

9.4.2014

A7-0105/59

Amendment 59

Michèle Rivasi

on behalf of the Verts/ALE Group

Report

A7-0105/2014

Teresa Riera Madurell

Innovative Medicines Initiative 2 Joint Undertaking

COM(2013)0495 – C7-0259/2013 – 2013/0240(NLE)

Proposal for a regulation

Article 2 – paragraph 1 – point b – introductory part

Text proposed by the Commission

Amendment

(b) to *contribute to the objectives of the Joint Technology Initiative on Innovative Medicines*, in particular to:

(b) to *support the implementation of public policy objectives in the field of health*, in particular to:

Or. en

Justification

The objectives of the joint undertaking should not be to fulfil privately driven research agendas outside the scope of public policy health objectives. There is a grave concern that the balance between private interest and public priorities is not met in the current joint undertaking and this should be rectified.

9.4.2014

A7-0105/60

Amendment 60

Michèle Rivasi

on behalf of the Verts/ALE Group

Report

Teresa Riera Madurell

Innovative Medicines Initiative 2 Joint Undertaking
COM(2013)0495 – C7-0259/2013 – 2013/0240(NLE)

A7-0105/2014

Proposal for a regulation

Article 2 – paragraph 1 – point b – point vi a (new)

Text proposed by the Commission

Amendment

via) Reinforce the capacity of smaller actors such as research organisations, universities and SMEs to participate in open innovation models;

Or. en

Justification

The Intellectual Property provisions are unfavourable for the academic communitie and SMEs. A clearer balance of rights and obligations should be provided and the capacity of the weaker players reinforced.

9.4.2014

A7-0105/61

Amendment 61

Michèle Rivasi

on behalf of the Verts/ALE Group

Report

A7-0105/2014

Teresa Riera Madurell

Innovative Medicines Initiative 2 Joint Undertaking
COM(2013)0495 – C7-0259/2013 – 2013/0240(NLE)

Proposal for a regulation

Article 3 – paragraph 1

Text proposed by the Commission

Amendment

1. The maximum Union contribution, including EFTA appropriations, to the IMI2 Joint Undertaking to cover administrative costs and operational costs shall be EUR 1 **725** million which shall **consist** of the **following**:

1. The maximum Union contribution, including EFTA appropriations, to the IMI2 Joint Undertaking to cover administrative costs and operational costs shall be EUR 1 **000** million which shall **match the contribution** of the **Members**.

(a) up to EUR 1 500 million to match the contribution of EFPIA, or its constituent entities or their affiliated entities;

(b) up to EUR 225 million to match additional contributions from other Members Associated Partners, or from their constituent or their affiliated entities.

The contribution of the Union shall be paid from the appropriations in the general budget of the Union allocated to the Horizon 2020 Specific Programme implementing the Horizon 2020 Framework Programme in accordance with Article 58(1)(c)(iv) and Articles 60 and 61 of Regulation (EU, Euratom) No 966/2012 for bodies referred to in Article 209 of that Regulation.

The contribution of the Union shall be paid from the appropriations in the general budget of the Union allocated to the Horizon 2020 Specific Programme implementing the Horizon 2020 Framework Programme in accordance with Article 58(1)(c)(iv) and Articles 60 and 61 of Regulation (EU, Euratom) No 966/2012 for bodies referred to in Article 209 of that Regulation.

Or. en

Justification

It is proposed to maintain the same budget as under the FP7, to ensure that enough funds under the Health Challenge of Horizon 2020 remain available for financing other important European public health priorities, where private sector funds are scarce and public funds are needed. In addition, any organisation active in the field of health willing to contribute should be able to become member to IMI.

9.4.2014

A7-0105/62

Amendment 62

Michèle Rivasi

on behalf of the Verts/ALE Group

Report

A7-0105/2014

Teresa Riera Madurell

Innovative Medicines Initiative 2 Joint Undertaking
COM(2013)0495 – C7-0259/2013 – 2013/0240(NLE)

Proposal for a regulation

Article 4 – paragraph 1

Text proposed by the Commission

Amendment

1. ***EFPIA shall make or*** arrange for its constituent entities or their affiliated entities to make contributions of at least EUR 1 ***500*** million. ***Other Members other than the Union or Associated Partners shall make, or arrange for their constituent entities or their affiliated entities to make, the contributions*** corresponding to the amounts they have committed when becoming a Member ***or an Associated Partner***.

1. ***Members other than the Union shall*** arrange for its constituent entities or their affiliated entities, ***established in the Union***, to make contributions of at least EUR 1 ***000*** million corresponding to the amounts they have committed when becoming a Member.

Or. en

Justification

Any private sector organisation, active in the field of Health, committed to the objectives and willing to contribute should be able to become member to IMI. In addition other organisations established in the Union, and contributing to the financing such as public sector bodies or research organisations should also be able to become member.

9.4.2014

A7-0105/63

Amendment 63

Michèle Rivasi

on behalf of the Verts/ALE Group

Report

A7-0105/2014

Teresa Riera Madurell

Innovative Medicines Initiative 2 Joint Undertaking
COM(2013)0495 – C7-0259/2013 – 2013/0240(NLE)

Proposal for a regulation

Article 16 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Members of the Governing Board, of the Scientific Committee and the Executive Director shall make publicly available and keep updated a declaration of full professional activities, of financial interests and of conflicts of interests. The declarations shall contain the following information:

(a) the person's occupation and his/her membership of boards or committees of private companies, non-governmental organisations and associations;

(b) holdings in companies or partnerships where there are potential public policy implications or where such holdings give the person significant influence;

Or. en

9.4.2014

A7-0105/64

Amendment 64

Michèle Rivasi

on behalf of the Verts/ALE Group

Report

A7-0105/2014

Teresa Riera Madurell

Innovative Medicines Initiative 2 Joint Undertaking
COM(2013)0495 – C7-0259/2013 – 2013/0240(NLE)

Proposal for a regulation

Article 17 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

As a general rule, the Joint Undertaking shall apply the rules for dissemination and exploitation established in Horizon 2020. In addition it shall develop binding guidelines to ensure:

- open access to research results after the conclusion of the projects, including access to data relating to clinical trials, including negative and positive results;

- management of intellectual property and licensing practices designed to ensure the widest and most affordable access to end products;

- the generation of benefits in terms of employment within the EU;

Attention shall be paid to ensure that smaller actors such as research organisation, universities and SMEs can successfully participate in open innovation models;

Or. en

Justification

The IPR regime in IMII has generated great difficulties in particular for smaller actors such as SMEs, universities and research organisations, to the advantage of the large private members that can also export exclusive rights out of the EU. While the aim of establishing

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open models of innovation should not be lost, attention should be paid to the needs of the weaker actors, the public need to deliver wider and affordable access to end products and to generate employment in the EU.

9.4.2014

A7-0105/65

Amendment 65

Michèle Rivasi

on behalf of the Verts/ALE Group

Report

A7-0105/2014

Teresa Riera Madurell

Innovative Medicines Initiative 2 Joint Undertaking
COM(2013)0495 – C7-0259/2013 – 2013/0240(NLE)

Proposal for a regulation

Annex 1 – part 2 – point 1 – point b

Text proposed by the Commission

Amendment

(b) upon acceptance of these Statutes by means of a letter of endorsement, *the European Federation of Pharmaceutical Industries and Associations (hereinafter "EFPIA")*.

(b) upon acceptance of these Statutes by means of a letter of endorsement, *any legal entity represented individually or by an association and established in the EU*.

Or. en

Justification

Any private sector organisation, active in the field of Health, committed to the objectives and willing to contribute should be able to become member to IMI. In addition other organisations established in the Union, and contributing to the financing such as public sector bodies or research organisations should also be able to become member.

9.4.2014

A7-0105/66

Amendment 66

Michèle Rivasi

on behalf of the Verts/ALE Group

Report

Teresa Riera Madurell

Innovative Medicines Initiative 2 Joint Undertaking
COM(2013)0495 – C7-0259/2013 – 2013/0240(NLE)

A7-0105/2014

Proposal for a regulation

Annex 1 – part 10 – point 2

Text proposed by the Commission

2. The members of the Scientific Committee shall reflect a balanced representation of world-wide recognized experts from academia, **industry** and regulatory bodies. Collectively, the Scientific Committee members shall have the necessary scientific competencies and expertise covering the technical domain needed to make strategic science-based recommendations to the IMI2 Joint Undertaking.

Amendment

2. The members of the Scientific Committee shall reflect a balanced representation of world-wide recognized **independent** experts from academia, **the medical profession, healthcare provider organisations** and regulatory bodies. Collectively, the Scientific Committee members shall have the necessary scientific competencies and expertise covering the technical domain needed to make strategic science-based recommendations to the IMI2 Joint Undertaking.

Or. en

Justification

A wider range of scientific experts active in the health and medical sphere should be involved in the Scientific Committees to convey a wider multi-disciplinary view on the activities of IMI. Industry experts are already widely represented in the governing board by the Members.

9.4.2014

A7-0105/67

Amendment 67

Michèle Rivasi

on behalf of the Verts/ALE Group

Report

Teresa Riera Madurell

Innovative Medicines Initiative 2 Joint Undertaking
COM(2013)0495 – C7-0259/2013 – 2013/0240(NLE)

A7-0105/2014

Proposal for a regulation

Annex 1 – part 10 – point 4 – point a a (new)

Text proposed by the Commission

Amendment

(aa) advise on scientific priorities to be included in the Strategic Research Agenda taking into consideration the results of the review of the Horizon 2020 Scientific Panel for Health and the societal preferences gathered through a public engagement exercise;

Or. en

Justification

The Scientific Committees should be more involved in setting the agenda which should adequately reflect the view a wide range of scientists in the field, public sector needs and citizen's views.

9.4.2014

A7-0105/68

Amendment 68

Michèle Rivasi

on behalf of the Verts/ALE Group

Report

A7-0105/2014

Teresa Riera Madurell

Innovative Medicines Initiative 2 Joint Undertaking
COM(2013)0495 – C7-0259/2013 – 2013/0240(NLE)

Proposal for a regulation

Annex 1 – part 10 – point 4 – point b b (new)

Text proposed by the Commission

Amendment

(bb) draw up recommendations to the Commission for the interim evaluation of the IMI 2 Joint Undertaking, assessing the take-up of societal preferences resulting from the public engagement exercise; the advice of the Scientific Committee shall duly be taken into account;

Or. en

Justification

The Scientific Committees should be clearly involved in the interim evaluation.

9.4.2014

A7-0105/69

Amendment 69

Michèle Rivasi

on behalf of the Verts/ALE Group

Report

Teresa Riera Madurell

Innovative Medicines Initiative 2 Joint Undertaking
COM(2013)0495 – C7-0259/2013 – 2013/0240(NLE)

A7-0105/2014

Proposal for a regulation

Annex 1 – part 12 – point 1

Text proposed by the Commission

1. The Stakeholder Forum shall be open to all public and private stakeholders, international interest groups from Member States, associated countries as well as from other countries.

Amendment

1. The Stakeholder Forum shall be open to all public and private stakeholders, international interest groups from Member States, associated countries as well as from other countries. ***It shall include representatives of patients organisations, healthcare provider organisations, and other civil society organisations.***

Or. en