

**AMENDMENTS 001-057**

by the Committee on Industry, Research and Energy

**Report**

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A7-0105/2014

**Innovative Medicines Initiative 2 Joint Undertaking**

Proposal for a regulation (COM(2013)0495 – C7-0259/2013 – 2013/0240(NLE))

**Amendment 1****Proposal for a regulation****Recital 4***Text proposed by the Commission*

(4) Regulation (EU) No .../2013 of the European Parliament and of the Council *of ... 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)*<sup>10</sup> aims to achieve a greater impact on research and innovation *by combining Horizon 2020 Framework Programme and private sector funds in* public-private partnerships in key areas where *research and innovation can contribute to* the Union's wider competitiveness goals and help tackle societal challenges. *Union* involvement in those partnerships could take the form of financial contributions to joint undertakings established on the basis of Article 187 of the Treaty under Decision No 1982/2006/EC.

*Amendment*

(4) Regulation (EU) No **1291**/2013 of the European Parliament and of the Council<sup>10</sup> (Horizon 2020) *seeks* to achieve a greater impact on research and innovation *using several instruments, including* public-private partnerships in key areas where *it is possible for research and innovation to contribute to* the Union's wider competitiveness goals, *to leverage private investment* and *to* help tackle societal challenges. *Those* partnerships *should reflect a balanced contribution from all partners, be accountable for the achievement of their targets and be aligned with the Union's strategic goals relating to research, development and innovation. The governance and functioning of those partnerships should be open, transparent, effective and efficient and should give a wide range of stakeholders active in the specific areas of those partnerships the opportunity to*

*participate. The involvement of the* Union in those partnerships could take the form of financial contributions to joint undertakings established on the basis of Article 187 of the Treaty under Decision No 1982/2006/EC.

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<sup>10</sup> OJ ... [H2020 FP]

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<sup>10</sup> *Regulation (EU) No° 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104).*

## Amendment 2

### Proposal for a regulation Recital 5

*Text proposed by the Commission*

(5) In accordance with Decision (EU) No .../2013 of the Council of ... 2013 establishing the Specific Programme implementing Horizon 2020 (2014-2020)<sup>11</sup> further support *should* be provided to joint undertakings established under Decision No 1982/2006/EC under the conditions specified in Decision (EU) No [...] /2013..

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<sup>11</sup> OJ ... [H2020 SP]

*Amendment*

(5) In accordance with *Horizon 2020 and Council* Decision 2013/743/EU<sup>11</sup> (the "*Horizon 2020* Specific Programme") further support *may* be provided to joint undertakings established under *Horizon 2020. Such support is subject to the conditions specified in Horizon 2020 and the Horizon 2020 Specific Programme, in particular those in Article 25 of Horizon 2020 as well as to full compliance with the general principles laid down in Horizon 2020, and in particular the principles on gender equality and open access.*

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<sup>11</sup> *Council Decision 2013/7438/EU of 3 December 2013 establishing the Specific Programme implementing Horizon 2020 - the Framework Programme for research and Innovation (2014-2020) and repealing Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC and 2006/975/EC (OJ L 347, 20.12.2013, p. 965)*

## Amendment 3

## Proposal for a regulation

### Recital 8

#### *Text proposed by the Commission*

(8) Research related to the future of medicine shall be undertaken in areas where combination of societal, public health and biomedical industry competitiveness goals requires pooling of resources and fostering collaboration between the public and private sectors, with the involvement of SMEs. The scope of the initiative should be expanded to **all** areas of life science research and innovation. The areas would be of public health interest, as identified by the World Health Organisation report on priority medicines for Europe and the World, which is currently being updated with the new version expected to be released in 2013. The initiative should consequently seek to involve a broader range of partners, including **mid-caps**, from different sectors (e.g. biomedical imaging, medical information technology, diagnostic and/or animal health industries). A wider participation would help to advance the development of new approaches and technologies for the prevention, diagnosis and treatment of diseases with high impact on public health.

#### *Amendment*

(8) Research related to the future of medicine shall be undertaken in areas where combination of societal, public health and biomedical industry competitiveness goals requires pooling of resources and fostering collaboration between the public and private sectors, with the involvement of SMEs. The scope of the initiative should be expanded to **those** areas of life science research and innovation **where the added value of this initiative has been demonstrated**. The areas would be of public health interest, as identified by the World Health Organisation report on priority medicines for Europe and the World, which is currently being updated with the new version expected to be released in 2013. The initiative should consequently seek to involve a broader range of partners, including **SMEs, midcaps and medium size companies that are not on equity capital markets and with innovation potential**, from different sectors (e.g. biomedical imaging, medical information technology, diagnostic and/or animal health industries) **and the level of participation should be one of the benchmarks against which the success of the IMI Joint Undertaking is to be evaluated ex-post**. A wider participation, **including a meaningful involvement of research organisations, patient organisations and civil society** would help to advance the development of new approaches and technologies for the prevention, diagnosis and treatment of diseases with high impact on public health.

#### Amendment 4

## Proposal for a regulation

### Recital 9

*Text proposed by the Commission*

(9) The continuation of this initiative should *also* take into account the *experience acquired from the operations of the IMI Joint Undertaking including the results of its interim evaluation and stakeholders' recommendations*<sup>14</sup> and be implemented using a more fit-for-purpose structure and rules in order to enhance efficiency and ensure simplification at operational level. To this effect, the Innovative Medicines Initiative 2 (hereinafter "IMI2") Joint Undertaking should adopt financial rules specific to its needs in accordance with Article 209 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and the Council *of 25 October 2012 on the financial rules applicable to the general budget of the Union*<sup>15</sup>.

<sup>14</sup>

[http://ec.europa.eu/research/consultations/ife\\_science\\_h2020/consultation\\_en.htm](http://ec.europa.eu/research/consultations/ife_science_h2020/consultation_en.htm)

<sup>15</sup> OJ L 298 26.10.2012, p. 1.

*Amendment*

(9) The continuation of this initiative should take into account the *results of its interim evaluation and stakeholders' recommendations, in particular regarding the concerns raised by the Innovative Medicines Initiative Intellectual Property Policy, and ensure clearer rules of governance. The continuation of this initiative should also take into account the experience acquired from the operations of the IMI Joint Undertaking* and be implemented using a more fit-for-purpose structure and rules in order to enhance efficiency and ensure simplification at operational level. To this effect, the Innovative Medicines Initiative 2 (hereinafter "IMI2") Joint Undertaking should adopt financial rules specific to its needs in accordance with Article 209 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and the Council<sup>15</sup>

<sup>14</sup>

[http://ec.europa.eu/research/consultations/ife\\_science\\_h2020/consultation\\_en.htm](http://ec.europa.eu/research/consultations/ife_science_h2020/consultation_en.htm)

<sup>15</sup> *Regulation (EU, Euratom) No 966/2012 of the European Parliament and the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002* (OJ L 298 26.10.2012, p. 1).

*Justification*

*IMI2 should be the result of a learning process and address the shortcomings identified in evaluations and day-to-day operation.*

**Amendment 5**

**Proposal for a regulation**

**Recital 14**

*Text proposed by the Commission*

(14) Participation in indirect actions funded

*Amendment*

(14) Participation in indirect actions funded

by the IMI2 Joint Undertaking *should* comply with Regulation (EU) No ... /2013 of the European Parliament and of the Council of ... 2013 laying down the rules for the participation and dissemination in 'Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)'<sup>16</sup> .

by the IMI2 Joint Undertaking *shall* comply with Regulation (EU) No 1290 /2013 of the European Parliament and of the Council<sup>16</sup> .*The IMI2 Joint Undertaking will ensure that participants protect, exploit and disseminate those results in a manner that ensures wide dissemination and exploitation of the research data and affordable access to the end product.*

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<sup>16</sup> OJ ... [H2020 RfP]

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<sup>16</sup> Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006 (OJ L 347, 20.12.2013, 81).

#### *Justification*

*Sharing of data resulting from IMI2 projects is essential to reinforce collaborative and cumulative processes to increase scientific knowledge.*

#### **Amendment 6**

##### **Proposal for a regulation**

Recital 14 a (new)

*Text proposed by the Commission*

*Amendment*

*(14a) Without prejudice to the interim evaluation referred to in Article 11 of this Regulation and in accordance with Article 26 of Horizon 2020 the Joint Technology Initiatives as a particular funding instrument should be subject to an in-depth interim assessment, which should specifically include an analysis of their openness, transparency effectiveness and efficiency.*

#### **Amendment 7**

##### **Proposal for a regulation**

Recital 15

*Text proposed by the Commission*

(15) The Union's financial contribution should be managed in accordance with the principle of sound financial management and with the relevant rules on indirect management set out in Regulation (EU, Euratom) No 966/2012 and Commission Delegated Regulation (EU) No 1268/2012 **of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012**<sup>26</sup>.

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<sup>26</sup> OJ L 362, 31.12.2012, p. 1.

*Amendment*

(15) The Union financial contribution should be managed in accordance with the principle of sound financial management and with the relevant rules on indirect management set out in **Article 60 (1) to (4) of Regulation (EU, Euratom) No 966/2012** and Commission Delegated Regulation (EU) No 1268/2012.<sup>26</sup>

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<sup>26</sup> **Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012** (OJ L 362, 31.12.2012, p. 1).

**Amendment 8**

**Proposal for a regulation  
Recital 18**

*Text proposed by the Commission*

(18) The Commission's internal auditor should exercise the same powers over the IMI2 Joint Undertaking as those exercised in respect of the Commission.

*Amendment*

(18) The Commission's internal auditor should exercise the same powers over the IMI2 Joint Undertaking as those exercised in respect of the Commission. **The same should apply to the European Court of Auditors and the European Parliament.**

**Amendment 9**

**Proposal for a regulation  
Recital 19**

*Text proposed by the Commission*

(19) **In accordance with Article 287(1) of the Treaty on the Functioning of the European Union, the constituent instrument of bodies, offices or agencies set up by the Union may preclude the examination of the accounts of all revenue and expenditure of those bodies, offices or agencies by the Court of**

*Amendment*

(19) **By way of derogation from Article 60(7) and Article 209 of Regulation (EU, Euratom) No 966/2012, discharge for the implementation of the budget of the IMI2 Joint Undertaking should be given by the European Parliament on the recommendation of the Council. Hence, the reporting requirements set out in**

**Auditors. In accordance with Article 60(5) of Regulation (EU, Euratom) No 966/2012, the accounts of the bodies under Article 209 Regulation (EU, Euratom) No 966/2012 are to be examined by an independent audit body which is to give an opinion inter alia on the reliability of the accounts and the legality and regularity of the underlying transactions. Avoidance of duplication of the examination of the accounts justifies that the accounts of the IMI2 Joint Undertaking should not be subject to examination by the Court of Auditors.**

**Article 60(5) of that Regulation should not apply to the contribution of the Union to the IMI2 Joint Undertaking but they should be aligned to the extent possible to the ones foreseen for bodies under Article 208 of Regulation (EU, Euratom) No 966/2012. The auditing of accounts and of the legality and regularity of the underlying transactions should be undertaken by the Court of Auditors.**

## **Amendment 10**

### **Proposal for a regulation Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

**(19a) The IMI2 Joint Undertaking should operate in a transparent way, providing all relevant available information to its bodies and making publicly available information related to its functioning including the draft agendas and minutes of the meeting of the Governing Board and Scientific Committee. In addition, Members of the Governing Board, the Scientific Committee and the Executive Director should publish and keep updated their full declaration of professional activities and financial interests.**

## **Amendment 11**

### **Proposal for a regulation Recital 19 b (new)**

*Text proposed by the Commission*

*Amendment*

**(19b) In order to guarantee a challenge-based approach, coordinated strategic planning of research and innovation activities under the specific objective "Health, Demographic Change and Wellbeing" of the priority "Societal Challenges" of Horizon 2020 is needed.**

***By contributing to defining research and innovation priorities, the Scientific Panel for Health should contribute to avoiding fragmentation and ensure that the different funding instruments under this Societal Challenge, including IMI2, contribute to improving the lifelong health and wellbeing of all in a coordinated manner.***

*Justification*

*Seeks alignment with Article 12 of the H2020 Framework Regulation*

**Amendment 12**

**Proposal for a regulation**

**Recital 21**

*Text proposed by the Commission*

(21) The IMI Joint Undertaking was set up for a period up to 31 December 2017. The IMI2 Joint Undertaking should provide continued support to the Innovative Medicines research programme by ***enlarging the scope of the activities under a modified set of rules***. The transition from the IMI Joint Undertaking to the IMI2 Joint Undertaking should be aligned and synchronized with the transition from the Seventh Framework programme to ***the Horizon 2020 Framework Programme*** to ensure optimal use of the funding available for research. In the interest of legal certainty and clarity, Council Regulation (EC) No 73/2008 should therefore be repealed and transitional provisions should be set out.

*Amendment*

(21) The IMI Joint Undertaking was set up for a period up to 31 December 2017. The IMI2 Joint Undertaking should provide continued support to the Innovative Medicines research programme by ***implementing the remaining activities foreseen in the IMI research programme under the rules of the IMI Joint Undertaking***. The transition from the IMI Joint Undertaking to the IMI2 Joint Undertaking should be aligned and synchronized with the transition from the Seventh Framework programme to Horizon 2020 to ensure optimal use of the funding available for research. In the interest of legal certainty and clarity, Council Regulation (EC) No 73/2008 should therefore be repealed and transitional provisions should be set out.

*Justification*

*It should be made clear that the IMI2 JU is merely implementing the remainder of the activities that were originally foreseen until 2017 under the IMI research programme - and nothing else. These remaining activities should follow the "old" set of rules of IMI, whereas the activities of IMI2 should follow the "new" set of rules. Whilst this is already cumbersome enough, no modifications or interferences of the two sets of rules should occur between 2014 and 2017.*



## Amendment 13

### Proposal for a regulation Recital 21 a (new)

*Text proposed by the Commission*

*Amendment*

***(21a) With a view to the overall aim of Horizon 2020 to achieve greater simplification and harmonisation of the research and innovation funding landscape at European level, Joint Undertakings should avoid different sets of rules from Horizon 2020 and the duration of all public-private partnerships financed under Horizon 2020 should be aligned with the duration of Horizon 2020, to avoid different sets of rules running in parallel and related additional administrative burden for participants and Union bodies in the future;***

## Amendment 14

### Proposal for a regulation Recital 21 b (new)

*Text proposed by the Commission*

*Amendment*

***(21b) In order to help close the research and innovation divide in Europe, complementarity and close synergies should be developed with the Structural Funds. Where possible, interoperability between Horizon 2020 and the Structural Funds should be promoted. Cumulative or combined funding will be encouraged. In this context, measures should aim at fully exploiting the potential of Europe's talent pool and thereby optimising the economic and social impact of research and innovation and will be distinct yet complementary with regard to policies and actions of the Structural Funds.***

## Amendment 15

### Proposal for a regulation Recital 21 c (new)

*Text proposed by the Commission*

*Amendment*

***(21c) Measures that promote the participation of SMEs, universities and research centres should be implemented. In this context, barriers preventing the participation of new comers to the program should be identified and addressed.***

## **Amendment 16**

### **Proposal for a regulation Recital 21 d (new)**

*Text proposed by the Commission*

*Amendment*

***(21d) Considering the importance of basic research to create breakthrough ideas that enable future innovation, 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;***

#### *Justification*

*According to the H2020 Regulation, R&D activities covered by JTIs should also be included in regular CfPs in Horizon 2020 work programmes. In the case of IMI2, collaborative research should be carried out in parallel to IMI2 activities at lower TRLs, to achieve a wider inclusion of universities and SMEs in EU-funded health research, to ensure the right balance between lower and upper TRLs, to create a competitive research environment, and to boost future innovation.*

## **Amendment 17**

### **Proposal for a regulation Recital 21 e (new)**

*Text proposed by the Commission*

*Amendment*

***(21e) Taking due account of the intended synergies between Horizon 2020 and the Structural Funds as well as relevant national and regional R&D funding programmes, regions across the Union***

*should be encouraged to contribute proactively to the activities of the IMI2 Joint Undertaking, e.g. by supporting financially relevant research infrastructure, the preparation of proposals, the exploitation of research results or networking activities of relevant actors, aiming at boosting the regional impact of the activities of the IMI2 Joint Undertaking and their potential to create jobs and growth at regional level.*

#### *Justification*

*The European Parliament successfully pushed for a new article in the Horizon 2020 Framework Regulation that explicitly demands better synergies between Horizon 2020 and the Structural Funds. In this context, JTIs should be no exception. Regions should be encouraged to contribute to their activities, particularly in view of their huge potential for strengthening regional clusters.*

#### **Amendment 18**

##### **Proposal for a regulation**

##### **Article 1**

###### *Text proposed by the Commission*

For the implementation of the Joint Technology Initiative on Innovative Medicines, a joint undertaking within the meaning of Article 187 of the Treaty (hereinafter 'IMI2 Joint Undertaking'), is established for a period from 1 January 2014 until 31 December 2024.

###### *Amendment*

For the implementation of the Joint Technology Initiative on Innovative Medicines, a joint undertaking within the meaning of Article 187 of the Treaty (hereinafter 'IMI2 Joint Undertaking'), is established for a period from 1 January 2014 until 31 December 2024. ***However, in line with the duration of Regulation (EU) No 1291/2013 ("the Horizon 2020 Framework Programme"), all calls for proposals shall be launched by 31 December 2020.***

#### **Amendment 19**

##### **Proposal for a regulation**

##### **Article 2**

###### *Text proposed by the Commission*

Objectives  
The IMI 2 Joint Undertaking shall have the

###### *Amendment*

Objectives  
The IMI 2 Joint Undertaking shall have the

following objectives:

(a) to contribute to the implementation of **Regulation (EU) No [...]/2013/EU** [the Horizon 2020 Framework Programme], in particular part ... of Decision **(EU) No [...]/2013/EU** [the **Specific Programme implementing the Horizon 2020 Framework Programme**], and in particular to improving European citizens' health and wellbeing.

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

i) increase the success rate in clinical trials of priority medicines identified by the World Health Organisation;

ii) reduce the time to reach clinical proof of concept in medicine development, such as for immunological, respiratory, neurological and neurodegenerative diseases;

iii) 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;

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

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

vi) improve the current drug development

following objectives:

(a) to contribute to the implementation of the Horizon 2020 Framework Programme, in particular part **III** of Decision **2013/743/EU** and in particular to improving European citizens' health and wellbeing.

(b) to **support the implementation of public policy objectives in the field of Health through** the Joint Technology Initiative on Innovative Medicines, **as determined by the research and innovation priorities set out in the Horizon 2020 Framework Programme**, in particular to:

i) increase the success rate in clinical trials **by supporting innovative projects on** priority medicines **and therapies** identified by the World Health Organisation **in order to meet therapeutic and public health needs, and where incentives for the private sector to invest alone are insufficiently met**;

ii) reduce the time to reach clinical proof of concept in medicine development, such as for immunological, respiratory, neurological and neurodegenerative diseases;

iii) develop new **vaccines, diagnostics, medicines and** therapies for diseases for which there is a high unmet need, such as Alzheimer's disease **and antimicrobial resistance in general**, and limited market incentives, such as **orphan/rare diseases**;

iv) **support the development of** diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators;

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

vi) improve the current drug development

process by providing support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products.

process by providing support for the development of tools, standards and approaches to assess efficacy, **effectiveness**, safety, **therapeutic benefit** and quality of regulated health products

**via) reinforce the capacity of smaller actors such as research organisations, universities and SMEs for participating in open innovation models;**

**(ba) to promote the involvement of SMEs in its activities, in line with the objectives of the Horizon 2020 Framework Programme;**

**(bb) to facilitate the move towards an open innovation system, reinforcing collaborative and cumulative processes to increase scientific knowledge;**

**(bc) to aim at delivering available and accessible therapies in alignment with Union objectives and priorities in health R&D as established in Horizon 2020;**

**Projects run under the IMI2 Joint Undertaking following open calls for proposals may include any eligible institution as participant and coordinator.**

## **Amendment 20**

### **Proposal for a regulation Article 2 a (new)**

*Text proposed by the Commission*

*Amendment*

#### **Article 2a**

##### **Scope of activities**

**1. In order to fulfil the objectives set out in Article 2 the IMI2 Joint Undertaking may fund the research and development activities comprising the Technology Readiness Levels from 2 to 6.**

**2. Where the IMI 2 research programme provides for innovation activities comprising the Technology Readiness Levels from 7 to 8, funding rates for indirect actions shall be reduced in accordance with Article 28 of Regulation**

*Justification*

*This article means to clarify the scope of activities of the IMI2 Joint Undertaking, in particular with respect to the relevant TRLs covered by its research programme. The RfP also call for a greater consideration of the TRL-concept to stipulate funding levels, which is taken up in this article with a view to the funding rates used in indirect actions.*

**Amendment 21**

**Proposal for a regulation**

**Article 3 – paragraph 1 – subparagraph 1 – introductory part**

*Text proposed by the Commission*

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:

*Amendment*

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 EUR **1 638 750 000** which shall consist of the following:

**Amendment 22**

**Proposal for a regulation**

**Article 3 – paragraph 1 – subparagraph 1 – point a**

*Text proposed by the Commission*

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

*Amendment*

(a) up to EUR **1 425 000 000** to *be added to* the contribution of EFPIA, or its constituent entities or their affiliated entities;

**Amendment 23**

**Proposal for a regulation**

**Article 3 – paragraph 1 – subparagraph 1 – point b**

*Text proposed by the Commission*

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

*Amendment*

(b) up to EUR **213 750 000** to *be added to* additional contributions from other Members Associated Partners, or from their constituent or their affiliated entities.

## Amendment 24

### Proposal for a regulation

#### Article 3 – paragraph 1 – second subparagraph

*Text proposed by the Commission*

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.

*Amendment*

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 Article 60 **(1) to (4)** and **Article** 61 of Regulation (EU, Euratom) No 966/2012 for bodies referred to in Article 209 of that Regulation.

## Amendment 25

### Proposal for a regulation

#### Article 3 – paragraph 3 – first subparagraph

*Text proposed by the Commission*

The delegation agreement referred to in paragraph 2 shall address the elements set out in Article 58(3) and Articles 60 and 61 of Regulation (EU, Euratom) No 966/2012 and in Article 40 of the **Commission delegated** Regulation (EU) No 1268/2012 as well as inter alia the following:

*Amendment*

The delegation agreement referred to in paragraph 2 shall address the elements set out in Article 58(3) and Article 60 **(1) to (4)** and Article 61 of Regulation (EU, Euratom) No 966/2012 and in Article 40 of the Regulation (EU) No 1268/2012 as well as inter alia the following:

## Amendment 26

### Proposal for a regulation

#### Article 3 – paragraph 3 – point c

*Text proposed by the Commission*

(c) the specific performance indicators related to the functioning of the IMI2 Joint Undertaking;

*Amendment*

(c) the specific performance indicators related to the functioning of the IMI2 Joint Undertaking **referred to in the Annex**;

## Amendment 27

### Proposal for a regulation

#### Article 3 – paragraph 3 – point d

*Text proposed by the Commission*

(d) the arrangements regarding the provision of data necessary to ensure that the Commission is able to meet its dissemination and reporting obligations;

*Amendment*

(d) the arrangements regarding the provision of data necessary to ensure that the Commission is able to meet its dissemination and reporting obligations, ***including complete information on all proposals and grant agreements and their partners to be inserted into the global H2020 database [ECORDA] in a timely manner;***

**Amendment 28**

**Proposal for a regulation  
Article 5**

*Text proposed by the Commission*

The IMI2 Joint Undertaking shall adopt its specific Financial rules in accordance with Article 209 of Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No ...

*Amendment*

***Without prejudice to Article 12,*** the IMI2 Joint Undertaking shall adopt its specific Financial rules in accordance with Article 209 of Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No ...

**Amendment 29**

**Proposal for a regulation  
Article 11**

*Text proposed by the Commission*

Evaluation

1. By ***31 December*** 2017 the Commission shall ***conduct*** an interim evaluation of the IMI2 Joint Undertaking. The Commission shall communicate the conclusions thereof, accompanied by its observations, to the European Parliament and to the Council by ***30 June 2018***.

*Amendment*

***Reports and*** Evaluation

1. 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 in accordance with Article 12(2) of the Horizon 2020 Framework Programme and the advice of the Scientific Committee. That evaluation shall, inter alia, compare the interim achievements of IMI2 against the specific indicators listed in Clause 18a of the Statutes contained in the Annex to this Regulation.*** The Commission shall communicate the conclusions thereof,



accompanied by its observations, to the European Parliament and to the Council by **31 December 2017. The results of the independent interim evaluation of the IMI2 Joint Undertaking shall be taken into account in the interim evaluation of the Horizon 2020 Framework Programme.**

***In accordance with Article 32 of the Horizon 2020 Framework Programme and as part of the Horizon 2020 Interim Evaluation, Joint Technology Initiatives as a funding instrument of the Horizon 2020 Framework Programme shall be subject to an in-depth assessment which shall include, inter alia, an analysis of the openness, transparency and efficiency of public-private partnerships based on Article 187 of the Treaty on the Functioning of the European Union.***

***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, within the annual budgetary procedure, the budget of the IMI2 Joint Undertaking.***

***The Executive Director shall present to the European Parliament and to the Council an annual report on the progress achieved by the IMI2 Joint Undertaking. This report shall contain details of implementation including number of proposals submitted, number of proposals selected for funding, type of participants, including SMEs, and country statistics***

## **Amendment 30**

### **Proposal for a regulation Article 12**

#### *Text proposed by the Commission*

1. The discharge of the budget implementation with regard to the Union contribution to the IMI2 Joint Undertaking shall be ***part of the discharge*** given by the

#### *Amendment*

1. The discharge of the budget implementation with regard to the Union contribution to the IMI2 Joint Undertaking shall be given by the European Parliament,

European Parliament, upon recommendation of the Council, **to the Commission** in accordance with the procedure provided for in **Article 319** of the **Treaty**.

**2. The IMI2 Joint Undertaking shall fully cooperate with the institutions involved in the discharge procedure and provide, as appropriate, any necessary additional information. In this context, it may be requested to be represented in meetings with the relevant institutions or bodies and assist the Commission authorising officer by delegation.**

upon recommendation of the Council in accordance with the procedure provided for in **the financial rules** of the **IMI2 Joint Undertaking**.

### Amendment 31

#### Proposal for a regulation Article 13 – paragraph 2

*Text proposed by the Commission*

2. To ensure coherence, the Commission may decide to carry out the audits referred to in paragraph 1 on those participants which have received funding from the IMI2 Joint Undertaking.

*Amendment*

2. To ensure coherence, the Commission may decide to carry out the audits referred to in paragraph 1 on those participants which have received funding from **or have contributed to the activities funded by** the IMI2 Joint Undertaking.

*Justification*

*All partners participating in IMI2 research and innovation activities should be subject to audits*

### Amendment 32

#### Proposal for a regulation Article 14 – paragraph 1

*Text proposed by the Commission*

1. **Without prejudice to Clause 17(4), of the Statutes contained in the Annex**, the IMI2 Joint Undertaking shall grant Commission staff and other persons authorised by it, as well as the Court of Auditors, access to its sites and premises and to all the information, including information in electronic format, needed in order to conduct their audits.

*Amendment*

1. The IMI2 Joint Undertaking shall grant Commission staff and other persons authorised by it, as well as the Court of Auditors, access to its sites and premises and to all the information, including information in electronic format, needed in order to conduct their audits.

### Amendment 33

#### Proposal for a regulation

#### Article 14 – paragraph 3 – point b

*Text proposed by the Commission*

(b) the Commission and the Court of Auditors to conduct such audits on ***the recipients of funding from*** the IMI2 Joint Undertaking according to their respective competences.

*Amendment*

(b) the Commission and the Court of Auditors to conduct such audits on ***participants in the research and innovation activities funded by*** the IMI2 Joint Undertaking according to their respective competences.

### Amendment 34

#### Proposal for a regulation

#### Article 14 – paragraph 5 a (new)

*Text proposed by the Commission*

*Amendment*

***5a. The staff of the IMI2 Joint Undertaking, the Executive Director and the members of the Governing Board shall without delay notify OLAF of any instances of fraud which have come to their attention in the fulfilment of their duties or remit, without in any way being made accountable for them as a result.***

*Justification*

*Anti-fraud measures should be a priority for the Union. This notification procedure, which already operates in at least one Member State, is a very useful instrument for this purpose.*

### Amendment 35

#### Proposal for a regulation

#### Article 16 – paragraph 2

*Text proposed by the Commission*

*Amendment*

***2. The IMI2 Joint Undertaking Governing Board may adopt practical arrangements for implementing Regulation (EC) No 1049/2001.***

***deleted***

*Justification*

*Regulation (EC) No 1049/2001 already sets out the arrangements for an EU Institution to*

*provide access to documents.*

## **Amendment 36**

### **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 conflict of interests. The declarations shall contain the following information :***

***(a) professional 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 that holding gives the person significant influence over the affairs;***

## **Amendment 37**

### **Proposal for a regulation Article 17**

*Text proposed by the Commission*

*Amendment*

Rules for participation and dissemination  
Regulation (EU) No ... ***[Rules for participation and dissemination in Horizon 2020]*** shall apply to the actions funded by the IMI2 Joint Undertaking. In accordance with that Regulation, the IMI2 Joint Undertaking shall be considered as a funding body and shall provide financial support to indirect actions as set out in Clause 1 of the Statutes contained in the Annex.

Rules for participation and dissemination  
Regulation (EU) No 1290/2013 ***and Commission Decisions relevant to its implementation*** shall apply to the ***indirect*** actions funded by the IMI2 Joint Undertaking. In accordance with that Regulation, the IMI2 Joint Undertaking shall be considered as a funding body and shall provide financial support to indirect actions as set out in Clause 1 of the Statutes contained in the Annex.

***Derogations foreseen in Article 1(3) of Regulation (EU) No 1290/2013 shall 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.*

## **Amendment 38**

### **Proposal for a regulation**

#### **Article 17 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

*As a general rule, the IMI2 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 a widest and affordable access to end products;*

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

*Justification*

*The attempts in IMI 1 to establish more open models of innovation within single projects is proving to generate difficulties in particular for smaller actors such as SMEs, universities and research organisations. While the aim of establishing open models of innovation should not be lost, more attention should be paid both to the needs of the weaker actors as well as the public need to deliver wider and affordable access to end products. Both this aspects are missing in the IMI proposal.*

## **Amendment 39**

### **Proposal for a regulation**

## Article 17 – paragraph 1 b (new)

*Text proposed by the Commission*

*Amendment*

***In accordance with the principles of transparency and non-discrimination as laid out in Article 60(1) and 128(1) of Regulation (EU, Euratom) No 966/2012 and Article 16 of this Regulation, calls for proposals organised by the IMI2 Joint Undertaking shall be published on the web-based Horizon 2020 Participant Portal.***

*Justification*

*During the Horizon 2020 trilogue negotiations the institutions agreed to promote a greater coherence of all call possibilities financed under Horizon 2020. To this effect, the Commission promised to promote the publication of CfPs organised by the JTI on the Horizon 2020 Participant Portal. All of them agreed to follow this approach. This amendment aims to turn a self-obligation into a legal requirement, guaranteeing simple and accessible information for applicants.*

### Amendment 40

#### Proposal for a regulation Article 19 – paragraph 5

*Text proposed by the Commission*

*Amendment*

5. ***Any unused*** appropriations under Regulation (EC) No 73/2008 shall be transferred to the IMI2 Joint Undertaking.

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

*Justification*

*Any IMI1 unused budget other than the indispensable administrative expenditure to wrap up IMI1 should be used to fund FP7 projects, e.g. for supporting projects in reserve list*

### Amendment 41

#### Proposal for a regulation Annex 1 – clause 1

*Text proposed by the Commission*

*Amendment*

The IMI2 Joint Undertaking shall carry out the following tasks:

(a) to mobilise the public and private sector resources needed to achieve the objectives of IMI2 Joint Undertaking;

(b) to regularly review and make any necessary adjustments to the Strategic Research Agenda of the IMI2 Joint Undertaking in light of scientific developments occurring during its implementation;

(c) to establish and develop close and long-term cooperation between the Union, other Members, Associated Partners, and the other stakeholders such as other industries, regulatory bodies, patient organisations, academia and clinical centres, as well as cooperation between industry and academia;

(d) to facilitate coordination with European, national and international activities in this area, and to communicate and interact with the Member States and the countries associated with Horizon 2020 Framework Programme;

(e) to effectively support research and innovation in life sciences **mainly through grants**;

(f) to define and carry out the IMI2 Joint Undertaking annual work plan mainly through calls for proposals;

(g) to initiate calls for proposals and any other necessary procedure for funding, to

The IMI2 Joint Undertaking shall carry out the following tasks:

(a) to **leverage private investments and** mobilise the public and private sector resources needed to achieve the objectives of IMI2 Joint Undertaking;

(b) to regularly review and make any necessary adjustments to the Strategic Research Agenda of the IMI2 Joint Undertaking in light of scientific developments occurring during its implementation **taking into consideration results of the reviews of the Horizon 2020 Scientific Panel for Health established in Article 12 of the Horizon 2020 Framework Programme**;

(c) to establish and develop close and long-term cooperation between the Union, other Members, Associated Partners, and the other stakeholders such as other industries, regulatory bodies, patient organisations, academia, **research organisation** and clinical centres, as well as cooperation between industry and academia, **while ensuring that participation is as wide as possible**;

(d) to facilitate coordination with European, national and international activities in this area, and to communicate and interact with the Member States and the countries associated with **the** Horizon 2020 Framework Programme;

(e) to effectively 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**.

(f) to define and carry out the IMI2 Joint Undertaking annual work plan mainly through **open and competitive** calls for proposals;

(g) to initiate **open and competitive** calls for proposals and any other necessary

evaluate proposals, to award funding to projects according to the applicable rules, within the limits of available funds;

(h) information, communication, exploitation and dissemination activities by applying *mutatis mutandis* the provisions of Article 22 of *the Regulation (EU) No [...]/2013* [the Horizon 2020 Framework Programme];

(i) to organise a meeting at least annually with interest groups to ensure openness **and** transparency of the research activities of the IMI2 Joint Undertaking with its stakeholders;

(j) any other task needed to achieve the objectives referred to in Article 2 of this Regulation.

## Amendment 42

### Proposal for a regulation Annex 1 – clause 2

#### *Text proposed by the Commission*

1. The Members of the IMI2 Joint Undertaking shall be the following:

(a) the Union, represented by the Commission;

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

2. Provided that it contributes to the funding referred to in Clause 13 of these

procedure for funding, to evaluate proposals, to award funding to projects according to the applicable rules, within the limits of available funds;

***(ga) to 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;***

(h) information, communication, exploitation and dissemination activities by applying the provisions of Article 22 of the Horizon 2020 Framework Programme;

(i) to organise a ***regular communication and a*** meeting at least annually with interest groups to ensure openness, transparency ***and accountability*** of the research activities of the IMI2 Joint Undertaking with its stakeholders ***via the Stakeholder Forum;***

(j) any other task needed to achieve the objectives referred to in Article 2 of this Regulation.

#### *Amendment*

1. The Members of the IMI2 Joint Undertaking shall be the following:

(a) the Union, represented by the Commission;

(b) upon acceptance of these Statutes by means of a letter of endorsement, the European Federation of Pharmaceutical Industries and Associations (hereinafter "EFPIA"), ***a non-profit association registered under Swiss law (registration number 4749) with its permanent office in Brussels, Belgium.***

2. Provided that it contributes to the funding referred to in Clause 13 of these



Statutes to achieve the objectives of the IMI2 Joint Undertaking set out in Article 2 of this Regulation and accepts these Statutes, any legal entity that directly or indirectly supports research and innovation in a Member State or in a country associated with the Horizon 2020 Framework Programme may apply to become a Member of the IMI2 Joint Undertaking.

3. Upon acceptance of these Statutes by means of a letter of endorsement, any legal entity other than a Member or a constituent entity of a Member or any affiliated entity of either, supporting the objectives of the IMI2 Joint Undertaking in its specific area of research, in a Member State or in a country associated with the Horizon 2020 Framework Programme, may apply to join IMI2 as an Associated Partner. The letter of endorsement shall detail the scope of the association in terms of content, of activities and duration.

4. Associated Partners shall contribute like Members other than the Union to the IMI2 Joint Undertaking's operational costs, in accordance with Clause 13 of these Statutes.

The letter of endorsement shall detail the Associated Partners' contribution to IMI2 Joint Undertaking and that the Union will match, in accordance with Articles 3 and 4 of this Regulation.

## **Amendment 43**

### **Proposal for a regulation**

Statutes to achieve the objectives of the IMI2 Joint Undertaking set out in Article 2 of this Regulation and accepts these Statutes, any legal entity that directly or indirectly supports research and innovation in a Member State or in a country associated with the Horizon 2020 Framework Programme may apply to become a Member of the IMI2 Joint Undertaking.

3. Upon acceptance of these Statutes by means of a letter of endorsement, any legal entity other than a Member or a constituent entity of a Member or any affiliated entity of either, supporting the objectives of the IMI2 Joint Undertaking in its specific area of research, in a Member State or in a country associated with the Horizon 2020 Framework Programme, may apply to join IMI2 as an Associated Partner. The letter of endorsement shall detail the scope of the association in terms of content, of activities and duration, ***and notify its decision without delay to the Commission, which, where the application is approved, shall have the right to object to membership except in the case of a Member State of the Union. Rules for accepting new members should be public and transparent, not pose undue obstacles, and any rejection must be clearly justified in writing and made available to the candidate and to the States Representative Group.***

4. Associated Partners shall contribute like Members other than the Union to the IMI2 Joint Undertaking's operational costs, in accordance with Clause 13 of these Statutes.

The letter of endorsement shall detail the Associated Partners' contribution to IMI2 Joint Undertaking and that the Union will match, in accordance with Articles 3 and 4 of this Regulation.

## Annex 1 – clause 3 – point 2

*Text proposed by the Commission*

2. The Governing Board shall assess the application taking into account the relevance and the potential added value of the applicant for the achievement of the objectives of the IMI2 Joint Undertaking. It shall then decide on the application.

*Amendment*

2. The Governing Board shall assess the application taking into account the relevance and the potential added value of the applicant for the achievement of the objectives of the IMI2 Joint Undertaking. It shall then decide on the application ***and notify its decision without delay to the Commission, which, where the application is approved, shall have the right to object to membership except in the case of a Member State of the Union. Rules for accepting new members should be public and transparent, not pose undue obstacles, and any rejection must be clearly justified in writing and made available to the candidate and to the States Representative Group.***

*Justification*

*It should be possible for the European Union, represented by the Commission, to object to membership.*

## Amendment 44

### Proposal for a regulation Annex 1 – clause 3 – point 3

*Text proposed by the Commission*

3. Any Member or Associated Partner may terminate its membership or association to the IMI2 Joint Undertaking. The termination shall become effective and irrevocable six months after notification to the other Members and Associated Partners. As of then, the former Member or Associated Partner shall be discharged from any obligations other than those approved or incurred by the IMI2 Joint Undertaking prior to terminating the membership or participation.

*Amendment*

3. Any Member or Associated Partner may terminate its membership or association to the IMI2 Joint Undertaking. The termination shall become effective and irrevocable six months after notification to the other Members and Associated Partners. As of then, the former Member or Associated Partner shall be discharged from any obligations other than those approved or incurred by the IMI2 Joint Undertaking prior to terminating the membership or participation. ***In such cases, an account shall be opened for settlement of financial obligations between the departing member and the IMI2 Joint Undertaking.***

## Amendment 45

### Proposal for a regulation Annex 1 – clause 3 – point 4

*Text proposed by the Commission*

4. Membership of or association to the IMI2 Joint Undertaking may not be transferred to a third party without prior agreement of the Governing Board.

*Amendment*

4. Membership of or association to the IMI2 Joint Undertaking may not be transferred to a third party without prior agreement of the Governing Board. ***The Commission shall be notified of this agreement and shall have the right to object.***

## Amendment 46

### Proposal for a regulation Annex 1 – clause 6

*Text proposed by the Commission*

Functioning of the Governing Board

1. Without prejudice to paragraph 2, each Member shall have a percentage out of 100 voting rights corresponding to the percentage of its contribution to the IMI2 Joint Undertaking.

The Commission shall hold 50% of the voting rights. The vote of the Commission shall be indivisible. Each Member may allocate its voting rights among its representatives in the Governing Board. The Members shall use their best efforts to achieve consensus. Failing consensus, the Governing Board shall take its decisions by a majority of at least 75% of all votes including the votes of those who are not in attendance.

The chairperson of the Governing Board shall be appointed on a rotating annual basis by each the Union and the other Members, in turn.

*Amendment*

Functioning of the Governing Board

1. Without prejudice to paragraph 2, each Member shall have a percentage out of 100 voting rights corresponding to the percentage of its contribution to the IMI2 Joint Undertaking.

The Commission shall hold 50% of the ***total*** voting rights. The vote of the Commission shall be indivisible. Each Member may allocate its voting rights among its representatives in the Governing Board. The Members shall use their best efforts to achieve consensus. Failing consensus, the Governing Board shall take its decisions by a majority of at least 75% of all votes including the votes of those who are not in attendance.

The chairperson of the Governing Board shall be appointed on a rotating annual basis by each the Union and the other Members, in turn.

***1a. The Commission shall ensure a constant coordination between the activities of Horizon 2020 and the activities of the IMI2 Joint Undertaking by regularly identifying possible***

*complementarities and synergies, including desirable overlaps, and implementing a formal coordination process to attune the research priorities covered by collaborative research under the framework programme and the activities covered by the IMI2 Joint Undertaking.*

2. The Governing Board shall hold its ordinary meetings at least twice a year. It may hold extraordinary meetings at the request of any Member or at the request of the chairperson. The meetings of the Governing Board shall be convened by its chairperson and shall normally take place at the seat of the IMI2 Joint Undertaking.

The Executive Director shall take part in the deliberations, but shall have no voting rights.

The Governing Board shall invite any Associated Partner to take part in its deliberations for those points on the agenda that concern its association. Associated Partners shall have no voting rights.

The chairperson of the States Representatives Group shall attend meetings of the Governing Board *as an observer*.

The Governing Board may invite, on a case-by-case basis, other persons to attend its meetings as observers, in particular representatives of regional authorities of

2. The Governing Board shall hold its ordinary meetings at least twice a year. It may hold extraordinary meetings at the request of any Member or at the request of the chairperson. The meetings of the Governing Board shall be convened by its chairperson and shall normally take place at the seat of the IMI2 Joint Undertaking.

*The draft agenda, final agenda and minutes of the meetings shall be published on the IMI website, without prejudice to confidentiality.*

The Executive Director shall take part in the deliberations, but shall have no voting rights.

The Governing Board shall invite any Associated Partner to take part in its deliberations for those points on the agenda that concern its association. Associated Partners shall have no voting rights.

The chairperson of the States Representatives Group *have the right to attend meetings of the Governing Board and take part in the deliberations, but shall have no voting rights*.

*The chairperson of the Scientific Committee shall have the right to attend meetings of the Governing Board and take part in the deliberations, but shall have no voting rights.*

*The chairperson of the Stakeholder Forum shall have the right to attend meetings of the Governing Board and take part in the deliberations, but shall have no voting rights*

The Governing Board may invite, on a case-by-case basis, other persons to attend its meetings as observers, in particular representatives of regional authorities of

the Union.

The representatives of the Members shall not be personally liable for actions they have undertaken in their capacity as representatives on the Governing Board.

The Governing Board shall adopt its own rules of procedure.

the Union.

The representatives of the Members shall not be personally liable for actions they have undertaken in their capacity as representatives on the Governing Board.

The Governing Board shall adopt ***and make publicly available*** its own rules of procedure.

## Amendment 47

### Proposal for a regulation

#### Annex 1 – clause 7

##### *Text proposed by the Commission*

#### 7. Tasks of the Governing Board

1. The Governing Board shall have overall responsibility for the strategic orientation and the operations of the IMI2 Joint Undertaking and shall supervise the implementation of its activities.

2. The Governing Board shall in particular carry out the following tasks:

(a) assess, accept or reject applications for new membership or association in accordance with Clause 3;

(b) decide on the termination of the membership or association in the IMI2 Joint Undertaking of any Member or Associated Partner that does not fulfil its obligations;

##### *Amendment*

#### 7. Tasks of the Governing Board

1. The Governing Board shall have overall responsibility for the strategic orientation and the operations of the IMI2 Joint Undertaking and shall supervise the implementation of its activities.

***1a. The Commission shall ensure a constant coordination between the activities of the Horizon 2020 Framework Programme and the activities of the IMI2 Joint Undertaking by regularly identifying possible complementarities and synergies, including desirable overlaps, and implementing a formal coordination process to attune the research priorities covered by collaborative research under the Horizon 2020 Framework Programme and the activities covered by the IMI2 Joint Undertaking.***

2. The Governing Board shall in particular carry out the following tasks:

(a) assess, accept or reject applications for new membership or association in accordance with Clause 3;

(b) decide on the termination of the membership or association in the IMI2 Joint Undertaking of any Member or Associated Partner that does not fulfil its obligations;

- (c) adopt the Financial rules of the IMI2 Joint Undertaking in accordance with Article 5 of this Regulation;
- (d) adopt the annual budget of the IMI2 Joint Undertaking, including the staff establishment plan indicating the number of temporary posts by function group and by grade as well as the number of contract staff and seconded national experts expressed in full-time equivalents;
- (e) exercise the appointing authority powers with respect to the staff, in accordance with Article 6(2);
- (f) appoint, dismiss, extend the term of office of, provide guidance to and monitor the performance of the Executive Director;
- (g) approve the organisational structure of the Programme Office referred to in Clause 9(5) upon recommendation by the Executive Director;
- (h) adopt the annual work plan and the corresponding expenditure estimates, proposed by the Executive Director in close cooperation with advisory groups referred to in Clause 7(2)(q), after having consulted the Scientific Committee *and* the States Representatives Group;
- (i) approve the annual accounts;
- (j) approve the annual activity report, including the corresponding expenditure;
- (k) arrange, as appropriate, for the establishment of an internal audit capability of the IMI2 Joint Undertaking;
- (l) approve the calls *for proposals as well as, where appropriate, the related rules for submission, evaluation, selection, award and evaluation review procedures*, proposed by the Executive Director in close cooperation with advisory groups referred to in Clause 7(2)(q);
- (m) approve the list of proposals selected for funding;

- (c) adopt the Financial rules of the IMI2 Joint Undertaking in accordance with Article 5 of this Regulation;
- (d) adopt the annual budget of the IMI2 Joint Undertaking, including the staff establishment plan indicating the number of temporary posts by function group and by grade as well as the number of contract staff and seconded national experts expressed in full-time equivalents;
- (e) exercise the appointing authority powers with respect to the staff, in accordance with Article 6(2);
- (f) appoint, dismiss, extend the term of office of, provide guidance to and monitor the performance of the Executive Director;
- (g) approve the organisational structure of the Programme Office referred to in Clause 9(5) upon recommendation by the Executive Director;
- (h) adopt the annual work plan and the corresponding expenditure estimates, proposed by the Executive Director in close cooperation with advisory groups referred to in Clause 7(2)(q), after having consulted the Scientific Committee, the States Representatives Group *and the Horizon2020 Scientific Panel for Health*
- (i) approve the annual accounts;
- (j) approve the annual activity report, including the corresponding expenditure;
- (k) arrange, as appropriate, for the establishment of an internal audit capability of the IMI2 Joint Undertaking;
- (l) approve the calls proposed by the Executive Director in close cooperation with advisory groups referred to in Clause 7(2)(q);
- (m) approve the list of proposals selected for funding *on the basis of the ranking list produced by a panel of independent experts in accordance with Article 37 of*

(n) establish the IMI2 Joint Undertaking's communications policy upon recommendation of the Executive Director;

(o) where appropriate, establish implementing rules in line with Article 6(3);

(p) where appropriate, establish rules on the secondment of national experts to the IMI2 Joint Undertaking and on the use of trainees in line with Article 7;

(q) where appropriate, set up advisory groups in addition to the bodies to the IMI2 Joint Undertaking;

(r) where appropriate, submit to the Commission any request to amend this Regulation proposed by any Member of the IMI2 Joint Undertaking;

(s) be responsible for any task which is not specifically allocated to one of the bodies of the IMI2 Joint Undertaking; it may assign such tasks to one of those bodies.

**Regulation (EU) NO 1290/2013;**

(n) establish the IMI2 Joint Undertaking's communications policy upon recommendation of the Executive Director;

***(n a) inform the States Representatives Group, the Scientific Committee and the Stakeholder Forum regularly on all matters relevant to their advisory role;***

(o) where appropriate, establish implementing rules in line with Article 6(3);

(p) where appropriate, establish rules on the secondment of national experts to the IMI2 Joint Undertaking and on the use of trainees in line with Article 7;

(q) where appropriate, set up advisory groups ***by open calls in*** addition to the bodies to the IMI2 Joint Undertaking;

(r) where appropriate, submit to the Commission any request to amend this Regulation proposed by any Member of the IMI2 Joint Undertaking;

(s) be responsible for any task which is not specifically allocated to one of the bodies of the IMI2 Joint Undertaking; it may assign such tasks to one of those bodies.

*Justification*

*There is an urgent need to coordinate the research activities under the framework programme and the activities carried out in the JTIs, including the management of desired overlap and needed synergies and complementarities. Naturally this task would be best fulfilled by the Commission whose role in the governance structure of the JTIs (50% of votes) should provide it with sufficient means to do so.*

**Amendment 48**

**Proposal for a regulation  
Annex 1 – clause 9**

*Text proposed by the Commission*

9. Tasks of the Executive Director

1. The Executive Director shall be the chief executive responsible for the day-to-day management of the IMI2 Joint Undertaking in accordance with the decisions of the

*Amendment*

9. Tasks of the Executive Director

1. The Executive Director shall be the chief executive responsible for the day-to-day management of the IMI2 Joint Undertaking in accordance with the decisions of the

Governing Board.

2. The Executive Director shall be the legal representative of the IMI2 Joint Undertaking. He/she shall be accountable to the Governing Board.

3. The Executive Director shall implement the budget of the IMI2 Joint Undertaking.

4. The Executive Director shall in particular carry out the following tasks in an independent manner:

(a) prepare and submit for adoption to the Governing Board the draft annual budget, including the corresponding staff establishment plan indicating the number of temporary posts in each grade and function group and the number of contract staff and seconded national experts expressed in full-time equivalents;

(b) prepare in close cooperation with advisory bodies referred to in Clause 7(2)(q) and submit for adoption to the Governing Board the annual work plan and the corresponding expenditure estimates;

(c) submit for approval to the Governing Board ***the annual accounts***;

(d) prepare and submit for approval to the Governing Board the annual activity report, including the corresponding expenditure;

(e) submit for approval to the Governing Board the list of proposals selected for funding;

(f) sign individual grant agreements or decisions;

(g) sign procurement contracts;

(h) implement the IMI2 Joint Undertaking's communications policy;

(i) organise, direct and supervise the operations and the staff of the IMI2 Joint Undertaking within the constraints of the delegation by the Governing Board as provided for in Article 6(2) of this Regulation;

Governing Board.

2. The Executive Director shall be the legal representative of the IMI2 Joint Undertaking. He/she shall be accountable to the Governing Board.

3. The Executive Director shall implement the budget of the IMI2 Joint Undertaking.

4. The Executive Director shall in particular carry out the following tasks in an independent manner:

(a) prepare and submit for adoption to the Governing Board the draft annual budget, including the corresponding staff establishment plan indicating the number of temporary posts in each grade and function group and the number of contract staff and seconded national experts expressed in full-time equivalents;

(b) prepare in close cooperation with advisory bodies referred to in Clause 7(2)(q) and submit for adoption to the Governing Board the annual work plan and the corresponding expenditure estimates;

(c) ***establish the annual accounts and*** submit ***them*** for approval to the Governing Board

(d) prepare and submit for approval to the Governing Board the annual activity report, including the corresponding expenditure;

(e) submit for approval to the Governing Board the list of proposals selected for funding;

(f) sign individual grant agreements or decisions;

(g) sign procurement contracts;

(h) implement the IMI2 Joint Undertaking's communications policy;

(i) organise, direct and supervise the operations and the staff of the IMI2 Joint Undertaking within the constraints of the delegation by the Governing Board as provided for in Article 6(2) of this Regulation;



(j) establish and ensure the functioning of an effective and efficient internal control system and report any significant change to it to the Governing Board;

(k) ensure that risk assessment and risk management are performed;

(l) take any other measures needed for assessing the progress of the IMI2 Joint Undertaking towards achieving its objectives;

5. The Executive Director shall set up a Programme Office for the execution, under his/her responsibility, of all support tasks arising from this Regulation. The Programme Office shall be composed of the staff of the IMI2 Joint Undertaking and shall in particular carry out the following tasks:

(a) provide support in establishing and managing an appropriate accounting system in accordance with the Financial rules of the IMI2 Joint Undertaking;

(b) manage the calls *for proposals* as provided for in the annual work plan and administer the grant agreements or decisions, including their coordination;

(c) provide to the Members and to the other bodies of the IMI2 Joint Undertaking all relevant information and support necessary for them to perform their duties as well as responding to their specific requests;

(d) act as the secretariat of the bodies of the Joint Undertaking and provide support to

(j) establish and ensure the functioning of an effective and efficient internal control system and report any significant change to it to the Governing Board;

(k) ensure that risk assessment and risk management are performed;

***(ka) implement and follow-up on any recommendations resulting from the final evaluation of the IMI Joint Undertaking, the interim evaluation of the IMI2 Joint Undertaking or any other relevant assessment of the IMI2 activities in a timely manner;***

(l) take any other measures needed for assessing the progress of the IMI2 Joint Undertaking towards achieving its objectives;

5. The Executive Director shall set up a Programme Office for the execution, under his/her responsibility, of all support tasks arising from this Regulation. The Programme Office shall be composed of the staff of the IMI2 Joint Undertaking and shall in particular carry out the following tasks:

(a) provide support in establishing and managing an appropriate accounting system in accordance with the Financial rules of the IMI2 Joint Undertaking;

(b) manage the calls, ***including the evaluation by a panel of independent experts***, as provided for in the annual work plan and administer the grant agreements or decisions, including their coordination;

***(ba) set up and manage an information and promotion system for wide participation in the JU activities, namely the calls for proposals, including a link to the National Contact Point system***

(c) provide to the Members and to the other bodies of the IMI2 Joint Undertaking all relevant information and support necessary for them to perform their duties as well as responding to their specific requests;

(d) act as the secretariat of the bodies of the Joint Undertaking and provide support to

any advisory group set up by the Governing Board.

any advisory group set up by the Governing Board.

#### Amendment 49

##### Proposal for a regulation Annex 1 – clause 10

###### *Text proposed by the Commission*

1. The Scientific Committee shall consist of no more than **7** members appointed for a renewable period of **one** year. It shall elect a chairperson from amongst its members **for one year**.

Additional experts may be appointed if necessary for specific ad-hoc tasks and limited duration.

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.

3. The Governing Board shall establish the specific criteria and selection process for the composition of the Scientific Committee and shall appoint its members. The Governing Board shall take into consideration the potential candidates proposed by the IMI2 States Representatives Group.

4. The Scientific Committee shall carry out the following tasks:

###### *Amendment*

1. The Scientific Committee shall consist of no more than **15** members appointed for a renewable period of **two** year. It shall elect a chairperson from amongst its members **up to two years. Its composition shall seek to achieve gender equality in accordance with Article 16 of the Horizon 2020 Framework Programme**

Additional experts may be appointed if necessary for specific ad-hoc tasks and limited duration, **and their selection will follow the same procedure as the permanent members of the Scientific Committee.**

2. The members of the Scientific Committee shall reflect a balanced representation of world-wide recognized **independent** experts from academia, **medical profession**, 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.

3. The Governing Board shall establish the specific criteria and selection process for the composition of the Scientific Committee and shall appoint its members. The Governing Board shall take into consideration the potential candidates proposed by the IMI2 States Representatives Group.

4. The Scientific Committee shall carry out the following tasks:

**(-a) advise on the scientific priorities to be included in the Strategic Research**

*Agenda taking into consideration, the results of the reviews of the Horizon 2020 Scientific Panel for Health as well as societal preferences gathered through public engagement exercises;*

(a) advise on the scientific priorities to be addressed in the annual work plans;

(a) advise on the scientific priorities to be addressed in the annual work plans, **including draft call texts;**

(b) advise on the scientific achievements described in the annual activity report.

(b) advise on the scientific achievements described in the annual activity report.

***(ba) draw up an annual report on the progress of the research and development activities and make it publicly available***

***(bb) draw up recommendations to the Commission for the interim evaluation of the IMI2 Joint Undertaking to be conducted by 31 June 2017. The interim evaluation will also assess the take-up of societal preferences resulting from the engagement exercises***

***The advice of the Scientific Committee shall duly be taken into account.***

***4a. The Scientific Committee may issue, on its own initiative, recommendations to the IMI2 Joint Undertaking on technical, managerial and scientific matters.***

***The IMI2 Joint Undertaking shall inform the Scientific Committee of the follow up it has given to such recommendations, giving reasons where it does not take up those recommendations***

5. The Scientific Committee shall meet at least **once** a year. The meetings shall be convened by its chairperson.

5. The Scientific Committee shall meet at least **twice** a year. The meetings shall be convened by its chairperson. ***The draft agenda, final agenda and minutes of the meetings shall be published on the IMI website, without prejudice to confidentiality***

6. The Scientific Committee may, with the agreement of the chairperson, invite other persons to attend its meetings.

6. The Scientific Committee may, with the agreement of the chairperson, invite other persons to attend its meetings.

***6a. The Scientific Committee shall receive information on a regular basis, in particular on the participation in indirect actions funded by the IMI2 Joint***

***Undertaking, on the outcome of each call and project implementation, on synergies with other relevant Union programmes, on the execution of the IMI2 budget and on the dissemination and exploitation of research results.***

7. The Scientific Committee shall adopt its own rules of procedure.

7. The Scientific Committee shall adopt ***and make publicly available*** its own rules of procedure.

## **Amendment 50**

### **Proposal for a regulation Annex 1 – clause 10 – paragraph 3**

*Text proposed by the Commission*

3. The Governing Board shall establish the specific criteria and selection process for the composition of the Scientific Committee and shall appoint its members. The Governing Board shall ***take into consideration*** the potential candidates proposed by the IMI2 States Representatives Group.

*Amendment*

3. The Governing Board shall establish the specific criteria and selection process for the composition of the Scientific Committee and shall appoint its members. The Governing Board shall ***appoint its members from*** the potential candidates proposed by the IMI2 States Representatives Group.

## **Amendment 51**

### **Proposal for a regulation Annex 1 – clause 11**

*Text proposed by the Commission*

States Representatives Group

1. The IMI2 States Representatives Group shall consist of one representative of each Member State and of each country associated to the Horizon 2020 Framework Programme. It shall elect a chairperson from amongst its members.

2. The States Representatives Group shall meet at least ***once*** a year. The meetings shall be convened by its chairperson. The chairperson of the Governing Board and the Executive Director or their representatives shall attend the meetings.

*Amendment*

States Representatives Group

1. The IMI2 States Representatives Group shall consist of one representative of each Member State and of each country associated to the Horizon 2020 Framework Programme. It shall elect a chairperson from amongst its members.

2. The States Representatives Group shall meet at least ***twice*** a year. The meetings shall be convened by its chairperson. The chairperson of the Governing Board and the Executive Director or their representatives shall attend the meetings. ***The draft agenda, final agenda and minutes of the meetings shall be***

*published on the IMI website, without prejudice to confidentiality.*

*The chairperson of the States Representatives Group may invite other persons to attend its meetings as observers, in particular representatives of regional authorities of the Union, representatives of SME associations, representatives of civil society organisations and representatives of patients' organisations.*

3. The States Representatives Group shall in particular review information and provide advice on the following matters:

(a) programme progress in the IMI2 Joint Undertaking and achievement of its targets;

(b) updating of strategic orientation;

(c) *links to* the Horizon 2020 Framework Programme;

(d) annual work plans;

(e) involvement of SMEs.

4. The States Representatives Group shall also provide information to and act as an interface with the IMI2 Joint Undertaking on the following matters:

(a) the status of relevant national or regional research and innovation programmes and identification of potential areas of cooperation, including deployment;

(b) specific measures taken at national level or regional level with regard to

3. The States Representatives Group shall in particular review information and provide advice on the following matters:

(a) programme progress in the IMI2 Joint Undertaking and achievement of its targets, ***including the calls for proposals, evaluation process and outcome at the same level of comprehensiveness and detail as the one provided to the Programme Committee;***

(b) updating of strategic orientation;

(c) ***compliance with*** the Horizon 2020 Framework Programme;

(d) annual work plans, ***including draft call texts;***

***(da) the advisability of including a given research priority covered by IMI2 Joint Undertaking in regular calls in the Horizon 2020 Framework Programme in order to develop new synergies with research and innovation activities of strategic importance;***

(e) involvement of SMEs.

4. The States Representatives Group shall also provide information to and act as an interface with the IMI2 Joint Undertaking on the following matters:

(a) the status of relevant national or regional research and innovation programmes and identification of potential areas of cooperation, including deployment;

(b) specific measures taken at national level or regional level with regard to

dissemination events, dedicated technical workshops and communication activities.

dissemination events, dedicated technical workshops and communication activities.

***4a. The States Representatives Group shall receive information on a regular basis, in particular on the participation in indirect actions funded by the IMI2 Joint Undertaking, on the outcome of each call and project implementation, on synergies with other relevant Union programmes, on the execution of the IMI2 budget and on the dissemination and exploitation of research results.***

5. The States Representatives Group may issue, on its own initiative, recommendations to the IMI2 Joint Undertaking on technical, managerial and financial matters, in particular when those matters affect national or regional interests.

5. The States Representatives Group may issue, on its own initiative, recommendations to the IMI2 Joint Undertaking on technical, managerial and financial matters, in particular when those matters affect national or regional interests.

The IMI2 Joint Undertaking shall inform the States Representatives Group of the follow up it has given to such recommendations.

The IMI2 Joint Undertaking shall inform the States Representatives Group of the follow up it has given to such recommendations.

6. The States Representatives Group shall adopt its own rules of procedure.

6. The States Representatives Group shall adopt ***and make publicly available*** its own rules of procedure.

## **Amendment 52**

### **Proposal for a regulation Annex 1 – clause 12**

#### *Text proposed by the Commission*

#### *Amendment*

#### 12. Stakeholder Forum

#### 12. Stakeholder Forum

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.

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's organisations, and other civil society organisations. It shall elect a chairperson among its members.***

2. The Stakeholder Forum shall be informed of the activities of the IMI2 Joint Undertaking and shall be invited to provide comments.

2. The Stakeholder Forum shall be informed of the activities of the IMI2 Joint Undertaking, and shall be invited to provide comments ***on a regular basis, in***

*particular on the participation in indirect actions funded by the IMI2 Joint Undertaking, on the outcome of each call and project implementation, on synergies with other relevant Union programmes, on the execution of the IMI2 budget and on the dissemination and exploitation of research results, and shall be invited to provide comments, including on the priorities of the Strategic Research Agenda.*

3. The meetings of the Stakeholder Forum shall be convened by the Executive Director.

3. The meetings of the Stakeholder Forum shall be convened by the Executive Director *at least once a year.*

### **Amendment 53**

#### **Proposal for a regulation Annex 1 – clause 14 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

*Where any member of the IMI2 Joint Undertaking is in default of its commitments concerning its agreed financial contribution, the Executive Director shall put this in writing and set a reasonable period within which such default shall be remedied. If the situation is not remedied within that period, the Executive Director shall convene a meeting of the Governing Board to decide whether the defaulting member's membership is to be revoked or if any other measures are to be taken until that member's obligations have been met. The Governing Board may initially suspend the voting rights of all members in breach of their obligations, once they have been heard and given the opportunity of regularising matters.*

### **Amendment 54**

#### **Proposal for a regulation Annex 1 – clause 17**

*Text proposed by the Commission*

*Amendment*

## Operational and financing reporting

1. The Executive Director shall report annually to the Governing Board on the performance of his duties in accordance with the Financial rules of the Joint Undertaking.

**By 15 February each year the** Executive Director shall submit to the Governing Board for approval an annual activity report on the progress made by the IMI2 Joint Undertaking in the previous calendar year, in particular in relation to the annual work plan for that year. That report shall include, inter alia, information on the following matters:

- (a) research, innovation and other actions carried out and the corresponding expenditure;
  - (b) proposals submitted, including a breakdown by participant type, including SMEs, and by country;
  - (c) the actions selected for funding, including a breakdown by participant type, including SMEs, and by country and indicating the contribution of the IMI2 Joint Undertaking to the individual participants and actions.
2. Once approved by the Governing Board, the annual activity report shall be made publicly available.
3. The IMI2 Joint Undertaking **shall report annually to the Commission in accordance with Article 60(5) of Regulation (EU, Euratom) No 966/2012.**

## Operational and financing reporting

1. The Executive Director shall report annually to the Governing Board on the performance of his duties in accordance with the financial rules of the IMI2 Joint Undertaking.

**Within two months of the closure of each financial year,** Executive Director shall submit to the Governing Board for approval an annual activity report on the progress made by the IMI2 Joint Undertaking in the previous calendar year, in particular in relation to the annual work plan for that year. That report shall include, inter alia, information on the following matters:

- (a) research, innovation and other actions carried out and the corresponding expenditure;
  - (b) proposals submitted, including a breakdown by participant type, including SMEs, and by country;
  - (c) the actions selected for funding, including a breakdown by participant type, including SMEs, and by country and indicating the contribution of the IMI2 Joint Undertaking to the individual participants and actions.
2. Once approved by the Governing Board, the annual activity report shall be made publicly available.
3. **By 1 March of the following financial year, the accounting officer of the IMI2 Joint Undertaking shall send the provisional accounts to the Commission's accounting officer and the Court of Auditors.**

**By 31 March of the following financial year, the IMI2 Joint Undertaking shall send the report on the budgetary and financial management to the European Parliament, the Council and the Court of Auditors.**

**On receipt of the Court of Auditors' observations on the IMI2 Joint Undertaking's provisional accounts**



*pursuant to Article 148 of the Financial Regulation, the accounting officer shall draw up the IMI2 Joint Undertaking's final accounts; the Executive Director shall submit them to the Governing Board for an opinion.*

*The Governing Board shall deliver an opinion on the IMI2 Joint Undertaking's final accounts.*

*The Executive Director shall, by 1 July following each financial year, send the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Governing Board's opinion.*

*The final accounts shall be published in the Official Journal of the European Union by 15 November of the following year.*

*The Executive Director shall send the Court of Auditors a reply to its observations made in its annual report by 30 September. The Executive Director shall also send this reply to the Governing Board.*

*The Executive Director shall submit to the European Parliament, at its request any information required for the smooth application of the discharge procedure for the financial year in question, in accordance with Article 165(3) of Regulation (EU, Euratom) No 966/2012.*

***4. The accounts of the IMI2 Joint Undertaking shall be examined by an independent audit body as laid down in Article 60(5) of Regulation (EU, Euratom) No 966/2012.***

**Amendment 55**

**Proposal for a regulation  
Annex 1 – clause 18 a (new)**

*Text proposed by the Commission*

*Amendment*

**18a - Indicators**

**The performance indicators for assessing progress against the objectives set in Article 2 are:**

**Scientific and technological progress**

	<b>Indicator</b>	<b>Target</b>
<b>Monitoring achievement of objectives of the JU</b>	<b>Monitoring the achievement of specific objectives</b>	<b>See section 3.2 of the Impact Assessment Report</b>
	<b>Number of open innovation networks established</b>	<b>3 open innovation network between different industry sectors, and 2 clinical trial networks</b>
	<b>Number of strategic agenda setting beyond JU</b>	<b>Strategic agenda setting in 3 research areas defined by the specific objectives in section 3.2;</b>
<b>Monitoring implementation of the strategic research agenda</b>	<b>Number of partnerships established</b>	<b>Partnerships in 16 research areas defined by the specific objectives in section 3.2</b>
	<b>Number of data points analysed for reaching at unbiased molecular taxonomy of disease</b>	<b>5 million data points</b>
	<b>Number of diseases classified</b>	<b>4 diseases area</b>
	<b>Number of trials analysed for learning from negative results</b>	<b>125 trials</b>
	<b>Level of taking account of health and demographic change and wellbeing policy goals</b>	<b>Strategic research agenda needs to address points 1.1.2, 1.2.2, parts of 1.2.3 and parts of 1.3.1 of partial general approach of the Horizon 2020 Framework Programme</b>
<b>Monitoring JU operations</b>		
<b>Selection of projects and allocation of funding</b>	<b>Time-to-grant</b>	<b>270 days</b>

	<i>Time-to-pay</i>	<i>30 days</i>
	<i>Level of adherence to time schedule</i>	<i>Budget committed and calls launched accordingly</i>
	<i>Level of SME participation and benefits</i>	<i>From the beginning 20% IMI2 funding going to SMEs, benefit to SMEs monitored as from 2nd year: at least 70% of SME respondents stating that they benefit from the expertise of industry and/or academic partners; 80% of SMEs stating that objectives could not have been met without IMI2 support.</i>
<i>Efficiency of research programme</i>	<i>Number of publications</i>	<i>On average 20 publications per EUR 10 million funding</i>
	<i>Impact factor of journals where articles are published</i>	<i>Average impact factor 10% above EU average</i>
	<i>Impact of publications</i>	<i>Citations 20% above average for EU publications</i>
	<i>Number of patents</i>	<i>On average 2 patent applications per EUR 10 million funding</i>
	<i>R&amp;D intensity</i>	<i>Percentage of interannual variation of the proportion of yearly expenditure in R&amp;D with respect to total expenditure of EFPIA companies</i>

*Justification*

*The rapporteur believes 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, has been introduced.*

**Amendment 56**

**Proposal for a regulation**  
**Annex 1 – clause 20**

*Text proposed by the Commission*

20. Conflict of interest

1. The IMI2 Joint Undertaking, its bodies and staff shall avoid conflict of interest in the implementation of their activities.
2. The IMI2 Joint Undertaking Governing Board may adopt rules for the prevention and management of conflicts of interest in respect of its Members, Associated Partners, bodies and staff. In those rules, provision shall be made to avoid conflict of interest for the representatives of the Members serving the Governing Board.

*Amendment*

20. Conflict of interest

1. The IMI2 Joint Undertaking, its bodies and staff shall avoid conflict of interest in the implementation of their activities.
2. The IMI2 Joint Undertaking Governing Board may **shall** adopt rules for the prevention and management of conflicts of interest in respect of its Members, Associated Partners, bodies and staff. In those rules, provision shall be made to avoid conflict of interest for the representatives of the Members serving the Governing Board. ***In particular those rules shall clarify the details to be published in the declaration of full professional activities, of financial interests and of conflict of interests.***

**Amendment 57**

**Proposal for a regulation  
Annex 1 – clause 21**

*Text proposed by the Commission*

21. Winding up

1. The IMI2 Joint Undertaking shall be wound up at the end of the period in Article 1 of this Regulation.
2. The winding up procedure shall be automatically triggered if the Commission or all other Members withdraw from the IMI2 Joint Undertaking.
3. For the purpose of conducting the proceedings to wind up the IMI2 Joint Undertaking, the Governing Board shall appoint one or more liquidators, who shall comply with the decisions of the Governing Board.
4. When the IMI2 Joint Undertaking is being wound up, its assets shall be used to cover its liabilities and the expenditure

*Amendment*

21. Winding up

1. The IMI2 Joint Undertaking shall be wound up at the end of the period in Article 1 of this ***or if the evaluation demonstrates that the objectives of the undertaking are not fulfilled.***
2. The winding up procedure shall be automatically triggered if the Commission or all other Members withdraw from the IMI2 Joint Undertaking.
3. For the purpose of conducting the proceedings to wind up the IMI2 Joint Undertaking, the Governing Board shall appoint one or more liquidators, who shall comply with the decisions of the Governing Board.
4. When the IMI2 Joint Undertaking is being wound up, its assets shall be used to cover its liabilities and the expenditure

relating to its winding up. Any surplus shall be distributed among the Members at the time of the winding up in proportion to their financial contribution to the IMI2 Joint Undertaking. Any such surplus distributed to the Union shall be returned to the Union budget.

5. An ad hoc procedure shall be set up to ensure the appropriate management of any agreement concluded or decision adopted by the IMI2 Joint Undertaking as well as any procurement contract with a duration longer than its duration.

relating to its winding up. Any surplus shall be distributed among the Members at the time of the winding up in proportion to their financial contribution to the IMI2 Joint Undertaking. Any such surplus distributed to the Union shall be returned to the *specific programme implementing the Horizon 2020 Framework Programme within the* Union budget.

5. An ad hoc procedure shall be set up to ensure the appropriate management of any agreement concluded or decision adopted by the IMI2 Joint Undertaking as well as any procurement contract with a duration longer than its duration.