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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	14 February 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2014) 954 final
Subject:	COMMISSION DELEGATED REGULATION (EU) No …/.. of 14.2.2014 establishing a derogation from Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" with regard to the Innovative Medicines Initiative 2 Joint Undertaking

Delegations will find attached document C(2014) 954 final.

Encl.: C(2014) 954 final

EUROPEAN
COMMISSION

Brussels, 14.2.2014
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COMMISSION DELEGATED REGULATION (EU) No …/..

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establishing a derogation from Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" with regard to the Innovative Medicines Initiative 2 Joint Undertaking

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

In the context of Horizon 2020, the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU) set up by Council Regulation (EU) No / has been proposed for the implementation of a public-private partnership in the field of innovative medicines. It replaces and succeeds IMI JU as established by Regulation (EC) No 73/2008. IMI2 JU will be a public-private partnership between the European Commission and the European Federation of Pharmaceutical Industries and Associations but open at the same time to life-science industries. It aims at improving the health and wellbeing of European citizens by providing new and more effective diagnostics and treatments, while helping safeguard the future international competitiveness of the European biopharmaceutical and life-science industries such as diagnostics, vaccines, biomedical imaging and medical information technologies

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)" will apply to the IMI2 JU. However, given the specific operating needs of this initiative as described in section 3 below, derogations from this regulation are necessary.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission organised two meetings, on 17 and 25 September 2013, with experts nominated by the Member States to present and discuss the draft delegated act. The comments made by experts during the meetings and received in writing after the meetings were taken into account to a wide extent. Consequently, a large majority of experts endorsed the attached version of the draft delegated act. Copies of the initial and final drafts were sent in parallel to the European Parliament and to the Council.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This delegated act is adopted on the basis of Article 290 TFEU and according with the empowerment given by the Council and the European Parliament to the Commission in Articles 1(3) and 56 of the 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)".

According to Article 1(3), in order to take into account the specific operating needs of funding bodies set up under Article 187 TFEU, the Commission is empowered to adopt delegated acts in accordance with Article 56 of the same regulation.

For the IMI2 JU, the Commission is empowered to adopt a delegated act regarding the eligibility for funding and the intellectual property rules. The first derogation is justified by the fact that IMI2 JU will continue to focus on funding entities such as SMEs, secondary and higher education establishments, and non-profit organizations. The second derogation is necessary in order to foster use of project results and innovation, and thus facilitate the delivery of innovative medicines to patients and the improvement of the drug research and development in Europe.

4. BUDGETARY IMPLICATION

There is no specific budgetary implication with respect to the EU contribution to the IMI2 JU as established in the proposed Council Regulation.

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[1], and in particular Article 1(3)(b) and points (i) to (vii) of Article 1(3)(c) thereof,

Whereas:

(1) Regulation (EU) No 1291/2013 of the European Parliament and of the Council[2] establishes the Framework Programme for Research and Innovation (2014-2020) (Horizon 2020) and provides for the involvement of the Union in public-private partnerships, including in joint undertakings, in key areas where research and innovation can contribute to the Union's wider competitiveness goals and help tackle societal challenges.

(2) Participation in indirect actions under Horizon 2020 should comply with Regulation (EU) No 1290/2013. However, in order to take into account the specific operating needs of joint undertakings established pursuant to Article 187 of the Treaty in the area of innovative medicines, the power to adopt acts in accordance with Article 290 of the Treaty was delegated to the Commission for the duration of Horizon 2020 with a view to allowing funding bodies established under Article 187 of the Treaty to limit the eligibility for funding to specific types of participants and to adopt specific intellectual property rules.

(3) The Innovative Medicines Initiative Joint Undertaking was set up by Council Regulation (EC) No 73/2008[3] for a period up to 31 December 2017 in order to foster

[1] OJ L 347, 20.12.2013, p. 81.
[2] OJ L 347, 20.12.2013, p. 104.
[3] Council Regulation (EC) No 73/2008 of 20 December 2007 setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines, (OJ L 30, 4.02.2008, p.38).

collaboration between all stakeholders such as industry, public authorities (including regulators), organisations of patients, universities and clinical centres and to improve the efficiency and effectiveness of the drug development process with the long term aim that the pharmaceutical sector produce more effective and safer innovative medicines.

(4) Specific operating needs, substantiated by the aim of the Innovative Medicines Initiative (IMI) to bring together large industrial partners with non-profits, public entities or other entities and to maximize exploitation of project results which could bring medicines to patients faster, have been identified as referring to eligibility for funding and intellectual property rules. The Innovative Medicines Initiative 2 Joint Undertaking set up by Council Regulation (EU) No /2014[4] should continue to provide funding to entities such as micro, small and medium-sized enterprises, secondary and higher education establishments, and non-profit organizations, therefore a derogation from Article 10(1) of Regulation (EU) No 1290/2013 is necessary.

(5) Specific operating needs have been identified regarding intellectual property rules in the context of the Innovative Medicines Initiative 2 objectives, in order to achieve an open innovation model, a dynamic system of knowledge sharing providing wider possibilities to create and exploit the knowledge resulted from the IMI projects and wide access of participants, affiliates and third parties to this knowledge, with the ultimate goal of speeding up the development of diagnostics and medical intervention for patients' benefit, including by stimulating clinical, translational research and clinical trials, in particular in the areas of public health interest and high unmet medical need, as identified in the World Health Organisation priority medicines report issued on 9 July 2013[5]. Those conditions should apply to all participants in order to protect their background, results and sideground. It is appropriate to allow for the transfer and licensing of results and background and for access rights to the results and background of other participants in order to allow research to be carried out. It is appropriate in that context to differentiate, in the context of exploitation, between research use and direct exploitation. Those conditions should also take into account the participants' prior obligations, while providing for potential direct exploitation of results, including clinical trials on the results *per se*. In order to widely exploit results and facilitate the delivery of innovative medicines to patients and to improve drug research and development, it is necessary to establish derogations from Articles 41 and 44 to 48 of Regulation (EU) No 1290/2013,

HAS ADOPTED THIS REGULATION:

Article 1

By way of derogation from Article 10(1) of Regulation (EU) No 1290/2013, with regard to the Innovative Medicines Initiative 2 Joint Undertaking only the following participants shall be eligible for funding from the Innovative Medicines Initiative 2 Joint Undertaking:

(a) legal entities established in a Member State or an associated country, or created under Union law; and

[4] [Complete title of Regulation + OJ ref.]

[5] Priority Medicines for Europe and the World Update Report, 2013, WHO, ISBN 978 92 4 150575 8 - http://www.who.int/medicines/areas/priority_medicines/en/.

(b) which fall within one of the following categories:

(i) micro, small and medium-sized enterprises and other companies with an annual turnover of EUR 500 million or less, the latter not being affiliated entities of companies with an annual turnover of more than 500 million; the definition of 'affiliated entities' within the meaning of Article 2(1)(2) of Regulation (EU) No 1290 /2013 shall apply *mutatis mutandis;*

(ii) secondary and higher education establishments;

(iii) non-profit organisations, including those carrying out research or technological development as one of their main objectives or those that are patient organisations.

(c) the Joint Research Centre;

(d) international European interest organisations.

Article 2

By way of derogation from Articles 41(2) and 45 to 48 of Regulation (EU) No 1290/2013, the following provisions shall apply to the ownership and access to sideground:

(a) results shall not include any sideground, as tangible or intangible output generated by a participant under the action, such as data, knowledge and information whatever their form or nature, whether or not they can be protected, but which are outside of the action objectives as defined in the grant agreement and which therefore are not needed for implementing the action or for research use of results;

(b) each participant shall remain the exclusive owner of its sideground but a different allocation of ownership may be agreed upon;

(c) participants are not required to grant access rights to sideground.

Article 3

By way of derogation from the fourth subparagraph of Article 44(1) of Regulation (EU) No 1290/2013, the following rules shall apply to the transfer and licensing of results and background for affiliated entities, purchasers and any other successor entity:

(a) a participant may, without the consent of the other participants but provided that the other participants are informed without undue delay and that the transferee agrees in writing to be bound by the grant agreement and the consortium agreement, transfer its results to any of the following:

(i) its affiliated entity;

(ii) any purchaser of all or a substantial amount of its relevant assets;

(iii) any successor entity resulting from the merger with or consolidation of such a participant.

The delay referred to in the first subparagraph shall be agreed by the participants in the consortium agreement

(b) each participant shall remain free to license, transfer or otherwise dispose of its ownership rights in background, subject to any rights and obligations of the grant agreement and the consortium agreement.

(c) where a participant transfers ownership of background, it shall pass on its obligations specified under the grant agreement and the consortium agreement, regarding that background, to the transferee including the obligation to pass those obligations on to any subsequent transferee.

(d) a participant may, without the consent of the other participants, but provided that the other participants are informed without undue delay and that the transferee agrees in writing to be bound by the grant agreement and the consortium agreement, transfer its background to any of the following:

(i) its affiliated entity;

(ii) any purchaser of all or a substantial amount of its relevant assets;

(iii) any successor entity resulting from the merger with or consolidation of such a participant.

The delay referred to in the first subparagraph shall be agreed by the participants in the consortium agreement.

Article 4

By way of derogation from Article 44(2) of Regulation (EU) No 1290/2013, the following shall apply to the transfer and licensing of results:

Provided that any access rights to the results can be exercised and that any additional obligations under the grant agreement or consortium agreement are complied with by the participant who owns results, the latter may grant licences or otherwise give the right to exploit them to any legal entity.

Article 5

By way of derogation from Article 46(2) of Regulation (EU) No 1290/2013, the following shall apply to access rights principles:

Any legal entity that enjoys access rights in order to complete the action or for research use may authorize another legal entity to exercise those rights on its behalf provided that the following conditions are fulfilled:

(a) the legal entity that enjoys access rights shall be liable for the acts of the other legal entity as if those acts have been performed by this former legal entity;

(b) access rights granted to the other legal entity shall not include the right to sub-license.

Article 6

By way of derogation from Article 47 of Regulation (EU) No 1290/2013, the following shall apply to the access rights for implementation:

(a) during the action, participants shall enjoy access rights to the results of the other participants solely for the purpose and to the extent necessary for undertaking and completing the action. Such access shall be granted on a royalty-free basis;

(b) during the action, the participants shall, unless prevented or restricted from doing so by obligations to others which exist at the date of accession to the grant agreement, enjoy access rights to the background of the other participants solely for the purpose and to the extent necessary for undertaking and completing the action. Such access shall be granted on a royalty-free basis.

Article 7

By way of derogation from Article 48 of Regulation (EU) No 1290/2013, the following rules shall apply:

(a) The following definitions as regards exploitation shall apply:

(i) 'research use' means the use of results or background needed to use results, for all purposes other than for completing the action or for direct exploitation and which includes but is not limited to the application of results as a tool for research, including clinical research and trials and which directly or indirectly contributes to the objectives set out in the Societal Challenge health, demographic change and well-being referred to in Regulation (EU) No 1291/2013.

(ii) 'direct exploitation' means developing results for commercialization, including through clinical trials, or commercializing results themselves.

(b) During and after completion of the action, participants and their affiliated entities shall enjoy access rights to the results of the other participants for research use.

Access rights for research use shall be granted on a non-exclusive basis under fair and reasonable conditions, i.e. appropriate conditions, including financial terms or royalty-free, taking into account the actual or potential value of the results to which access is requested and other characteristics of the research use envisaged.

Where direct exploitation by a participant or third party requires results owned by another participant, the access rights may be negotiated between the parties involved.

(c) During and after completion of the action, participants and their affiliated entities shall enjoy access rights to the background of the other participants, only to the extent reasonably required for the purpose of the research use of results.

Such access rights for research use shall be granted on a non-exclusive basis under fair and reasonable conditions, i.e. appropriate conditions, including financial terms

or royalty-free, taking into account the actual or potential value of the background to which access is requested and other characteristics of the research use envisaged.

Participants are not required to grant access rights for direct exploitation to their own background and may use, exploit, sublicense or otherwise commercialize their background as they see fit, subject to access rights for research use.

Where direct exploitation by a participant or third party, requires background necessary to use results owned by another participant, the access rights may be negotiated between the parties involved.

(d) After the completion of the action, third parties shall have the right to request and receive access rights to the results of the participants for research use.

Such access rights shall be granted on a non-exclusive basis under conditions considered appropriate by the owner of the results and the third party concerned. Those conditions shall not be more favorable than the conditions applied to participants and affiliates for research use.

(e) After completion of the action, third parties shall have the right to request and receive access rights to the background of the participants, only to the extent reasonably required for the purpose of the research use of results.

Such access rights shall be granted on a non-exclusive basis under conditions considered appropriate by the owner of the background and the third party concerned.

(f) Before the signature of the grant agreement, a participant may identify specific elements of the background and provide a reasoned request to the Innovative Medicines Initiative 2 Joint Undertaking Programme office that such elements shall be wholly or partially excluded from the obligations referred to in Article 7(e).

The Innovative Medicines Initiative 2 Joint Undertaking Programme office shall only grant such request in exceptional circumstances and in making its decision shall consider the objectives referred to in Article of Regulation (EU) No /2014, the tasks of the Innovative Medicines Initiative 2 Joint Undertaking referred to in its statutes and the legitimate interests of the participant concerned. It may grant such request on conditions agreed with the participant. Any exceptions shall be included in the grant agreement and cannot be changed unless such change is permitted by the grant agreement.

(g) Participants shall agree in the consortium agreement on a time-limit in respect of requests for access under points (b) to (e).

Article 8

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14.2.2014

For the Commission
The President
José Manuel BARROSO