Commission Delegated Regulation (EU) No 622/2014 of 14 February 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 (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) No 622/2014

of 14 February 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

(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

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) No 622/2014. (See end of Document for details)*

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 557/2014[(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

(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.