Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (Text with EEA relevance)

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 187 and the first paragraph of Article 188 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the European Economic and Social Committee,

Whereas:

(1) Public-private partnerships in the form of Joint Technology Initiatives were initially provided for in Decision No 1982/2006/EC of the European Parliament and of the Council[(1)].

(2) Council Decision 2006/971/EC[(2)] identified specific public-private partnerships to be supported, including a public-private partnership on Innovative Medicines Joint Technology Initiative between the Union and the European Federation of Pharmaceutical Industries and Associations ('EFPIA').

(3) Commission Communication entitled 'Europe 2020 A Strategy for smart, sustainable and inclusive growth' (the 'Europe 2020 Strategy'), endorsed by the European Parliament and the Council, emphasises the need to develop favourable conditions for investment in knowledge and innovation so as to achieve smart, sustainable and inclusive growth in the Union.

(4) Regulation (EU) No 1291/2013 of the European Parliament and of the Council[(3)] established Horizon 2020 — The Framework Programme for Research and Innovation (2014-2020) ('Horizon 2020'). Horizon 2020 aims to achieve a greater impact with respect to research and innovation by combining Horizon 2020 and private sector funds in public-private partnerships in key areas where research and innovation can contribute to the Union's wider competitiveness goals, leverage private investment and help tackle societal challenges. Those partnerships should be based on a long-term commitment, including a balanced contribution from all partners, be accountable for the achievement of their objectives 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 give the opportunity to a wide

Changes to legislation: *There are currently no known outstanding effects for the Council Regulation (EU) No 557/2014. (See end of Document for details)*

range of stakeholders active in their specific areas to participate. In accordance with Regulation (EU) No 1291/2013, Union involvement in those partnerships may take the form of financial contributions to joint undertakings established on the basis of Article 187 of the Treaty on the Functioning of the European Union under Decision No 1982/2006/EC.

(5) In accordance with Regulation (EU) No 1291/2013 and Council Decision 2013/743/EU[(4)], further support should be provided to joint undertakings established under Decision No 1982/2006/EC under the conditions specified in Decision 2013/743/EU.

(6) The Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines ('IMI Joint undertaking') set up by Council Regulation (EC) No 73/2008[(5)] has demonstrated the effective mobilisation of resources by bringing together several partners from the pharmaceutical industry, academia, small and medium-sized enterprises ('SMEs'), patient organisations and regulators.

(7) The IMI Joint Undertaking has also stepped up cooperation between stakeholders in the health research and innovation field by allowing access to other partners' expertise and increasing the collaboration between the pharmaceutical industry and other stakeholders in the Union by developing comprehensive research agendas and horizontal policy coordination. No other European or national programme has enabled cross-company collaboration within the pharmaceutical sector on the scale that has been achieved by the Joint Technology Initiative on Innovative Medicines. The interim evaluation of the IMI Joint Undertaking underlined that it enables mutual learning and provides an opportunity to improve the reciprocal understanding of the stakeholders, thus benefiting all parties, and that it has significantly contributed to the transition towards an open innovation model in biopharmaceutical research.

(8) Research related to the future of medicine should be undertaken in areas where combination of societal, public health and biomedical industry competitiveness goals requires the 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 cover all areas of life science research and innovation of public health interest, as identified by the World Health Organisation report on priority medicines for Europe and the World, which has been updated in 2013. The initiative should consequently seek to involve a broader range of partners, including mid-caps, from different sectors, such as biomedical imaging, medical information technology, diagnostic and 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.

(9) A new joint undertaking should be established for the implementation of the Joint Technology Initiative on Innovative Medicines ('IMI2 Joint Undertaking') and should replace and succeed the IMI Joint Undertaking. The IMI2 Joint Undertaking should seek to foster the capacity of smaller actors such as research organisations, universities and SMEs for participating in open innovation models and to promote the involvement of SMEs in its activities, in line with its objectives.

(10) 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 and should be implemented using a structure and rules that are more fit for its purpose in order to enhance efficiency and ensure simplification at operational level. To that effect, the 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 of the Council[(6)].

(11) The Members other than the Union of the IMI2 Joint Undertaking have agreed to pursue the research activities in the area of activities of the IMI2 Joint Undertaking within a structure better adapted to the nature of a public-private partnership. It is appropriate that the Members other than the Union of the IMI2 Joint Undertaking accept the Statutes contained in the Annex to this Regulation by means of a letter of endorsement.

(12) As a means to further develop the IMI2 Joint Undertaking's objectives, membership should also be open to other legal entities. Moreover, legal entities interested in supporting the IMI2 Joint Undertaking's objectives in their specific areas of research should be offered the possibility to become Associated Partners of the IMI2 Joint Undertaking.

(13) It should be possible for any eligible institution to become a participant or a coordinator in the selected projects.

(14) To achieve its objectives, the IMI2 Joint Undertaking should provide financial support to participants mainly in the form of grants following open and competitive calls for proposals.

(15) The participants should be fully informed about applicable legal and procedural conditions, including those laid down on the basis of Article 1(3) of Regulation (EU) No 1290/2013 of the European Parliament and of the Council[(7)], especially regarding eligibility for funding and the exploitation and dissemination of results. Those conditions should be consistent and reasonable and should ensure equitable and fair treatment of participants regarding ownership of and access to the results generated within the IMI2 Joint Undertaking's projects.

(16) The contributions from the Members other than the Union should relate to the administrative costs of the IMI2 Joint Undertaking and, together with the contributions from the Associated Partners for their specific area of research, to the co-financing required to carry out research and innovation actions supported by the IMI2 Joint Undertaking.

(17) Participation in indirect actions funded by the IMI2 Joint Undertaking should comply with Regulation (EU) No 1290/2013. The IMI2 Joint Undertaking should, moreover, ensure consistent application of those rules based on relevant measures adopted by the Commission.

(18) The IMI2 Joint Undertaking should also use electronic means managed by the Commission to ensure openness and transparency and facilitate participation.

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Therefore, the calls for proposals launched by the IMI2 Joint Undertaking should also be published on the single portal for participants as well as through other Horizon 2020 electronic means of dissemination managed by the Commission. Moreover, relevant data on, inter alia, proposals, applicants, grants and participants should be made available by the IMI2 Joint Undertaking for inclusion in Horizon 2020 reporting and dissemination electronic systems managed by the Commission, in an appropriate format and with the periodicity corresponding to the Commission's reporting obligations.

(19) 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 Regulation (EU, Euratom) No 966/2012 and Commission Delegated Regulation (EU) No 1268/2012[8].

(20) For the purpose of simplification, the administrative burden should be reduced for all parties. Double audits and disproportionate amounts of documentation and reporting should be avoided. Audits of recipients of Union funds under this Regulation should be carried out in compliance with Regulation (EU) No 1291/2013.

(21) The financial interests of the Union and of the other Members of the IMI2 Joint Undertaking should be protected through proportionate measures throughout the expenditure cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, administrative and financial penalties in accordance with Regulation (EU, Euratom) No 966/2012.

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

(23) In view of the specific nature and the current status of the joint undertakings, and to ensure continuity with the Seventh Framework Programme, the joint undertakings should continue to be subject to a separate discharge. By way of derogation from Articles 60(7) and 209 of Regulation (EU, Euratom) No 966/2012, discharge for the implementation of the budget of the IMI2 Joint Undertaking should therefore be given by the European Parliament on the recommendation of the Council. Hence, the reporting requirements set out in Article 60(5) of Regulation (EU, Euratom) No 966/2012 should not apply to the Union financial contribution 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.

(24) The IMI2 Joint Undertaking should operate in an open and transparent way providing all relevant information in a timely manner to its appropriate bodies as well as promoting its activities, including information and dissemination activities to the wider public. The rules of procedure of the bodies of the IMI2 Joint Undertaking should be made publicly available.

(25) The Scientific Panel for Health was set up by Horizon 2020 as a science-led stakeholder platform, in order to elaborate scientific input, to provide a coherent scientific focused

analysis of research and innovation bottlenecks and opportunities related to the Horizon 2020 societal challenge on health, demographic change and well-being, to contribute to the definition of its research and innovation priorities and to encourage Union-wide scientific participation. Through active cooperation with stakeholders, it helps to build capabilities and to foster knowledge-sharing and stronger collaboration across the Union in that field. The IMI2 Joint Undertaking should, therefore, collaborate and exchange information with the Scientific Panel for Health, where appropriate.

(26) Horizon 2020 should contribute to the closing of the research and innovation divide within the Union by promoting synergies with the European Structural and Investment Funds (ESIF). Therefore the IMI2 Joint Undertaking should seek to develop close interactions with the ESIF, which can specifically help to strengthen local, regional and national research and innovation capabilities in the area of the IMI2 Joint Undertaking and underpin smart specialisation efforts.

(27) 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 actions initiated under Regulation (EC) No 73/2008 in accordance with that Regulation. The transition from the IMI Joint Undertaking to the IMI2 Joint Undertaking should be aligned and synchronised 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, Regulation (EC) No 73/2008 should therefore be repealed and transitional provisions should be set out.

(28) Given the aim of Horizon 2020 to achieve greater simplification and coherence, all calls for proposals by the IMI2 Joint Undertaking should take into account the duration of Horizon 2020.

(29) Since the objective of this Regulation, namely establishment of the IMI2 Joint Undertaking in order to strengthen industrial research and innovation across the Union cannot be sufficiently achieved by the Member States but can rather, by reason of avoiding duplication, retaining critical mass and ensuring that public financing is used in an optimal way, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAS ADOPTED THIS REGULATION:

Article 1

Establishment

1 For the implementation of the Joint Technology Initiative on Innovative Medicines, a joint undertaking within the meaning of Article 187 of the Treaty on the Functioning of the European Union ('IMI2 Joint Undertaking'), is established for a period until 31 December 2024. In order to take into account the duration of Horizon 2020, calls for proposals by the IMI2 Joint