Regulation (EU) 2020/1043 of the European Parliament and of the Council of 15 July 2020 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19) (Text with EEA relevance)

REGULATION (EU) 2020/1043 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

After consulting the European Economic and Social Committee,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[(1)],

Whereas:

(1) Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus. On 30 January 2020, the World Health Organization (WHO) declared the outbreak a public health emergency of international concern. On 11 March 2020, WHO characterised COVID-19 as a pandemic.

(2) Directive 2001/83/EC[(2)] and Regulation (EC) No 726/2004[(3)] of the European Parliament and of the Council require that applications for authorisation to place a medicinal product on the market, in a Member State or in the Union, be accompanied by a dossier containing the results of clinical trials carried out on the product.

(3) It follows from Directive 2001/20/EC of the European Parliament and of the Council[(4)] that, before commencing any clinical trial, sponsors are required to request authorisation from the competent authority of the Member State in which the clinical trial is to be conducted. The purpose of the authorisation is to protect the rights, safety and well-being of clinical trial subjects and to ensure the reliability and robustness of the data generated by the clinical trial.

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) 2020/1043 of the European Parliament and of the Council. (See end of Document for details)*

(4) Under Directive 2001/20/EC, the authorisation for a clinical trial is issued without prejudice to the application of Directives 2001/18/EC[(5)] and 2009/41/EC[(6)] of the European Parliament and of the Council.

(5) Directive 2001/18/EC provides that a deliberate release into the environment of genetically modified organisms ('GMOs') for any purpose other than for placing on the market is subject to a notification to and to written consent by the competent authority of the Member State within whose territory the release is to take place. The notification is to include an environmental risk assessment performed in accordance with Annex II to Directive 2001/18/EC and a technical dossier supplying the information specified in Annex III to that Directive.

(6) Directive 2009/41/EC provides that the risks to human health and the environment associated with the contained use of genetically modified micro-organisms are to be assessed on a case-by-case basis. To that end, that Directive provides that the user is to assess the risks to human health and the environment that the specific type of contained use may pose, using as a minimum the elements of assessment and the procedure set out in Annex III to that Directive.

(7) Clinical trials necessitate the performance of multiple operations, including the manufacture, transport and storage of the investigational medicinal products, packaging and labelling, the administration thereof to clinical trial subjects and subsequent monitoring of the subjects, and the disposal of waste and unused investigational medicinal products. Those operations may fall within the scope of Directive 2001/18/EC or 2009/41/EC in cases where the investigational medicinal product contains or consists of GMOs.

(8) Experience shows that, in clinical trials with investigational medicinal products containing or consisting of GMOs, the procedure to achieve compliance with the requirements of Directives 2001/18/EC and 2009/41/EC as regards the environmental risk assessment and consent by the competent authority of a Member State is complex and can take a significant amount of time.

(9) The complexity of that procedure increases greatly in the case of multi-centre clinical trials conducted in several Member States, as sponsors of clinical trials need to submit multiple requests for authorisation to multiple competent authorities in different Member States in parallel. In addition, national requirements and procedures for the environmental risk assessment and written consent by competent authorities for the deliberate release of GMOs under Directive 2001/18/EC vary greatly from one Member State to another. Whereas in some Member States a single request for authorisation concerning the conduct of the clinical trial and the GMO aspects can be submitted to a single competent authority, in other Member States parallel requests need to be submitted to different competent authorities. Furthermore, some Member States apply Directive 2001/18/EC, others apply Directive 2009/41/EC and there are Member States that apply either Directive 2009/41/EC or 2001/18/EC depending on the specific circumstances of a clinical trial, so it is not possible to determine *a priori* the national procedure that is to be followed. Other Member States apply both Directives simultaneously to different operations within the same clinical trial.

Attempts to streamline the process through informal coordination between Member States' competent authorities have been unsuccessful. There are also variations between national requirements as to the content of the technical dossier.

(10) It is therefore particularly difficult to conduct multi-centre clinical trials with investigational medicinal products that contain or consist of GMOs involving several Member States.

(11) The COVID-19 pandemic has created an unprecedented public health emergency that has claimed the life of thousands of people, affecting in particular the elderly and those with pre-existing health conditions. In addition, the very drastic measures that Member States have had to adopt to contain the spread of COVID-19 have inflicted major disruptions to national economies and the Union as a whole.

(12) COVID-19 is a complex disease that affects multiple physiological processes. Potential treatments and vaccines are in development. Some of the vaccines in development contain attenuated viruses or live vectors, which may fall within the definition of a GMO.

(13) In this situation of public health emergency, it is of major interest for the Union that safe and efficacious medicinal products intended to treat or prevent COVID-19 can be developed and be made available within the Union as soon as possible.

(14) To achieve the objective of making available safe and efficacious medicinal products intended to treat or prevent COVID-19, a range of measures have been taken at Union level by the European Medicines Agency (EMA) and by the network of national competent authorities to facilitate, support and speed up the development and marketing authorisation of treatments and vaccines.

(15) To generate the robust clinical evidence necessary to support applications for marketing authorisation of medicinal products intended to treat or prevent COVID-19 multi-centre clinical trials involving several Member States will need to be conducted.

(16) It is of paramount importance that clinical trials with investigational medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19 can be conducted within the Union, that they can begin as soon as possible and that they are not delayed due to the complexity of differing national procedures put in place by Member States in implementation of Directives 2001/18/EC and 2009/41/EC.

(17) The main objective of Union legislation on medicinal products is to safeguard public health. That legislative framework is supplemented by the rules in Directive 2001/20/EC laying down specific standards for the protection of clinical trial subjects. Directives 2001/18/EC and 2009/41/EC have as their objective to ensure a high level of protection of human health and the environment through the assessment of the risks from the deliberate release or the contained use of GMOs. In the unprecedented situation of public health emergency created by the COVID-19 pandemic, it is necessary that the protection of public health prevails. Therefore, it is necessary to grant a temporary derogation from the requirements concerning a prior environmental risk assessment and consent under Directives 2001/18/EC and 2009/41/EC for the duration of the COVID-19 pandemic or as long as COVID-19 is a public health emergency. The

derogation should be limited to clinical trials with investigational medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19. During the period in which the temporary derogation applies, the environmental risk assessment and consent under Directives 2001/18/EC and 2009/41/EC should not be a prerequisite for the conduct of those clinical trials.

(18) With a view to ensuring a high level of protection of the environment, sites where the genetic modification of wild-type viruses and related activities take place should continue to be required to comply with Directive 2009/41/EC. Therefore, the manufacturing of medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19, including investigational medicinal products, should be excluded from the temporary derogation. In addition, sponsors should be required to implement appropriate measures to minimise negative environmental impacts that, on the basis of the available knowledge, can be expected as a result of the intended or unintended release of investigational medicinal products into the environment.

(19) Consequently, when making an application for marketing authorisation under Directive 2001/83/EC or Regulation (EC) No 726/2004 for medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19 for which the clinical trials would be covered by the derogation provided for in this Regulation, the applicant should not be required to include the written consent of the competent authority for the deliberate release into the environment of GMOs for research and development purposes as set out in Part B of Directive 2001/18/EC.

(20) This Regulation does not affect the Union rules on medicinal products for human use. As provided in Regulation (EC) No 726/2004, the environmental impact of medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19 will continue to be assessed by the EMA in parallel with the evaluation of the quality, safety and efficacy of the medicinal product concerned, respecting the environmental safety requirements set out in Directive 2001/18/EC.

(21) Directive 2001/20/EC continues to apply and clinical trials with investigational medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19 continue to require written authorisation granted by the competent authority in each Member State in which the trial will be conducted. Compliance with ethical requirements and good clinical practice in the conduct of clinical trials continues to be mandatory as well as compliance with good manufacturing practice in the manufacture or importation of investigational medicinal products containing or consisting of GMOs.

(22) As a general rule, no medicinal product may be placed on the market in the Union or in a Member State unless a marketing authorisation has been granted by the competent authorities under Directive 2001/83/EC or Regulation (EC) No 726/2004. Nonetheless, Directive 2001/83/EC and Regulation (EC) No 726/2004 provide for exceptions from that requirement in situations characterised by an urgent need to administer a medicinal product to address the specific needs of a patient, for compassionate use or in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation that could cause harm. In particular, Article 5(1) of Directive 2001/83/EC allows Member States to fulfil special needs, to exclude from the provisions