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

2020/0128(COD) - 17/06/2020 - Legislative proposal

PURPOSE: to provide a temporary derogation from EU legislation on GMOs in order to avoid delays in the conduct of clinical trials with investigational medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: EU legislation requires that applications for marketing authorisation for a medicinal product, in a Member State or in the Union, be accompanied by a dossier containing the results of clinical trials carried out on the product. Sponsors are required, before the commencement of any clinical trial, to request authorisation from the competent authority of the Member State in which the clinical trial is to be conducted.

Clinical trials necessitate the performance of multiple operations which may fall within the scope of Directive 2001/18/EC (Directive on the deliberate release into the environment of genetically modified organisms) or Directive 2009/41/EC (Directive on the contained use of genetically modified micro-organisms) in cases where the investigational medicinal product contains or consists of GMOs.

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 impact assessment and authorisation by the competent authority of a Member State is complex and may take a significant amount of time.

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.

The Commission considers that it is of paramount importance that clinical trials with investigational medicinal products against COVID-19 containing or consisting of GMOs 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.

CONTENT: in the public health emergency created by the COVID-19 pandemic, the proposed Regulation aims to ensure that clinical trials with medicinal products for human use containing or consisting of GMOs to treat or prevent COVID-19 can start swiftly and without a prior environmental risk assessment and/or prior consent under Directive 2001/18/EC or Directive 2009/41/EC.

The Regulation shall apply for as long as COVID-19 is considered a pandemic by the World Health Organisation (WHO) or declared an emergency situation in accordance with Decision No 1082/2013/EU and remains so.