

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) - 10/07/2020 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 507 votes to 67, with 9 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council 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.

The European Parliament's position adopted at first reading in accordance with the ordinary legislative procedure supported the Commission proposal.

The proposal 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.

Under the proposed Regulation, no operations related to the conduct of clinical trials with medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19), with the exception of the manufacture of investigational medicinal products, shall require a prior environmental risk assessment or consent where these operations relate to the conduct of a clinical trial authorised in accordance with Directive 2001/20/EC.

Sponsors shall implement appropriate measures to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the investigational medicinal product into the environment.

This Regulation shall apply as long as World Health Organisation (WHO) has declared COVID-19 to be a pandemic or as long as an implementing act by which the Commission recognises a situation of public health emergency due to COVID-19 applies.