

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)

- Article 1 For the purposes of this Regulation, the following definitions apply:...
- Article 2 (1) All operations related to the conduct of clinical trials,...
- Article 3 (1) Articles 6 to 11 and 13 to 24 of...
- Article 4 (1) This Regulation shall apply as long as WHO has...
- Article 5 This Regulation shall enter into force on the day following...
- Signature

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)

- (1) Position of the European Parliament of 10 July 2020 (not yet published in the Official Journal) and decision of the Council of 14 July 2020.
- (2) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ([OJ L 311, 28.11.2001, p. 67](#)).
- (3) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ([OJ L 136, 30.4.2004, p. 1](#)).
- (4) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use ([OJ L 121, 1.5.2001, p. 34](#)).
- (5) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ([OJ L 106, 17.4.2001, p. 1](#)).
- (6) Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms ([OJ L 125, 21.5.2009, p. 75](#)).

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EU) 2020/1043 of the European Parliament and of the Council.