Official Journal
of the European Union

EN
C series

C/2024/1960

6.3.2024

NOTICE FROM THE COMMISSION

on the fulfilment of the conditions for the application of Regulation (EU) 2020/1043 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 (COVID-19)

(C/2024/1960)

1. INTRODUCTION

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

2. On 18 July 2020, as a matter of urgency in the light of making vaccines or treatments for COVID-19 available to the public as soon as they were ready for that purpose and to avoid delays or uncertainties as regards the status of those products in certain Member States, Regulation (EU) 2020/1043 became applicable.

3. That Regulation provides for a temporary derogation from Union legislation on genetically modified organisms ('GMOs') to ensure that the conduct of clinical trials in the territory of several Member States with investigational medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19 is not delayed; and a clarification on the application of Article 5(1) and (2) of Directive 2001/83/EC of the European Parliament and of the Council ([1]) and Article 83(1) of Regulation (EC) No 726/2004 of the European Parliament and of the Council ([2]) as regards medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19,

4. In particular, the temporary derogation included in Article 2(1) of Regulation (EU) 2020/1043 provides that a prior environmental risk assessment or consent in accordance with Articles 6 to 11 of Directive 2001/18/EC of the European Parliament and of the Council ([3]) or Articles 4 to 13 of Directive 2009/41/EC of the European Parliament and of the Council ([4]) is not required. In addition, Article 3(1), points (a), (b) and (c), of Regulation (EU) 2020/1043 clarifies the application of Article 5(1) and (2) of Directive 2001/83/EC and Article 83(1) of Regulation (EC) No 726/2004 as regards medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19.It was considered appropriate that, where Member States adopt decisions pursuant to Article 5(1) and (2) of Directive 2001/83/EC or Article 83(1) of Regulation (EC) No 726/2004 concerning medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19, an environmental risk assessment or consent in accordance with Directive 2001/18/EC or Directive 2009/41/EC were not a prerequisite.

5. Article 4(1) of Regulation (EU) 2020/1043 provides that that Regulation applies for the duration of the COVID-19 pandemic as declared by the WHO or in the event of a public health emergency due to COVID-19, as recognised by an implementing act issued by the Commission in accordance with Article 12 of Decision No 1082/2013/EU of the

([1]) 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, ELI: http://data.europa.eu/eli/dir/2001/83/oj).

([2]) 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 use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/726/oj).

([3]) 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, ELI: http://data.europa.eu/eli/dir/2001/18/oj).

([4]) 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, ELI: http://data.europa.eu/eli/dir/2009/41/oj).

European Parliament and of the Council ([5]). In addition, Article 4(2) of Regulation (EU) 2020/1043 provides that the Commission is to publish a notice in the *Official Journal of the European Union* when the conditions for the application of that Regulation are no longer met. Finally, Article 4(3) of Regulation (EU) 2020/1043 clarifies transitional rules according to which clinical trials falling within the scope of that Regulation, which have been authorised under Directive 2001/20/EC prior to the publication of the Commission's notice, may continue validly.

6. On 5 May 2023, the WHO declared the end of the public health emergency of international concern for COVID-19. In addition, there is no implementing act by which the Commission recognises a situation of public health emergency due to COVID-19 in accordance with Article 12 of Decision No 1082/2013/EU of the European Parliament and of the Council.

2. CONCLUSIONS ON THE FULFILLEMENT OF THE CONDITIONS FOR THE APPLICATION OF REGULATION (EU) 2020/1043

7. Regulation (EU) 2020/1043, adopted as a response to the COVID-19 pandemic, provides for a time limited derogation in its Article 4(1).

8. With the declaration by the WHO on 5 May 2023, signalling the end of the public health emergency of international concern for COVID-19, and the absence of an implementing act by which the Commission recognises a situation of public health emergency due to COVID-19 in accordance with Article 12 of Decision 1082/2013/EU of the European and of the Council, it is evident that the circumstances that necessitated the temporary derogation have changed.

9. The conditions for the application of Regulation (EU) 2020/1043 are no longer fulfilled.

([5]) Repealed by Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj)