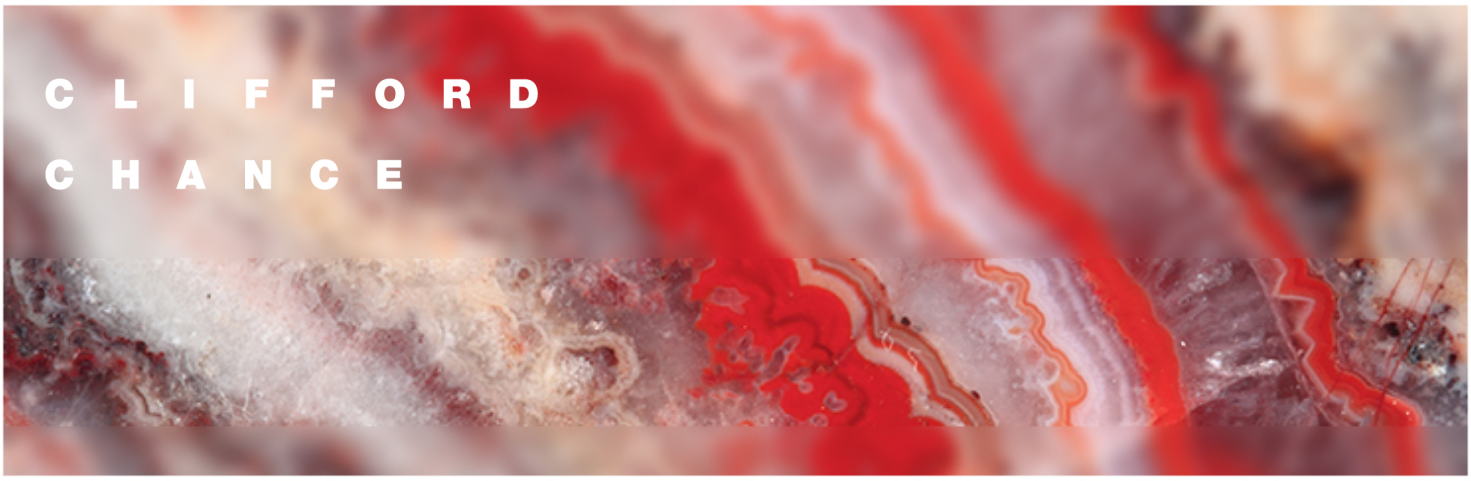

NEW EUROPEAN REGULATION FACILITATES DEVELOPMENT OF CORONAVIRUS VACCINE

In the fight against COVID-19, the European vaccines strategy intends to speed up the development and deployment of a vaccine. In this light, Regulation (EU) 2020/1043, which entered into force on 18 July 2020, grants temporary derogations from certain prerequisites for the conduct of clinical trials and the supply of medicinal products containing genetically modified organisms.

Key issues

- The new Regulation grants derogations from GMO legislation facilitating the timely development of a COVID-19 vaccine.
- The Regulation waives the requirement for an environmental risk assessment prior to clinical trials.
- Companies are relieved from the requirement to obtain prior written consent for the deliberate release of GMOs.
- The Regulation also applies to scenarios in which unauthorised medicinal products are permitted for distribution based on exceptional circumstances.
- The development, authorisation and availability of vaccines shall be accelerated while maintaining the EU standards for quality, safety and efficacy.

BACKROUND

The timely development of effective and safe vaccines and therapies against COVID-19 is essential for a sustainable and effective response to the pandemic and is therefore of major public interest. However, current regulations lead to complex and time-consuming progress. As some of the investigational vaccines are based on genetically modified organisms ("**GMOs**"), their development must comply with the requirements of the European legislation on GMOs, in particular the Directives 2001/18/EC and 2009/41/EC (together "**GMO Directives**"). As of today, the GMO Directives are non-uniformly implemented into national procedures by the different EU member states, so multi-centre clinical trials involving several states face complex hurdles under current law. However, these multi-centre studies covering various countries are critical to generate robust clinical evidence for medicinal products intended to treat or prevent COVID-19.

CONTENT OF THE REGULATION

Derogation for clinical trials from prior environmental risk assessment and consent for deliberate release

Following their purpose to protect both human health and the environment, the GMO Directives require an environmental risk assessment prior to the conduct of clinical trials of medicinal products containing GMOs. Additionally, Directive 2001/18/EC demands a written consent by the competent authority for the deliberate release of GMOs into the environment for research and development purposes. However, the transposing of the GMO Directives into national law differs across EU member states, leading to different practices with respect to the required consents and authorisations within the EU and thereby impeding the conduct of multi-centre studies.

To ensure a preferably early kick-off of clinical trials of investigational medicinal products against COVID-19, the new Regulation (EU) 2020/1043 ("**GMO COVID-19 Regulation**") provides a temporary derogation from the requirements of an environmental risk assessment and a written consent with respect to the deliberate release of GMOs. However, this does not completely remove the requirement for an environmental risk assessment, but this assessment is required to be performed in advance of the marketing of the medicinal product as part of the marketing authorisation procedure. Regardless of the environmental risk assessment, clinical trials of investigational medicinal products containing or consisting of GMOs continue to require general written authorisation on their execution in accordance with Directive 2001/20/EC.

Respective application for exceptional distribution of unauthorised medicinal products

The European legal framework regulating medicinal products (in particular Directive 2001/83/EC and Regulation 726/2004/EC) provides for certain defined exceptions from the requirement that no medicinal product may be placed on the market in the EU or in a member state unless a marketing authorisation has been granted by the competent authorities. These exceptions apply for situations characterised by an urgent need to address a medical need, for compassionate use or in response to a suspected or confirmed spread of pathogenic agents and similar scenarios.

In response to doubts that have been expressed by certain member states in this respect, the GMO COVID-19 Regulation clarifies that its temporary derogations from GMO legislation also apply to these exceptional situations. This means that, when permitting the distribution of certain unauthorised products or authorising the compassionate use of a medicinal product, the member states have to reflect the facilitations provided in the GMO COVID-19 Regulation.

Duration of application

The regulation will apply as long as the World Health Organisation declares 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.

EVALUATION AND IMPACTS

By adapting the EU's regulatory framework to the current demands, the development, authorisation and availability of vaccines shall be accelerated while maintaining the EU standards for quality, safety and efficacy. In line with this goal, the GMO COVID-19 Regulation ensures that research activities for vaccines against COVID-19 are not hindered by complex statutory provisions or different national standards, but are instead encouraged by pooled resources and joint efforts.

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