Vaccine against COVID-19: Council adopts measures to facilitate swift development

Today, the Council adopted a regulation which aims to speed up the development and the deployment of a vaccine against COVID-19 in the EU. The act provides for a temporary derogation for clinical trials with such vaccines from the prior environmental risk assessment required in the EU legislation on the deliberate release in the environment and the contained use of genetically modified organisms (GMOs). In addition, it clarifies that this temporary derogation also applies when member states allow medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19 to be used in certain exceptional and urgent situations defined in the pharmaceuticals legislation. The environmental impact of medicinal products (including vaccines) containing or consisting of GMOs intended to treat or prevent COVID-19 will remain part of the marketing authorisation process, respecting the environmental safety requirements set out in the GMO legislation.

The regulation will apply only as long as COVID-19 is regarded as a pandemic by the World Health Organisation (WHO) or as long as an implementing act by which the Commission recognises a situation of public health emergency due to COVID-19 applies.

> A vaccine against COVID-19 is urgently needed. This regulation will ensure that clinical trials in the EU can start without delay and that no precious time is lost. The act adopted today shows that the EU is ready to take the lead in the global effort to secure the development of a safe and efficient vaccine.
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> *Jens Spahn, Federal minister of Health of Germany*

The regulation provides for a derogation from certain provisions of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and Directive 2009/41/EC on the contained use of genetically modified micro-organisms. The derogation provides that most operations related to the conduct of clinical trials will not require a prior environmental risk assessment or consent. These operations include packaging and labelling, storage, transport, destruction, disposal, distribution, supply, administration or use of investigational medicinal products for human use containing or consisting of GMOs intended to treat or prevent COVID-19. The manufacturing of such products will however still be subject to all provisions in those directives.

The regulation also clarifies that certain provisions of Directives

2001/18/EC and 2009/41/EC are not applicable when member states grant access to medicinal products containing or consisting of GMOs in certain exceptional and urgent situations. These cases are defined in Directive 2001/83/EC on the Community code relating to medicinal products for human use and Regulation (EC) No 726/2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use.

The regulation was adopted by written procedure.

Background and next steps

The Commission adopted its proposal on 17 June 2020. The European Parliament voted in favor of the proposed regulation on 10 July 2020. The regulation will be published in the Official Journal of the European Union on 17 July and enter into force on the following day.