Press release – Parliament to allow COVID-19 vaccines to be developed more quickly

Parliament today adopted a new Regulation by 505 votes to 67 and 109 abstentions, via the urgent procedure, that will allow COVID-19 vaccines and treatments to be developed more quickly.

Developing and deploying an effective and safe vaccine against the virus is the most likely permanent solution to stop the pandemic. To this end, the Commission has proposed an EU vaccines strategy for COVID-19 including a temporary and strictly COVID-19-related derogation from certain rules for clinical trials.

Clinical trials for COVID-19 vaccines are a time-consuming step before authorisation, as they need to be carried out in several member states to ensure the populations for whom the vaccines are intended are represented and to generate robust and conclusive data.

Some COVID-19 vaccines and treatments already being developed may be defined genetically modified organisms (GMOs) and are thus covered by the relevant EU GMO Directives. As national requirements to assess the environmental risks of clinical trials on medicinal products that contain or consist of GMOs vary considerably across member states, a derogation from these rules is needed to avoid significant delay in developing life-saving vaccines and treatments.

Background

The Commission has proposed a Regulation to derogate temporarily – only for the period during which COVID-19 is a public health emergency – from certain provisions of the GMO Directive for clinical trials on COVID-19 vaccines and treatments that contain or consist of GMOs. The derogation should apply only

to operations necessary to conduct the clinical trial phase and for compassionate or emergency use in the context of COVID-19.

The derogation will facilitate the development, authorisation and consequently availability of COVID-19 vaccines and treatments. When debated last week in the Committee on the Environment, Public Health and Food Safety, members agreed on the need to adapt the rules but stressed that standards for vaccine quality, safety and efficacy must be maintained.