Question for written answer E-001166/2021
to the Commission
Rule 138
Joanna Kopcińska (ECR)

Subject: Coronavirus mutations and revision of contracts with producers

On 25 February 2021 the European Medicines Agency (EMA) issued guidelines laying down requirements for producers planning to modify their Covid-19 vaccines in response to new coronavirus variants. The recommendation rightly addresses one of the growing problems in the current pandemic.

Viruses mutate and several strains of SARS-CoV-2 have been identified worldwide. For example, only yesterday in the United States it was reported that in addition to the California variant a group of coronaviruses known as B.1.526 is spreading rapidly in New York, and that it accounts for 27% of the viral sequences identified in the city.

During yesterday's joint hearing of the ENVI and ITRE Committees in the European Parliament, Pfizer said it needed 100 days to modify/update its vaccine to combat new variants. The likelihood that the current COVID-19 vaccines will need to be modified is high.

On the issue of quality, point 2.1 of the EMA document referred to above indicates that the requirements for authorising modified vaccines will largely depend on the technology underlying the design of the parent vaccine (e.g. mRNA vaccine, viral vector, purified protein produced by recombinant DNA, inactivated viral vaccine).

In light of the above, is the Commission considering revising the agreements signed with the current manufacturers? How is the clause on updating the vaccine against future variants safeguarded and legally binding under the agreements signed so far?