Question for written answer E-005659/2021
to the Commission
Rule 138
Andreas Glück (Renew)

Subject: Full marketing authorisation for COVID-19 vaccines in the EU

Exactly one year ago, the European Medicines Agency recommended granting the Comirnaty vaccine a conditional marketing authorisation. This was an important step to start the vaccination campaign in Europe while continuing to collect and analyse data on the safety and effectiveness of the vaccine. At the beginning of November 2021, the Commission decided to renew the conditional marketing authorisation for Comirnaty for another year.

In the United States, on the other hand, Comirnaty already received full approval by the U.S. Food and Drug Administration in August 2021.

Given that hundreds of millions of doses of Comirnaty and other COVID-19 vaccines were administered in the EU in the course of last year, one can hardly speak of a lack of data to judge the safety and effectiveness of these vaccines. A full marketing authorisation would therefore be a strong signal to counter vaccine hesitancy in the EU.

Does the Commission have information about the progress on granting of a full marketing authorisation for Comirnaty and other COVID-19 vaccines? When can a final decision be expected?