Question for written answer E-001275/2021
to the Commission
Rule 138
Jaak Madison (ID)

Subject: COVID-19 vaccine approval

On 27 February 2021, the US Food and Drug Administration authorised emergency use of the Johnson & Johnson COVID-19 vaccine: the first single-dose vaccine in the world, which was developed by the Janssen pharmaceutical company in Leiden, the Netherlands. South Africa already started administering this vaccine on 17 February 2021.

Despite the vaccine having been submitted to the European Medicines Agency (EMA) by mid-February, the EMA is only expected to approve the vaccine by mid-March. The EU's slow approval of vaccines, coupled with its poor negotiation and organisational abilities when it comes to vaccine acquisition, serve as evidence to its ineffectiveness and the unnecessary bureaucracy it has in place.

1. How is it possible that it takes the EMA longer to approve a vaccine developed in the EU than it does for the US or South Africa, where the vaccine is already being administered?

2. Is healthcare not an exclusive competence of the Member States? If so, is EMA approval needed for COVID-19 vaccines or could national bodies decide to proceed with the vaccine without such approval?

3. Why are far-reaching and devastating lockdown policies preferred over fast and effective, yet voluntary, vaccine acquisition and administration?