Priority question for written answer P-006689/2020
to the Commission
Rule 138
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Subject: Authorisation of new SARS-COV-2 vaccines

The European Medicines Agency has recently voiced strong criticism of the UK decision granting emergency authorisation to commence the Pfizer/BioNTech vaccine rollout.

The EMA itself has been testing this vaccine since October and has publicly announced its intention of deciding whether to grant the necessary authorisation on 29 December.

At the same time, the Medicines and Healthcare Products Regulatory Agency (MHRA) has very rapidly announced its approval of the vaccine manufactured by the two companies, in line with EU legislation applicable in the United Kingdom up to 1 January and with relevant international standards.

It must be acknowledged that the different decisions announced by the two agencies have left the European public bewildered and understandably perplexed on the question of whether or not the vaccine can be made available sooner.

In view of this:

1. Can the Commission specify the principal concerns of the EMA regarding the MHRA's decision to issue provisional authorisation?

2. What are the data being used by the EMA and what checks is it carrying out for the purposes of authorising the vaccine?

3. What stage has been reached by the EMA in assessing each of the vaccines purchased by the Commission from all contracted manufacturers? When will they be authorised for use by the Member States with the EMA's blessing?