**Question for written answer E-000092/2021**
**to the Commission**
Rule 138
**Joanna Kopcińska** (ECR)

Subject: Vaccine approval process

On 6 January 2021 the European Medicines Agency (EMA) recommended the Moderna coronavirus vaccine for widespread use across the whole of the EU, thereby issuing a second conditional marketing authorisation (CMA) for the coronavirus vaccine.

As a result of the Union's approval process for new vaccines, the BioNTech/Pfizer vaccines developed in Germany were in use outside the EU long before they were given the regulatory green light in the EU itself, which has contributed to public discontent and comments from policymakers about the slow authorisation process.

1. While completely understanding and in awareness of the procedural differences between the urgent issuing of an authorisation and a conditional marketing authorisation by the EMA, taking into account product liability, the temporary nature of the urgent approval procedure and the additional bureaucracy necessary for the EU to sign agreements, how will the EU streamline the decision-making process for authorising potential vaccines in future in a significantly shorter time?

2. How will the EU deal with the current central problem, which is not the amount of orders but a global shortage of production capacity, which will also link directly in to the issue of distribution and utilisation times in the Member States?