Question for written answer E-001356/2021 to the Commission Rule 138 Angelo Ciocca (ID)

Subject: Speeding up the authorisation of the Sputnik vaccine

The third wave of the COVID-19 pandemic is bringing to light serious vaccine shortages across Europe. Despite the delays with regard to the vaccination strategy and the contracts signed, the European Union does not seem inclined to assess every possible way of combating the pandemic. Some forty countries around the world have already granted permission for the emergency use of the Sputnik vaccine, but not Europe, which, instead of streamlining the vaccine authorisation procedure, continues to opt for a strategy that is slow, belated and is dividing individual Member States.

In normal times, it is up to pharmaceutical companies to put forward their scientific data for assessment by the EMA. However, since we are in the midst of a health crisis, the EMA should be invited to follow the example of the American FDA and to issue a temporary emergency authorisation exempting the Sputnik vaccine from the usual authorisation procedures, so that it can test and assess the vaccine's effectiveness and safety for itself.

In the light of the above:

- 1. Does the Commission plan to respond rapidly to vaccine shortages by calling on the EMA to significantly speed up its 'rolling review' time frame?
- 2. Does it not agree that the emergency situation calls for a revision of the current procedure?