Question for written answer E-002002/2021 to the Commission Rule 138 Joanna Kopcińska (ECR)

Subject: European Medicines Agency, AstraZeneca vaccine and clear information communication

procedure

On 7 April 2021, the European Medicines Agency (EMA) announced that unusual blood clots and a low platelet count should be regarded as very rare side effects of the Vaxzevria vaccine. The Agency also decided not to introduce additional restrictions on the use of this vaccine in people over 18 and underlined that 'the benefits from administering the vaccine still significantly outweigh the risk of side effects'. The EMA has called for new studies and formal changes to ongoing tests in order to gather more information with a view to taking any further action which is necessary.

- 1. How does the Commission envisage additional support for a proper communication process, which is already difficult because of disinformation and a widespread reluctance to be vaccinated?
- 2. How can the centralised European database (EudraVigilance) for analysing information on suspected adverse reactions to medicines which have been authorised in the EEA and the Pharmacovigilance Risk Assessment Committee (PRAC), together with the Committee for Medicinal Products for Human Use (CHMP), jointly promote a clear, reliable information flow process to avoid more accusations pointing, among other things, to the fact that on 18 March 2021, the EMA reported that the number of thrombotic effects in people vaccinated with the preparation was lower than the average for the general population and that the cases recorded and studied at the time had no connection to the vaccine?