Question for written answer E-006865/2020
to the Commission
Rule 138
Joanna Kopcińska (ECR)

Subject: COVID-19 vaccine

According to the Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 Vaccines, responsible entities will be required to submit monthly summary safety reports regarding vaccines to the EMA, in addition to the regular periodic safety update reports (PSURs). The responsible entity will provide, inter alia, information on reported suspected adverse reactions, including adverse events of special interest (AESIs) and sales data.

1. How will these data be processed and published, and is an additional safety procedure mechanism based on the newly acquired information foreseen? When and how will these data contribute to the subsequent post-authorisation safety study (PASS)?

2. Conditional marketing authorisations are valid for one year and may be renewed annually. How will the post-authorisation safety study (PASS) play a decisive role in the possible renewal of an authorisation or conversion to a standard marketing authorisation?