Question for written answer E-001384/2021
to the Commission
Rule 138
Francesca Donato (ID)

Subject: Adverse reactions from COVID vaccination

According to the data provided by supervisory bodies regarding spontaneous reporting (passive pharmacovigilance) following the administration of COVID-19 vaccines, there has been an extremely high incidence of serious adverse reactions that has never been hitherto detected for any medicinal product placed on the market.

VAERS[1], EUDRA Vigilance, the EMA and AIFA have collected tens of thousands of reports of severe adverse reactions, including thousands of deaths after inoculation of the Pfizer-Biontech, Astra-Zeneca and Moderna vaccines. There have reportedly been 1265 deaths following COVID vaccination in the European Economic Area[2] and the number of serious adverse reactions in Italy alone, in two months, stands at 1830[3].

In view of the above:

1. Does the Commission intend to suspend or withdraw authorisation for the emergency use of these vaccines pending the results of investigations into the causal link between serious or fatal adverse reactions and vaccination?

2. Will it put in place an active pharmacovigilance system for all vaccines authorised for emergency use?

3. Will it conduct a risk/benefit assessment of vaccination broken down by age group?

[1] Selected Adverse Events Reported after COVID-19 Vaccination | CDC 1637 deaths have been recorded since 14 December 2020
[2] https://www.comilva.org/informazione/covid-dallitalia-dal-mondo/casi-di-sospette-reazioni-avverse-alla-profilassi-anti
[3] https://www.aifa.gov.it/documents/20142/1315190/Rapporto_sorveglianza_vaccini_COVID-19_2.pdf/5f35b7a5-bdde-e245-f5a4-f8c04d20f06c p.5 (6,1% di 30.015 reazioni avverse)