Priority question for written answer P-003960/2021
to the Commission
Rule 138
Francesca Donato (ID)

Subject: Withdrawal of vaccine authorisation

The EU has granted conditional approval for the emergency use of COVID-19 vaccines, with a six-week review of post-vaccination safety data[1].

To date, EUDRAVIGILANCE has received around 20 000 reports of deaths probably related to the vaccines and some 700 000 adverse reactions, 9% of which severe. These data are, however, underestimated when it comes to the true magnitude of adverse effects, given that there is no active surveillance. The EMA has recently updated the list of adverse reactions to vaccines, adding new diseases[2].

Moreover, the trend in infections among vaccinated people in countries such as Israel and the UK shows that the vaccines themselves are not effective against the variants that are currently predominant.

The possible long-term reactions to mRNA vaccines, which have never before been authorised for humans, remain unknown[3].

In view of this, will the Commission:

1. withdraw or suspend authorisation for the use of those vaccines owing to the lack of safety and efficacy requirements in terms of preventing infection and contagion with the SARS-CoV2 virus;

2. authorise the use of medicines that have proven to be effective in treating COVID-19, such as Ivermectin, and large-scale early home treatment protocols;

3. put in place an active surveillance system for vaccinated people, providing them with support and facilitating the necessary treatment for adverse effects?

---

1 At the end of the 'primary completion' of the trial, no provision has been made for data on 'adverse effects' to be collected or provided. The EMA has stated that once marketing authorisation for the vaccines has been granted, vaccinated people all over Europe would have to be monitored for at least one year in order to document any belated adverse reactions.

2 See: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-authorised#safety-updates-for-authorised-covid-19-vaccines-section

3 The BioNTech/Pfizer and Moderna vaccines use this technique, which would thus require much longer time for evaluation before being given to entire populations.