

(English version)

**Question for written answer E-001127/23
to the Commission
Harald Vilimsky (ID), Georg Mayer (ID)
(3 April 2023)**

Subject: After-effects of the COVID-19 pandemic

The COVID-19 pandemic is coming to an end, but the psychological, physical and economic consequences continue to be felt in all EU Member States.

1. COVID-19 vaccination causes many after-effects, which continue beyond the immunisation period, as shown for example in Austria by an increased number of cases of multiple sclerosis. However, reporting systems and research on their correlation are not developed and subsidies are highly imbalanced. Why has the Commission so far failed to respond to these reports and to compensate the support payments to an appropriate degree?
2. A leaked interview with a Pfizer employee indicated that their mRNA vaccine may have an influence on the menstruation cycle and that it is not certain whether and how long the mRNA remains in the body. This could have a dramatic impact on the next generation. To what extent does the Commission intend to follow up on these reports?

Submitted: 3.4.2023

**Answer given by Ms Kyriakides on behalf of the European Commission
(7 June 2023)**

1. The European Medicines Agency (EMA) put in place an enhanced pharmacovigilance system ⁽¹⁾ to monitor and evaluate safety of COVID-19 vaccines. The reported frequency of multiple sclerosis is not increased following vaccination with messenger ribonucleic acid (mRNA) vaccines.

The agreements for the purchase of the COVID-19 vaccines by the EU include certain risk-sharing arrangements with vaccine manufacturers. However, those arrangements do not impact the primary responsibility and liability of the company for its product.

2. EMA evaluated evidence on two potential menstruation cycle side effects of the COVID-19 mRNA vaccines. The product information of Spikevax and Comirnaty were updated regarding the heavy menstrual bleeding. The evidence is not suggesting that the menstrual disorders experienced by some people have any impact on reproduction and fertility ⁽²⁾.

Studies in animal models give confidence that after vaccination, no safety problems due to the temporal accumulation of mRNA in organs is expected. No safety issues that could be linked to the distribution of the vaccine in the human body have been reported so far.

The study published in Cell.com was reviewed by EMA and it does not change the overall benefit-risk assessment for the mRNA vaccines. Results of additional studies to characterise the biodistribution and degradation of mRNA will be submitted in 2023-2024.

⁽¹⁾ <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/safety-covid-19-vaccines>

⁽²⁾ <https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-24-27-october-2022>