

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
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The Commission, in close collaboration with the European Medicines Agency (EMA) and Member States, continuously monitors the safety of all authorised medicines, including COVID-19 vaccines, through a robust pharmacovigilance system¹.

While there have been some reports about the short-term variation of fertility trends during the pandemic, this was attributed to behavioural changes, as in most of the studied countries the fertility rates returned to pre-pandemic levels and no evidence of effect of COVID-19 vaccinations on fertility trends was found².

The long-term safety data of COVID-19 vaccines to date remain very reassuring, including regarding fertility. The findings come from some of the largest clinical trials ever conducted for vaccines, involving tens of thousands of participants, as well as real-world data collected over more than three years of large vaccination campaigns.

Companies are also legally obliged to submit periodic safety update reports³, which provide a re-evaluation of the benefit-risk balance of a medicine at regular timepoints after its authorisation. Any new or emerging data is included in these reports and assessed by the EMA.

Finally, the Commission places strong importance on women's health and the safety of all authorised medicinal products, including vaccines. It expects that potential adverse effects are thoroughly investigated, irrespective of the patient's gender. While certain differences in vaccine reactions between sexes may occur, often linked to hormonal factors, these are closely monitored and evaluated. As for every authorised product, the patient and prescriber information summarise the current scientific knowledge, including benefits, risks and specific warnings.

¹ https://health.ec.europa.eu/medicinal-products/pharmacovigilance_en, <https://www.ema.europa.eu/en/human-regulatory-overview/pharmacovigilance-overview>.

² Exploring associations between the Covid-19 vaccination campaign and fertility trends: A population-level analysis for 22 countries, MPIDR - How have Covid-19 vaccinations affected birth rates? Birth rate decline in the later phase of the COVID-19 pandemic: the role of policy interventions, vaccination programmes, and economic uncertainty; Human Reproduction Open; Oxford Academic.

³ <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/periodic-safety-update-reports-psurs>.