

EN

E-002241/2026

Answer given by Mr Várhelyi
on behalf of the European Commission
(22.7.2026)

Once a COVID-19 vaccine has received approval, each batch can only be released following quality control testing to confirm that the product is in line with the specifications approved as part of the marketing authorisation. For most centrally authorised vaccines, an additional independent control is performed by a Member State Official Medicines Control Laboratory before their release in the EU. The Commission also refers the Honourable Member to the reply to parliamentary question (PQ) E-001537/2023¹, where this point was addressed.

Only batches complying with the approved quality specifications can be released. The Commission does not hold comparative batch-level quality control data by Member State. However, the European Medicines Agency (EMA) has no evidence suggesting that some batches of COVID-19 vaccines caused more, or more serious, side effects than other batches. For Comirnaty, this was already indicated in the reply to PQ P-002990/2024².

Furthermore, pharmacovigilance systems are in place to monitor the suspected adverse reactions and detect safety issues potentially related to quality. The EMA and national authorities continuously monitor safety, including EudraVigilance reports, medical literature and product quality issue detection tools³. Analyses performed by the EMA of suspected cases of adverse reactions did not reveal an increased risk of side effects for specific batches. This was also indicated in the answer to PQ E-001537/2023.

¹ https://www.europarl.europa.eu/doceo/document/E-9-2023-001537-ASW_EN.html.

² https://www.europarl.europa.eu/doceo/document/P-10-2024-002990-ASW_EN.html.

³ <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/signal-management>.