

EN
P-002990/2024
Answer given by Mr Várhelyi
on behalf of the European Commission
(20.2.2025)

The Commission is in contact with Member States and the European Medicines Agency (EMA) to ensure the continuous quality, safety and efficacy of medicines, including COVID-19 vaccines.

EMA continuously monitors safety signals and investigates whether there is a causal link between specific batches and reported adverse events. EMA has no evidence so far suggesting that some batches of Comirnaty caused more (or more serious) side effects than other batches¹. The quality of every batch is checked by Official Medicines Control Laboratories in Member States and only those complying with the approved quality specifications can be released in the EU.

Regulators request and collect batch numbers for vaccines to allow them to establish patterns and determine whether *suspected* side effects are linked to a specific batch. The Paul-Ehrlich-Institut (PEI) reports *suspected* side effects with Comirnaty, but it does not confirm these as side effects, nor does it link them to specific batches. Most side effects of Comirnaty are mild. These are not batch specific and are clearly listed in the product information with the respective frequency.

A conditional marketing authorisation was granted by the Commission to Comirnaty in December 2020, based on EMA's rigorous scientific evaluation, weighing up the benefits and risks. The conditional marketing authorisation was converted into a standard marketing authorisation on 10 October 2022. After authorisation in 2020, EMA has been continuously monitoring suspected side effects and evaluating any new information that emerges². This evaluation is conducted by EMA's expert committees, and action is taken, if necessary.

Comirnaty continues to fulfil the necessary requirements for authorisation in the EU.

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

² <https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty#authorisation-details>