

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
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The highest standards in the evaluation of COVID-19 vaccines were applied by the European Medicines Agency (EMA). As for every other product it evaluates, EMA's human medicines committee¹ (CHMP) considered the need for good clinical practice (GCP) inspections.

Studies supporting the authorisation of a medicine must comply with GCP. Regulators can request and conduct inspections to verify compliance with the standards. Criteria used to select a GCP inspection is published². When a GCP inspection is requested by the CHMP, EMA makes a call for available EU national GCP inspection resources. The Member States have the final say on whether to send inspectors for an EMA-coordinated inspection. During the COVID-19 pandemic, due to the restrictions to travel with a view to protect public health, regulators assessed the need for inspections and decided on a case-by-case basis the most appropriate and viable approach to take.

The European Public Assessment Reports for Vaxzevria³ and Comirnaty⁴ are publicly available.

The first cases of myocarditis that occurred in Israel in 2021 following vaccination with Comirnaty triggered a formal review by EMA⁵. The outcome was that the risk for myocarditis and pericarditis was overall 'very rare' (up to one in 10,000 vaccinated people may be affected) with the highest risk in younger males⁶. The product information of Comirnaty and Spikevax was revised adding myocarditis and pericarditis as new side effects with a warning to raise awareness.

¹ <https://www.ema.europa.eu/en/committees/committee-medicinal-products-human-use-chmp>.

² https://www.ema.europa.eu/en/documents/other/points-consider-assessors-inspectors-european-medicines-agency-inspection-coordinators-identification-triggers-selection-applications-routine-cause-inspections-their-investigation-scope-such_en.pdf.

³ Vaxzevria (previously COVID-19 Vaccine AstraZeneca), INN-COVID-19-Vaccine-(ChAdOx1-S-[recombinant]) https://www.ema.europa.eu/en/documents/assessment-report/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-public-assessment-report_en.pdf.

⁴ https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf.

⁵ https://www.ema.europa.eu/en/documents/report/report-pharmacovigilance-tasks-eu-member-states-and-european-medicines-agency-ema-2019-2022_en.pdf.

⁶ Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 29 November - 2 December 2021 <https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-29-november-2-december-2021>.