

(English version)

**Question for written answer E-003611/25
to the Commission
Barbara Bonte (Pfe)
(17 September 2025)**

Subject: Guidance on the use of the 2025-2026 formulation of the Comirnaty vaccine (LP.8.1-adapted monovalent COVID-19 vaccine)

On 27 August 2025, the US Food and Drug Administration (FDA) approved the adapted Comirnaty vaccine (LP.8.1-adapted monovalent COVID-19 vaccine). This vaccine is specifically for adults aged 65 and older, as well as for people aged 5 to 64 with underlying conditions that put them at high risk of a severe bout of COVID-19. In the EU, however, the European Medicines Agency (EMA) recommends a broader application, namely for everyone aged 6 months and older, regardless of their risk status.

1. Why is there a significant difference between the recommendations of the FDA and the EMA? What specific parameters or criteria do these authorities use to arrive at such divergent guidelines, even though both are based on the same available scientific data on the safety and effectiveness of the vaccine?
2. In the United States, single-dose vials of Comirnaty are available. Are these also available in the EU? If so, why? If not, why not?

Submitted: 17.9.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(14 November 2025)**

The Commission adopts decisions on authorisation and monitoring of medicinal products in the EU, including COVID-19 vaccines, based on recommendations issued by the European Medicines Agency (EMA), and it cannot comment on criteria applied by other regulatory authorities.

Nevertheless, the recommendations issued by the EMA and those issued by the United States Food and Drug Administration (FDA) regarding the COVID-19 vaccine Comirnaty in 2025 are not divergent, as they both indicate the preferential use of LP.8.1 for the new SARS-CoV-2 variant JN.1.

The EMA's recommendations are based on the assessment of the available scientific evidence. EMA's guidance on the antigenic composition of COVID-19 vaccines for 2025-2026, including Comirnaty, is based on a wide range of data. These include data on the evolution of the virus and data from animal studies on the effects of candidate vaccines targeting LP.8.1.

The scientific rationale and other conditions underpinning the recommendation for the 2025-2026 formulation are explained in detail in the published guidance ⁽¹⁾.

In reaching its recommendations, EMA's Emergency Task Force (ETF) consulted with the World Health Organisation, international partners, including the FDA, and marketing authorisation holders for COVID-19 vaccines.

Single dose vials of Comirnaty are authorised for use in the EU ⁽²⁾, ⁽³⁾. Single dose vials are a standard presentation for vaccines. Together with multidose vials, they provide Member States with options when implementing their national vaccination campaigns.

⁽¹⁾ https://www.ema.europa.eu/en/documents/other/ema-recommendation-update-antigenic-composition-authorised-covid-19-vaccines-2025-2026_en.pdf.

⁽²⁾ https://ec.europa.eu/health/documents/community-register/2025/20250725167118/anx_167118_en.pdf.

⁽³⁾ https://www.ema.europa.eu/en/documents/all-authorised-presentations/comirnaty-epar-all-authorised-presentations_en.pdf.