

**Question for written answer E-003611/2025
to the Commission**
Rule 144
Barbara Bonte (Pfe)

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?

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