

(English version)

**Question for written answer E-002214/25
to the Commission
Christine Anderson (ESN)
(3 June 2025)**

Subject: Reassessment of the EU's COVID-19 vaccine authorisation in the light of long-term effectiveness and international policy developments, particularly in the United States

A recent study published in the New England Journal of Medicine ⁽¹⁾ reviews long-term data on COVID-19 vaccinations. It concludes that repeated booster doses provide only limited added benefit for healthy adults under 65 years of age, especially those with a history of prior infection or complete primary vaccination. The study raises concerns over the reliance on non-inferiority trials and short-term immunogenicity data as the basis for vaccine approvals.

The authors focus in particular on updated mRNA vaccines, including bivalent formulations (targeting ancestral and BA.4/BA.5 variants) and monovalent XBB.1.5-based boosters. They argue that these vaccines provide only modest and short-lived protection for low-risk groups and call for more targeted vaccination strategies supported by robust clinical evidence.

1. Can the Commission clarify how the European Medicines Agency ensures that its evaluation and authorisation of updated COVID-19 vaccines — specifically bivalent and monovalent XBB.1.5-based mRNA boosters — are based on clinically meaningful outcomes, particularly in light of the study's critique of non-inferiority trials and short-term immunogenicity data?
2. Does the Commission intend to revise its guidance on booster vaccinations to reflect growing evidence supporting more targeted, risk-based approaches?
3. In the light of the recent decision by US health authorities to remove COVID-19 vaccinations from the recommended immunisation schedule for healthy children and healthy pregnant women, does the Commission intend to consider a similar adjustment to EU-level guidance?

Submitted: 3.6.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(20 August 2025)**

The European Medicines Agency (EMA) recommends granting marketing authorisation to new vaccines that are similar to authorised vaccines on the basis of adequate comparative immunogenicity and safety data showing a positive benefit-risk balance.

Such an approach is possible because the level and type of antibodies triggered against SARS-CoV-2 can be compared with those triggered by an already authorised vaccine whose efficacy has been established in large placebo-controlled efficacy studies.

If a new vaccine can trigger an immune response in people comparable to that of an existing vaccine, it is concluded that the vaccine provides protection against the disease. This approach, called immune-bridging, is in line with established EU guidance for the development of vaccines ⁽¹⁾, ⁽²⁾.

The EMA is currently updating its guideline regarding the authorisation of novel COVID-19 vaccines, i.e., those for which a similar comparator is not yet authorised.

In such cases, the EMA may require demonstration of clinical efficacy against placebo, in addition to immunogenicity data, at least in some age groups.

Studies have shown that matching the content of vaccines to the circulating viruses improves protection against the disease ⁽³⁾, ⁽⁴⁾, ⁽⁵⁾. For these reasons, the COVID-19 vaccine composition has been updated since the virus established itself in humans.

¹ 120 May 2025, DOI: 10.1056/NEJMs2506929, <https://www.nejm.org/doi/10.1056/NEJMs2506929>.

⁽¹⁾ Multidisciplinary: vaccines <https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/multidisciplinary-guidelines/multidisciplinary-vaccines>.

⁽²⁾ https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-clinical-evaluation-vaccines-revision-1_en.pdf.

⁽³⁾ ETF statement on use of recently updated COVID-19 vaccines: https://www.ema.europa.eu/en/documents/other/etf-statement-use-recently-updated-covid-19-vaccines_en.pdf.

⁽⁴⁾ Cele S, Jackson L, Khoury DS, et al. Omicron extensively but incompletely escapes Pfizer BNT162b2 neutralization. *Nature*. 2022;602(7898):654-656. doi:10.1038/s41586-021-04387-1.

⁽⁵⁾ Winokur P, Gayed J, Fitz-Patrick D, et al. Bivalent Omicron BA.1-Adapted BNT162b2 Booster in Adults Older than 55 Years. *N Engl J Med*. 2023;388(3):214-227. doi:10.1056/NEJMoa2213082.

While the EMA recommends the authorisation of vaccines based on evidence that they protect against disease and a positive benefit-risk balance, it is up to the national authorities in the Member States to decide who should be offered COVID-19 vaccination and when, based on infection and hospitalisation rates, risks to vulnerable people, vaccination coverage and other factors.
