25 June 2026
EMADOC-1700519818-3254604
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Imvanex

smallpox and monkeypox vaccine (live modified vaccinia virus Ankara)

On 25 June 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Imvanex. The marketing authorisation holder for this medicinal product is Bavarian Nordic A/S.

The CHMP adopted an extension to an existing indication, as follows:[2]

> Active immunisation against smallpox, monkeypox and disease caused by vaccinia virus in individuals **2** ~~12~~ years of age and older (see sections 4.4 and 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

[2] New text in bold, removed text as strikethrough.

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