21 July 2022
EMA/CHMP/642836/2022
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 21 July 2022, 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 a new indication for the active immunisation against monkeypox and disease caused by vaccinia virus.

For information, the full indication for Imvanex will therefore be as follows:[2]

> Active immunisation against smallpox**, monkeypox and disease caused by vaccinia virus** in adults.

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

[1] Summaries 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**

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