24 February 2022
EMA/CHMP/70705/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Spikevax

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On 24 February 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 Spikevax. The marketing authorisation holder for this medicinal product is Moderna Biotech Spain, S.L..

The CHMP adopted an extension to the existing indication to include use in children from 6 years of age. For information, the full indication for Spikevax will be as follows:[2]

> Spikevax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals ~~12~~ **6** years of age and older.
>
> The use of this vaccine should be in accordance with official recommendations.

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, removed text as strikethrough

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