25 April 2025
EMADOC-1700519818-2059670
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zoonotic Influenza Vaccine Seqirus

zoonotic influenza vaccine (H5N8) (surface antigen, inactivated, adjuvanted)

On 25 April 2025, 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 Zoonotic Influenza Vaccine Seqirus. The marketing authorisation holder for this medicinal product is Seqirus S.r.l.

The CHMP adopted an extension to the existing indication to include active immunisation of children from 6 months of age. For information, the full indication will be as follows:[2]

> Zoonotic Influenza Vaccine Seqirus H5N8 is indicated for active immunisation against H5 subtype influenza A viruses **in individuals 6 months of age and above**~~in adults 18 years of age and above (see sections 4.4 and 5.1)~~.
>
> 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 on the 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] 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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