19 September 2024
EMA/CHMP/435295/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Aflunov

zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)

On 19 September 2024, 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 Aflunov. The marketing authorisation holder for this medicinal product is Seqirus S.r.l.

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

> Active immunisation against H5N1 subtype of Influenza A virus **in individuals 6 months of age and above.**
>
> ~~This indication is based on immunogenicity data from healthy subjects from the age of 18 years onwards following administration of two doses of the vaccine containing A/turkey/Turkey/1/2005 (H5N1)-like strain (see sections 4.4 and 5.1).~~
>
> AFLUNOV should be used 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 made 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union