14 September 2023
EMA/CHMP/387186/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zoonotic Influenza Vaccine Seqirus

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

On 14 September 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zoonotic Influenza Vaccine Seqirus, intended for the active immunisation against H5N1 subtype of Influenza A virus. The applicant for this medicinal product is Seqirus S.r.l.

Zoonotic Influenza Vaccine Seqirus will be available as a 7.5 mg/0.5 ml suspension for injection. The active substance of Zoonotic Influenza Vaccine Seqirus is zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted), an influenza vaccine (ATC code: J07BB02) that induces an immune response (circulating antibodies) against H5N1 antigens.

The benefit of Zoonotic Influenza Vaccine Seqirus is its ability to induce an appropriate immune response in individuals that are immunologically naïve against the vaccine strain. The most common side effects are injection site reactions, myalgia, headache and fatigue.

The application for Zoonotic Influenza Vaccine Seqirus was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Zoonotic Influenza Vaccine Seqirus is Aflunov.

The full indication is:

> Active immunisation against H5N1 subtype of Influenza A virus.
>
> 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 H5N1 subtype strain (see sections 4.4 and 5.1).
>
> Zoonotic Influenza Vaccine Seqirus should be used in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

[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

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.