18 October 2018
EMA/CHMP/641495/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Flucelvax Tetra

Influenza vaccine (surface antigen, inactivated, prepared in cell cultures)

On 18 October 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Flucelvax Tetra, intended for prophylaxis against influenza. The applicant for this medicinal product is Seqirus Netherlands B.V.

Flucelvax Tetra will be available as a suspension for injection in pre-filled syringes. The active substance of Flucelvax Tetra consists of influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated and prepared in cell cultures, of 4 different influenza virus strains (two A subtypes and two B types) (ATC code: J07BB02). Flucelvax Tetra provides active immunisation against influenza virus by inducing humoral antibodies against the haemagglutinins. These antibodies neutralise influenza viruses.

The benefits with Flucelvax Tetra are its ability to induce an immune response in vaccinees similar to the previously authorised trivalent cell-based vaccine, with the added benefit of potentially protecting against both circulating type B viruses. The most common side effects are pain at the injection site, headache, fatigue, myalgia, erythema and induration.

The full indication is: "Prophylaxis of influenza in adults and children from 9 years of age. Flucelvax Tetra 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 made available in all official European Union languages after 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

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