26 March 2020
EMA/CHMP/132960/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Fluad Tetra

influenza vaccine (surface antigen, inactivated, adjuvanted)

On 26 March 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fluad Tetra, a vaccine intended for prophylaxis against influenza. The applicant for this medicinal product is Seqirus Netherlands B.V.

Fluad Tetra will be available as a suspension for injection in pre-filled syringes. The active substance of Fluad Tetra is influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, from 4 different influenza virus strains (two A subtypes and two B types) (ATC code: J07BB02). Fluad Tetra contains the adjuvant MF59C.1 (MF59), which is designed to increase and broaden the antigen-specific immune response and to extend the duration of the immune response. Fluad Tetra provides active immunisation against influenza virus by inducing neutralising antibodies against viral haemagglutinin.

The benefits with Fluad Tetra are its ability to induce an immune response in vaccinees similar to the previously authorised adjuvanted trivalent 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 and fatigue.

The full indication is:

> Prophylaxis of influenza in the elderly (65 years of age and older). Fluad 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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