17 September 2020
EMA/CHMP/355381/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Supemtek

Quadrivalent Influenza Vaccine (recombinant, prepared in cell culture)

On 17 September 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 Supemtek, a vaccine intended for prophylaxis against influenza. The applicant for this medicinal product is Sanofi Pasteur.

Supemtek will be available as solution for injection in pre-filled syringes. The active substance is recombinant influenza virus haemagglutinin proteins, from 4 different influenza virus strains (two A subtypes (H1N1, H3N2) and two B types) (ATC code: J07BB02). Supemtek provides active immunisation against influenza virus by inducing neutralising antibodies against viral haemagglutinin.

The benefits of Supemtek are its ability to induce at least a comparable immune response to an authorised egg-based quadrivalent inactivated influenza vaccine. The most common side effects are injection-site reactions (tenderness and pain), headache and fatigue. In adults 18 to 49 years of age also myalgia and arthralgia.

The full indication is:

> Supemtek is indicated for active immunization for the prevention of influenza disease in adults. Supemtek 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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