EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2013
EMA/CHMP/547873/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Fluenz Tetra

Influenza vaccine (live attenuated, nasal)

On 19 September 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fluenz Tetra, $10^{7.0 \pm 0.5}$ fluorescent focus units (FFU) of live attenuated influenza virus reassortants of each of the four strains selected for the particular influenza season per 0.2 ml dose, nasal spray suspension, intended for prophylaxis of influenza in children and adolescents 24 months to less than 18 years of age. The applicant for this medicinal product is MedImmune LLC. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

Fluenz Tetra, a quadrivalent seasonal influenza vaccine (J07BB03), contains cold-adapted, live attenuated influenza viruses that induce an immune response (mucosal and circulating antibodies) against the antigens (A/H3N2, A/H1N1, and B strains of the Victoria and Yamagata lineages). The type of influenza strains included in the vaccine will conform to the official recommendation for the season.

The benefits with Fluenz Tetra are its ability to efficiently protect children and adolescents from 2 to 18 years of age against seasonal influenza via intranasal administration. The most common side effects are nasal congestion/rhinorrea, decreased appetite, headache and malaise.

A pharmacovigilance plan for Fluenz Tetra will be implemented as part of the marketing authorisation.

The approved indication is: "Prophylaxis of influenza in children and adolescents 24 months to less than 18 years of age. The use of Fluenz Tetra should be based on 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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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Fluenz Tetra and therefore recommends the granting of the marketing authorisation.