21 October 2010
EMA/CHMP/503333/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Fluenz

influenza vaccine (live attenuated, nasal)

On 21 October 2010 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, 10 7.0 ± 0 fluorescent focus units (FFU) of live attenuated influenza virus reassortant of each of the three strains selected for the particular influenza season per 0.2 ml dose, nasal spray suspension, intended for prophylaxis of influenza in individuals 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.

The active substance of Fluenz is influenza vaccine (live attenuated, nasal), a trivalent seasonal influenza vaccines (J07BB03). Fluenz contains cold-adapted, live attenuated influenza viruses that induce an immune response (circulating antibodies) against the antigens (A/H3N2, A/H1N1, and B strains). The composition of the influenza strains will be those officially recommended for the season.

The benefits with Fluenz 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, malaise and fever.

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

The approved indication is: "Prophylaxis of influenza in individuals 24 months to less than 18 years of age. The use of Fluenz 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 will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Fluenz and therefore recommends the granting of the marketing authorisation.

[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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