1 April 2016
EMA/CHMP/170789/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pandemic influenza vaccine H5N1 MedImmune

pandemic influenza vaccine (H5N1) (live attenuated, nasal)

On 1 April 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Pandemic influenza vaccine H5N1 MedImmune, intended for prophylaxis against influenza in an officially declared pandemic situation in children and adolescents. The applicant for this medicinal product is MedImmune LLC.

Pandemic influenza vaccine H5N1 MedImmune will be available as a nasal spray (suspension). The active substance is a live, cold-adapted, temperature sensitive and attenuated reassortant influenza virus of the strain A/Vietnam/1203/2004 (H5N1), produced in Vero cells and subsequently propagated in eggs (ATC code: J07BB03). The virus contained in the vaccine is able to induce protective immunity by infecting and replicating in cells lining the nasopharynx of the vaccine's recipient.

The benefit with Pandemic influenza vaccine (H5N1) MedImmune is its ability to robustly prime naïve individuals against H5N1, resulting in an immune memory response that could be achieved as early as 4 weeks post priming and last for at least 4-5 years, as detected by subsequent re-exposure to H5N1 antigens. Boosted immune responses lasted for up to 6 months and showed broad cross-neutralising activity against up to 4 different H5N1 clades. Similar results were seen with other potential pandemic strains, such as H7N9 and H7N7.

The most common side effects are headache and events of the upper respiratory tract including nasal congestion and rhinorrhoea in the adult population tested. The vaccine's safety profile is considered similar to that of Fluenz Tetra (live attenuated influenza seasonal vaccine); hence decreased appetite, headache, nasal congestion/rhinorrhoea and malaise are expected to be very common side effects in children, and myalgia and pyrexia are expected to be common.

The full indication is: "Prophylaxis of influenza in an officially declared pandemic situation in children and adolescents from 12 months to less than 18 years of age. Pandemic influenza vaccine H5N1 MedImmune should be used in accordance with official guidance".

[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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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.