22 February 2024
EMA/71759/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Incellipan

pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures)

On 22 February 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Incellipan, intended for active immunisation against influenza in an officially declared pandemic.

The applicant for this medicinal product is Seqirus Netherlands B.V.

Incellipan will be available as a 7.5 micrograms per 0.5 ml dose suspension for injection. Incellipan is an influenza vaccine (ATC code J07BB02). It contains haemagglutinin and neuraminidase surface antigens purified from inactivated A/turkey/Turkey/1/2005 (H5N1)-like strain (NIBRG-23) viruses produced in MDCK cell cultures and the adjuvant M59C.1. The Incellipan vaccine triggers an immune response against the H5N1 subtype of the influenza A virus.

The benefits of Incellipan are a robust immune response in adults and children three weeks after two doses of the vaccine given three weeks apart, as measured by haemagglutinin inhibition titres against H5N1. The most common side effects in adults are pain at the injection site, fatigue, headache, malaise, myalgia and arthralgia. In children aged between 6 and 18 years, the most common side effects are injection site pain, myalgia, fatigue, malaise, headache, loss of appetite, nausea, and arthralgia. In children 6 months to less than 6 years of age, the most common side effects are tenderness at the injection site, irritability, sleepiness, change in eating habits and fever.

The full indication is:

> Incellipan is indicated for active immunisation against influenza in an officially declared pandemic.
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> Incellipan should be used in accordance with official recommendations.

[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

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage.

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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.