EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2011
EMA/CHMP/932537/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vepacel

A/H5N1 pre-pandemic influenza vaccine (whole virion, vero cell derived, inactivated)

On 15 December 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vepacel, 7.5 µg Haemagglutinin (HA) antigen per 0.5 ml dose, suspension for injection intended for the prophylaxis of H5N1 subtype of influenza A in either a pre-pandemic or pandemic situation in adults aged 18 years and older. The applicant for this medicinal product is Baxter Innovations GmbH. 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 Vepacel is A/H5N1 pre-pandemic influenza vaccine (whole virion, vero cell derived, inactivated), an influenza vaccine (J07BBOI). Vepacel is a non-adjuvanted vaccine that induces an immune response (circulating antibodies) against the H5N1 antigen.

The benefits with Vepacel are the ability to mount an appropriate immune response in individuals from the age of 18 years onwards that are immunologically naïve against the vaccine strain, including immunocompromised and chronically ill subjects. The most common side effects are injection site reactions, headache and fatigue.

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

The approved indication is: "Active immunisation against H5N1 subtype of influenza A virus. This indication is based on immunogenicity data from healthy subjects from the age of 18 years onwards as well as immunocompromised and chronically ill patients following administration of two doses of vaccine prepared with H5N1 subtype strains".

Vepacel should be used in accordance with official guidance.

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

[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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made 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 Vepacel and therefore recommends the granting of the marketing authorisation.