EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2013
EMA/CHMP/648050/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Vepacel

A/H5N1 prepandemic influenza vaccine (whole virion, Vero cell-derived, inactivated)

On 24 October 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Vepacel. The marketing authorisation holder for this medicinal product is Baxter Innovations GmbH. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows[2]:
"Active immunisation against H5N1 subtype of influenza A virus.

This indication is based on immunogenicity data from subjects **from the age of 6 months onwards** following administration of two doses of vaccine prepared with H5N1 subtype strains (see section 5.1).

VEPACEL should be used in accordance with Official guidance".

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to 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 within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] New indication in bold

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