European Medicines Agency
Evaluation of Medicines for Human Use

London, 29 May 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
PREPANDEMIC INFLUENZA VACCINE (H5N1) (split virion, inactivated, adjuvanted)
GlaxoSmithKline Biologicals

Common Name: ***Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) A/VietNam/1194/2004 NIBRG-14***

On 29 May 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion** to recommend the variation to the terms of the marketing authorisation for the medicinal product Prepandemic Influenza Vaccine. The Marketing Authorisation Holder for this medicinal product is GlaxoSmithKline Biologicals S.A..

The CHMP adopted a change to the indication to extend the current age range (18-60 years) to include subjects aged 61 and older.

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) 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.

For information, the full indication(s) for Prepandemic Influenza Vaccine will be as follows***:

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** following administration of two doses of vaccine prepared from A/VietNam/1194/2004 NIBRG-14 (H5N1) (see section 5.1).

Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals 3.75 µg should be used in accordance with official guidance.

* 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.

** Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

*** The text in bold represents the new or the amended indication.

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