



**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION***

**for
Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline
Biologicals**

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

On 23 July 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation under exceptional circumstances for the medicinal product Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals, 3.75 µg HA suspension and emulsion for emulsion for injection intended for Prophylaxis of influenza in an officially declared pandemic situation in accordance with official guidance. The applicant for this medicinal product is GlaxoSmithKline Biologicals S.A. Belgium.

The active substance of Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals is composed of purified antigen fractions of inactivated split virions of A/Vietnam/1194/2004 NIBRG-14 (H5N1), an Influenza vaccines, ATC Code J07BB02. It is an adjuvanted vaccine that induces an immune response (circulating antibodies) against the H5N1 antigen. This vaccine will only be used in an officially declared influenza pandemic and after inclusion of the exact matching pandemic influenza vaccine strain into the vaccine. For more information on mock-up (pandemic) vaccines, please consult the [Question and Answer](#) document.

The benefits with Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals are that it can mount an appropriate immune response in individuals that are immunologically naïve against the mock-up vaccine strain. Data obtained with this mock-up vaccine will support a vaccination strategy that is likely to be used for the pandemic vaccine. The most common side effects are injection site reactions, headache, tiredness, fever, aching muscles and joint pain.

A pharmacovigilance plan for Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: “Prophylaxis of influenza in an officially declared pandemic situation. Pandemic influenza vaccine 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 (SPC) which will be published in the European Public Assessment Report (EPAR) and will be 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 of the authorised medicinal product, Pandemrix, considers that there is a favourable benefit to risk balance for Pandemic influenza vaccine

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants 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.

(H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals and therefore recommends the granting of the marketing authorisation under exceptional circumstances^{***}.

^{***} Marketing Authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.