European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 21 February 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
PREPANDRIX

Common Name: **Pre-pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)**

On 21 February 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Prepandrix, 3.75 Micrograms of haemagglutinin (HA), Suspension and emulsion for emulsion for injection intended for active immunisation against H5N1 subtype of Influenza A virus. In accordance with official guidance. The applicant for this medicinal product is GlaxoSmithKline Biologicals S.A. Belgium.

The active substance of Prepandrix is composed of purified antigen fractions of inactivated split virions 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.

The benefits with Prepandrix are that it can mount an appropriate immune response in individuals that are immunologically naïve against the vaccine strain and the assumption that vaccination with Prepandrix will provide a clinically useful degree of cross-protection against the strain that causes the next pandemic. The most common side effects are injection side reactions, headache, tiredness, fever, aching muscles and joint pain.

A pharmacovigilance plan for Prepandrix, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "Active immunisation against H5N1 subtype of Influenza A virus".

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 submitted, considers that there is a favourable benefit to risk balance for Prepandrix and therefore recommends the granting of the marketing authorisation.

* 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.

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