18 November 2010
EMA/CHMP/692469/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Pumarix

active substance: Split influenza virus, inactivated, containing antigen*: A/Indonesia/05/2005 (H5N1), *produced in eggs

On 18 November 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Pumarix, 3.75 µg HA derived from A/Indonesia/05/2005 (H5N1), 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.. 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 Pumarix is pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted), an influenza vaccine, 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.

The benefits with Pumarix are that it can mount an appropriate immune response in individuals that are immunologically naïve against the mock-up vaccine strain A/Indonesia/05/2005 (H5N1). 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 pain at the injection site, headache, fatigue, aching muscles and joint pain.

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

The approved indication is: “Prophylaxis of influenza in an officially declared pandemic situation”. It is proposed that Pumarix is prescribed by physicians experienced in the treatment of influenza.

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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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 there to be a favourable benefit to risk balance for Pumarix and therefore recommends the granting of the marketing authorisation under exceptional circumstances[2].

[2] In exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety of the medicinal product, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data.