20th January 2010
EMA/CHMP/30965/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Arepanrix

Common name: Pandemic Influenza vaccine (H1N1) (split virion, inactivated, adjuvanted) A/California/7/2009 (H1N1)v like strain (X-179A)

On 20th January 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion[2], recommending the granting of a conditional marketing authorisation for the medicinal product Arepanrix, 3.75 µg HA derived from A/California/7/2009 (H1N1)v like strain (X-179A), 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 Arepanrix is Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted) A/California/7/2009 (H1N1)v like strain (X-179A), an influenza vaccine, ATC code J07BB02. This vaccine will be used for active immunization against the (H1N1)v 2009 influenza strain in an official declared influenza pandemic situation.

The benefits with Arepanrix are that it can mount an appropriate immune response in individuals that are immunologically naïve against the pandemic strain A/California/7/2009 (H1N1)v. The most common side effects are pain at the injection site, headache, fatigue, aching muscles and joint pain.

A pharmacovigilance plan for Arepanrix 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 Arepanrix 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 Arepanrix and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional[3].

[3] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.