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

London, 18 December 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
CELVAPAN

Common Name: **Pandemic Influenza Vaccine (H5N1 whole virion, Vero cell derived, inactivated)**

On 18 December 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending the granting of a marketing authorisation for the medicinal product Celvapan, 7.5 µg HA, suspension 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 Baxter AG, Vienna, Austria.

The active substance of Celvapan is composed of Vero cell derived, purified and inactivated whole virions of A/Vietnam/1203/2004 (H5N1) or A/Indonesia/05/2005 (H5N1), an Influenza vaccine, ATC Code J07BB02. Celvapan is a non-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 Celvapan 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, arthralgia and myalgia.

A pharmacovigilance plan for Celvapan, 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".

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 Celvapan and therefore recommends the granting of the marketing authorisation under exceptional circumstances***.

* 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.

*** Marketing Authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations.

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