European Medicines Agency
Evaluation of Medicines for Human Use

Doc.Ref.: EMEA/538427/2009

ASSESSMENT REPORT

FOR

PANDEMIC INFLUENZA VACCINE H5N1 BAXTER

Common Name: Pandemic influenza vaccine (H5N1 whole virion, Vero cell derived, inactivated)

Procedure No. EMEA/H/C/001200

Assessment Report as adopted by the CHMP with
all information of a commercially confidential nature deleted.

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1. BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Baxter AG submitted on 9 July 2009 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for PANDEMIC INFLUENZA VACCINE H5N1 BAXTER, through the centralised procedure falling within the Article 3(1) and point 1 of Annex of Regulation (EC) No 726/2004.

The legal basis for this application refers to Article 10(c) of Directive 2001/83/EC, as amended – relating to informed consent from the marketing authorisation holder, for the authorised medicinal product: Celvapan (EU/1/08/506/001).

Licensing status:
The initial product, Celvapan, was given a Community Marketing Authorisation on 4 March 2009.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: Dr Christian Schneider Co-Rapporteur: Dr Andrea Laslop

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 9 July 2009.
- The procedure started on 10 July 2009.
- The draft CHMP Assessment Report was circulated to all CHMP members on 15 July 2009.
- During the meeting on 20-23 July 2009, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation under exceptional circumstances to PANDEMIC INFLUENZA VACCINE H5N1 BAXTER on 23 July 2009.
- The applicant provided the letter of undertaking on the specific obligations and follow-up measures to be fulfilled post-authorisation on 23 July 2009.

2 SCIENTIFIC DISCUSSION

2.1 Introduction

This application has been submitted as an informed consent application in accordance with Article 10c of Directive 2001/83/EC as amended.
Therefore, consent from the MAH of the Celvapan application, which had been submitted as a full application under Art 8(3) of Directive 2001/83/EC as amended, has been given allowing access to Module 2 to Module 5 of the initial dossier of this authorised product and any subsequent post-marketing procedures submitted, assessed and approved at the time of the submission of the informed consent application. The application for PANDEMIC INFLUENZA VACCINE H5N1 BAXTER consists only of Module 1 information.

As a consequence, quality, safety and efficacy of the PANDEMIC INFLUENZA VACCINE H5N1 BAXTER medicinal product are identical to the quality, safety and efficacy profile of PANDEMIC INFLUENZA VACCINE H5N1 BAXTER at the time of the submission of the informed consent application. Information on the scientific discussions can be found in the Celvapan CHMP assessment report and in the European Public Assessment Report (EPAR).

Celvapan is a whole virion inactivated influenza vaccine, which is produced in Vero cells and employing a wild type virus H5N1strain. The final vaccine comprises 7.5µg of HA antigen of strain A/Vietnam/1203/2004 (or A/Indonesia/05/2005) per 0.5 ml dose and is presented in a 10-dose vial with no preservative added.

Celvapan is indicated for prophylaxis of influenza in an officially declared pandemic situation. Pandemic influenza vaccine should be used in accordance with official guidance.

Future pandemics might not be caused by a H5N1 virus but will be due to another subtype of influenza virus (e.g. with haemagglutinin of type H1, H2, H7 or H9). In line with the core dossier concept, a variation would therefore have to be submitted to introduce the WHO/EU recommended strain, prepared from the influenza virus causing the pandemic, prior to use of PANDEMIC INFLUENZA VACCINE H5N1 BAXTER in a pandemic. PANDEMIC INFLUENZA VACCINE H5N1 BAXTER is not indicated for prophylactic use during the prepandemic period.

2.2 Quality aspects

Since this application is an informed consent of the Celvapan application, the quality data in support of the PANDEMIC INFLUENZA VACCINE H5N1 BAXTER application are identical to the quality data of the Celvapan dossier which have been assessed and approved (including all post-marketing procedures finalised at the time of the submission of the informed consent application).

2.3 Non-clinical aspects

Since this application is an informed consent of the Celvapan application, the non-clinical data in support of the PANDEMIC INFLUENZA VACCINE H5N1 BAXTER application are identical to the non-clinical data of the Celvapan dossier which have been assessed and approved (including all post-marketing procedures finalised at the time of the submission of the informed consent application).

2.4 Clinical aspects

Since this application is an informed consent of the Celvapan application, the clinical data in support of the PANDEMIC INFLUENZA VACCINE H5N1 BAXTER application are identical to the clinical

data of the Celvapan dossier which have been assessed and approved (including all post-marketing procedures finalised at the time of the submission of the informed consent application).

2.5 Pharmacovigilance

Detailed description of the Pharmacovigilance system

The CHMP considered that the Pharmacovigilance system as described by the applicant, which is identical to that of the authorised product Celvapan, fulfilled the legislative requirements.

Risk Management Plan

The risk management plan, which is identical to that of the authorised product Celvapan, was drafted in accordance with the CHMP core RMP for vaccines intended for use in a pandemic declared situation.
The applicant committed to update the RMP for the current application in line with the outcome of the assessment of the RMP submitted on 14 August 2008 for Celvapan, if required.

2.6 Overall conclusions, risk/benefit assessment and recommendation

Since this application is an informed consent of the Celvapan application, the CHMP considered that the risk-benefit balance of PANDEMIC INFLUENZA VACCINE H5N1 BAXTER was favourable and therefore recommended the granting of the marketing authorisation under exceptional circumstances for the following indication:

“Prophylaxis of influenza in an officially declared pandemic situation. Pandemic influenza vaccine should be used in accordance with official guidance.

PANDEMIC INFLUENZA VACCINE H5N1 BAXTER has been evaluated in adults 18-59 years of age and in elderly 60 years of age and above.”