



European Medicines Agency
Evaluation of Medicines for Human Use

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ASSESSMENT REPORT

FOR

Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals

Common Name: Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)
A/VietNam/1194/2004 NIBRG-14

Procedure No. EMEA/H/C/1206

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 GlaxoSmithKline Biologicals S.A. submitted on 14 July 2009 an application for Marketing Authorisation to the European Medicines Agency (EMA) for Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals, 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: Pandemrix (EU/1/08/452/001).

The applicant applied for the following indication: Prophylaxis of influenza in an officially declared pandemic situation. Pandemic influenza vaccine should be used in accordance with official guidance.

Licensing status:

The initial product, Pandemrix, was given a Community Marketing Authorisation on 20 May 2008.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:

Rapporteur: Dr Rafe Suvarna Co-Rapporteur: Dr Barbara van Zwieten-Boot

1.2 Steps taken for the assessment of the product

- The application was received by the EMA on 14 July 2009.
- The procedure started on 15 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) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals 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 22 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 Pandemrix 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) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals consists only of Module 1 information.

As a consequence, quality, safety and efficacy of the Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals medicinal product are identical to the quality, safety and efficacy profile of Pandemrix at the time of the submission of the informed consent application. Information on the scientific discussions can be found in the Pandemrix CHMP assessment report and in the European Public Assessment Report (EPAR).

Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals is a split virion inactivated influenza vaccine, containing the mock-up strain H5N1 (NIBRG-14) derived by reverse genetics from the avian influenza virus A/Viet Nam/1194/2004. The final formulation contains 3.75 µg haemagglutinin (HA) per 0.5 ml dose adjuvanted by AS03. Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals 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) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals in a pandemic. Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals is not indicated for prophylactic use during the prepandemic period.

2.2 Quality aspects

Since this application is an informed consent of the Pandemrix application, the quality data in support of the Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals application are identical to the quality data of the Pandemrix 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 Pandemrix application, the non-clinical data in support of the Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals application are identical to the non-clinical data of the Pandemrix 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 Pandemrix application, the clinical data in support of the Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals application are identical to the clinical data of the Pandemrix 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 Pandemrix, fulfilled the legislative requirements.

Risk Management Plan

The risk management plan, which is identical to that of the authorised product Pandemrix, 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 29 March 2009 for Pandemrix, if required.

2.6 Overall conclusions, risk/benefit assessment and recommendation

Since this application is an informed consent of the Pandemrix application, the CHMP considered that the risk-benefit balance of Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals 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 (see sections 4.2 and 5.1).”