European Medicines Agency

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P/79/2009

EUROPEAN MEDICINES AGENCY DECISION

of 24 April 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05 (H5N1) (EMEA-000134-PIP01-07) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use as amended and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by GlaxoSmithKline Biologicals S.A. on 11 January 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 March 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision granting a Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a deferral.

(4) It is therefore appropriate to adopt a Decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

A Paediatric Investigation Plan for purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05 (H5N1), emulsion and suspension for emulsion for injection, intramuscular injection, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05 (H5N1), emulsion and suspension for emulsion for injection, intramuscular injection, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05 (H5N1), emulsion and suspension for emulsion for injection, intramuscular injection, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to GlaxoSmithKline Biologicals S.A., 89 rue de l'Institut, 1330 Rixensart, Belgium.

Done at London, 24 April 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency

Doc. Ref.:EMEA/PDCO/127070/2009
EMEA-000134-PIP01-07

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance:
Purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05 (H5N1)

Condition(s):
Influenza infection caused by an influenza strain contained in the vaccine or related to a strain contained in the vaccine

Pharmaceutical form(s):
Emulsion and suspension for emulsion for injection

Route(s) of administration:
Intramuscular injection

Name/corporate name of the PIP applicant:
GlaxoSmithKline Biologicals S.A.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Biologicals S.A. submitted for agreement to the EMEA on 11 January 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 14 February 2008.

Supplementary information was provided by the applicant on 23 December 2008.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
- grant a deferral in accordance with Article 21 of said Regulation,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex(es) and appendix.

London, 6 March 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S)
Influenza infection caused by an influenza strain contained in the vaccine or related to a strain contained in the vaccine

B. WAIVER

- **Condition**

Influenza infection caused by an influenza strain contained in the vaccine or related to a strain contained in the vaccine

The waiver applies to:

- Newborn and infants from birth to less than 2 months for suspension and emulsion for emulsion for injection

on the grounds that the specific medicinal product is likely to be ineffective

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Influenza infection caused by an influenza strain contained in the vaccine or related to a strain contained in the vaccine

- **Proposed PIP indication**

Active immunisation against H5N1 subtype of influenza A virus

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 2 months to less than 18 years.

- **Formulation(s)**

Suspension and emulsion for emulsion for injection

- **Studies**

Area	Number of studies	Description
Clinical	4	A randomised, open-label, active-controlled study to evaluate the safety and immunogenicity of the paediatric formulation of the (pre-) pandemic H5N1 influenza candidate vaccine following a heterologous prime-boost schedule (six months apart) in children aged from 6 months to less than 36 months. A randomised, double-blind, active-controlled study to evaluate the safety and immunogenicity of a prime-boost schedule of the paediatric formulation of H5N1 candidate vaccine administered to subjects aged from 3 years to less than 18 years. A randomised, active-controlled study to evaluate the safety and immunogenicity of a prime-boost schedule of the paediatric formulation of the H5N1 candidate vaccine administered to subjects aged from 2 months to less than 6 months. A randomised, active-controlled, double-blind study to evaluate the safety and immunogenicity of a two-dose vaccination series of Quebec manufactured monovalent A/Indonesia/5/2005 (H5N1) vaccine antigen adjuvanted with AS03 in children from 6 months to less than 36 months of age.

Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By September 2012**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**