

EMA/78783/2011

European Medicines Agency decision P/47/2011

of 4 March 2011

on the acceptance of a modification of an agreed paediatric investigation plan for purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005 (H5N1) /purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004 (H5N1) (Prepandrix / Prepandemic influenza vaccine (H5N1 Vietnam) (split virion, inactivated, adjuvanted) / Pandemic influenza vaccine (H5N1 Vietnam) (split virion, inactivated, adjuvanted)), (EMEA-000160-PIP01-07-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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on the acceptance of a modification of an agreed paediatric investigation plan for purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005 (H5N1) /purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004 (H5N1) (Prepandrix / Prepandemic influenza vaccine (H5N1 Vietnam) (split virion, inactivated, adjuvanted) / Pandemic influenza vaccine (H5N1 Vietnam) (split virion, inactivated, adjuvanted)), (EMEA-000160-PIP01-07-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

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 and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/80/2009 issued on 24 April 2009,

Having regard to the application submitted by GlaxoSmithKline Biologicals S.A. on 3 November 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 January 2011, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005 (H5N1) / purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004 (H5N1) (Prepandrix / Prepandemic influenza vaccine (H5N1 Vietnam) (split virion, inactivated, adjuvanted) / Pandemic influenza vaccine (H5N1 Vietnam) (split virion, inactivated, adjuvanted)), suspension and emulsion for emulsion for injection, intramuscular use, including changes to the deferral are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

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

Done at London, 4 March 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/825122/2010

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMA-000160-PIP01-07-M01

Scope of the application

Active substance(s):

Purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005 (H5N1)

Purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004 (H5N1)

Invented name:

Prepandrix

Prepandemic influenza vaccine (H5N1 Vietnam) (split virion, inactivated, adjuvanted)

Pandemic influenza vaccine (H5N1 Vietnam) (split virion, inactivated, adjuvanted)

Condition(s):

Prevention of influenza infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Suspension and emulsion for emulsion for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Biologicals S.A.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Biologicals S.A. submitted to the European Medicines Agency on 3 November 2010 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/80/2009 issued on 24 April 2009.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 18 November 2010.

A meeting with the Paediatric Committee took place on 13 January 2011.

Scope of the modification

Some measures and/or timelines of the agreed paediatric investigation plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
 - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

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

London, 14 January 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

1.1. Condition: Prevention of influenza infection

The waiver applies to:

- Newborn and infants from birth to less than 2 months,
- for suspension and emulsion for emulsion for injection, intramuscular use,
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan

2.1. Condition: Prevention of influenza infection

2.1.1. Indication(s) targeted by the PIP

Active immunisation against H5N1 subtype of influenza A virus in a pandemic situation

Active immunisation against H5N1 subtype of influenza A virus in a pre-pandemic situation

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 2 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Suspension and emulsion for emulsion for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	3	An open-label 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, open-label 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

Area	Number of studies	Description
		than 6 months.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

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

Authorised indications:

1. Prepandrix:

Active immunisation against H5N1 subtype of Influenza A virus.

This indication is based on immunogenicity data from healthy subjects from the age of 18 years onwards following administration of two doses of vaccine prepared with H5N1 subtype strains (see SmPC section 5.1).

Prepandrix should be used in accordance with official guidance.

2. Prepandemic influenza vaccine (H5N1 Vietnam) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals:

Active immunisation against H5N1 subtype of Influenza A virus.

This indication is based on immunogenicity data from healthy subjects from the age of 18 years onwards following administration of two doses of vaccine prepared from A/VietNam/1194/2004 NIBRG-14 (H5N1) (see SmPC section 5.1).

Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals 3.75 µg should be used in accordance with official guidance.

3. Pandemic influenza vaccine (H5N1 Vietnam) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals:

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).

<u>EU Number</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of Administration</u>	<u>Packaging</u>	<u>Content</u>	<u>Package size</u>
EU/1/08/45 3/002	Prepandrix	3.75 µg HA	Suspension and emulsion for injection	Intramuscular use	emulsion: vial (glass); suspension: vial (glass)	suspension: 2.5 ml; emulsion: 2.5 ml	50 vials (suspension) + 2 x 25 vials (emulsion)
EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/09/57 8/001	Pandemic influenza vaccine (H5N1 Vietnam) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals	3.75 µg HA	Suspension and emulsion for injection	Intramuscular use	suspension (H5N1): vial (glass) emulsion (adjuvant): vial (glass)	2.5 ml (suspension) 2.5 ml (emulsion)	50 vials (suspension) 2 x 25 vials (emulsion)
EMA Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size

EU/1/08/47 8/001	Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKl ine Biologicals	3.75 µg HA	Suspension and emulsion for emulsion for injection	Intramuscular use	emulsion: vial (glass); suspension: vial (glass)	suspensi on: 2.5 ml; emulsion : 2.5 ml	50 vials (suspensio n) + 2 x 25 vials (emulsion)
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