EMA/698108/2011

European Medicines Agency decision

P/228/2011

of 28 September 2011

on the acceptance of a modification of an agreed paediatric investigation plan for split Influenza virus, inactivated, containing antigen: A/California/7/2009 (H1N1)v like strain (X-179A) (Pandemrix), (EMEA-000725-PIP01-09-M03) 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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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 726/2004[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 European Medicines Agency's decision P/205/2009 issued on 30 October 2009, and the decision P/132/2010 issued on 28 July 2010,

Having regard to the application submitted by GlaxoSmithKline Biologicals S.A. on 30 May 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 August 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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 split Influenza virus, inactivated, containing antigen: A/California/7/2009 (H1N1)v like strain (X-179A) (Pandemrix), suspension and emulsion for injection, intramuscular use, 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, 28 September 2011

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

EMA/PDCO/578869/2011

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

EMEA-000725-PIP01-09-M03

Scope of the application

Active substance(s):

Split Influenza virus, inactivated, containing antigen: A/California/7/2009 (H1N1)v like strain (X-179A)

Invented name:

Pandemrix

Condition(s):

Prevention of Influenza infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Suspension and 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

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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 30 May 2011 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/205/2009 issued on 30 October 2009, and the decision P/132/2010 issued on 28 July 2010.

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

The procedure started on 15 June 2011.

Scope of the modification

Some measures of the 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 in the scope set out in the Annex I of this opinion.

   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 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 European Medicines Agency, together with its annex(es) and appendix.

London, 12 August 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 of age
- For suspension and emulsion for emulsion for injection, intramuscular use
- On the grounds that the specific medicinal product is likely to be ineffective.

And:

- Infants from 2 months to less than 6 months of age
- For suspension and emulsion for emulsion for injection, intramuscular use
- On the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: Prevention of Influenza infection

2.1.1. Indication(s) targeted by the PIP

Prevention of infection by pandemic influenza virus (H1N1 strain)

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

From 6 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Suspension and emulsion for emulsion for injection, intramuscular use

2.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	5	Open-label study to evaluate the safety and immunogenicity of a 2-dose priming schedule of the pandemic influenza vaccine (H1N1) (split virion, inactivated, full-dose adjuvant AS03), containing antigen (full dose) equivalent to Influenza A/California/7/2009 (Dresden manufacturing site), in children and adolescents from 3 to less than 18 years. (#1). Open-label study to evaluate the safety and immunogenicity of a 2-dose priming schedule of the pandemic influenza vaccine (H1N1) candidate (split virion, inactivated, half-dose adjuvant AS03), containing antigen (half dose) equivalent to A/California/7/2009 (H1N1)v-like strain (Dresden manufacturing site) in children and adolescents from 3 to less than 18 years (#2). Open-label study to evaluate the safety and immunogenicity of two dose levels of the pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted), containing antigen equivalent to Influenza A/California/7/2009 (Dresden manufacturing site) in toddlers and children from 6 to less than 36 months. (#3). Open-label study to evaluate the safety and immunogenicity of an non-adjuvanted trivalent influenza vaccine as booster in subjects from 10 years to 17 years (at time of priming) vaccinated with the pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted), containing antigen equivalent to Influenza A/California/7/2009 (Dresden manufacturing site) as part of the pandemic national vaccination campaign (#5). Open-label study to evaluate the safety and immunogenicity of an non-adjuvanted trivalent influenza vaccine as booster in subjects from 6 months to 9 years (at time of priming) vaccinated with the pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted), containing antigen equivalent to Influenza A/California/7/2009 (Dresden manufacturing site) as part of the pandemic national vaccination campaign (#6).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By November 2011
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):

1. Prevention of Influenza Infection

   Authorised indications:

   Prophylaxis of influenza caused by A (H1N1)v 2009 virus. (see section 4.4).

   Pandemrix should be used in accordance with Official Guidance.

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/08/452/001	Pandemrix	--1	Suspension and emulsion for emulsion for injection	Intramuscular use	suspension (H1N1): vial (glass); emulsion (adjuvant): vial (glass)	suspension : 2.5 ml emulsion : 2.5 ml	50 vials (suspension) + 2 x 25 vials (emulsion)

--1

3.75 µg HA

After mixing, 1 dose (0.5 ml) contains:

Split influenza virus, inactivated, containing antigen* equivalent to:

A/California/7/2009 (H1N1)v-like strain (X-179A) 3.75 micrograms**

* propagated in eggs

** haemagglutinin

AS03 adjuvant composed of squalene (10.69 milligrams), DL-α-tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams)