EMA/425529/2010

European Medicines Agency decision

P/148/2010

of 3 August 2010

on the acceptance of a modification of an agreed paediatric investigation plan for pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted), containing antigen equivalent to Influenza A/California/7/2009 (Produced at Quebec manufacturing site), Arepanrix (EMEA-000687-PIP01-09-M02) 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/219/2009 issued on 30 October 2009,

Having regard to the application submitted by GlaxoSmithKline Biologicals S.A. on 5 April 2010 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 11 June 2010, 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 waiver.

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

Changes to the agreed paediatric investigation plan for pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted), containing antigen equivalent to Influenza A/California/7/2009 (Produced at Quebec manufacturing site), Arepanrix, suspension and emulsion for emulsion for injection, intramuscular use, including changes to a waiver, 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, 1330 – Rixensart, Belgium.

Done at London, 3 August 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/349905/2010

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

EMEA-000687-PIP01-09-M02

Scope of the application

Active substance(s):

Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted), containing antigen equivalent to Influenza A/California/7/2009 (Produced at Quebec manufacturing site)

Invented name:

Arepanrix

Condition(s):

Influenza

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

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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 5 April 2010 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/219/2009 issued on 30 October 2009.

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

The procedure started on 15 April 2010.

Scope of the modification

The request of modification regards an extension of the scope of the waiver in infants 2-6 months of age, changes in the measures and timelines, and an agreement on the conduct of 2 additional studies.

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 waiver in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member(s) agree(s) 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 annexes and appendix.

London, 11 June 2010

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

1. Condition(s)

Influenza

2. Waiver

2.1. Condition

Influenza

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.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Influenza

3.1.1. Indication targeted by the PIP

Prevention of infection by pandemic influenza virus (H1N1 strain)

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

From 6 months to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Suspension and emulsion for emulsion for injection, intramuscular use

3.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	6	• Open-label study to evaluate the safety and immunogenicity of a 2-

Area	Number of studies	Description
		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) • Biosimilarity study in adult healthy volunteers, to assess the immunological equivalence of the Quebec-manufactured (H1N1)v-like antigen to the Dresden-manufactured (H1N1)v-like antigen (both adjuvanted with ASO3) (#5). • 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 (#6) • 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 (#7)

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	By May 2011
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Invented name Name	Strength	Pharmaceutical form	Route of administration
Arepanrix	3.75 micrograms haemagglutinin per dose	Suspension and emulsion for emulsion for injection	Intramuscular use