EMA/205462/2015

European Medicines Agency decision

P/0088/2015

of 8 May 2015

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) like strain used (PR8-IBCDC-RG2) (Pumarix), (EMEA-000178-PIP01-07-M04) 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/81/2009 issued on 24 April 2009, the decision P/48/2011 issued on 4 March 2011, the decision P/0153/2012 issued on 25 July 2012 and the decision P/0254/2013 issued on 30 October 2013,

Having regard to the application submitted by GlaxoSmithKline Biologicals S.A. on 18 December 2014 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 20 March 2015, 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 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 deferral and 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 purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005(H5N1) like strain used (PR8-IBCDC-RG2) (Pumarix), emulsion and suspension for emulsion for injection, intramuscular use, including changes to the deferral and to the 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, B-1330 - Rixensart

Belgium.

Done at London, 8 May 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/1883/2015
London, 20 March 2015

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

EMEA-000178-PIP01-07-M04

Scope of the application

Active substance(s):

Purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005(H5N1) like strain used (PR8-IBCDC-RG2)

Invented name:

Pumarix

Condition(s):

Prevention of influenza infection

Pharmaceutical form(s):

Emulsion and suspension for emulsion for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Biologicals S.A.

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 18 December 2014 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/81/2009 issued on 24 April 2009, the decision P/48/2011 issued on 4 March 2011, the decision P/0153/2012 issued on 25 July 2012 and the decision P/0254/2013 issued on 30 October 2013.

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

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The procedure started on 20 January 2015.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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 and to the waiver 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 and appendix.

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 (PIP)

1. Waiver

1.1. Condition: prevention of influenza infection

The waiver applies to:

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

and to

- infants from 2 to less than 6 months;
- for emulsion and suspension 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

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

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)

Emulsion and suspension for emulsion for injection.

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical	0	Not applicable.

Area	Number of measures	Description
Clinical studies	4	**Study 1:** 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. **Study 2:** 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. **Study 3:** Randomised, observer-blind, dose-range study to assess immunogenicity and safety of varying quantities of the Quebec manufactured H5N1 HA antigen (Q-Pan) adjuvanted with varying quantities of AS03 as compared to the reference vaccine dose of 1.9 µg HA with AS03B. **Study 4:** Open-label, dose-confirmatory study to assess immune response of the selected dose (from the Q-Pan-023 study).
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

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 April 2021
Deferral for one or more studies contained in the paediatric investigation plan:	Yes