EMA/478120/2012

# European Medicines Agency decision

P/0153/2012

of 25 July 2012

on the acceptance of a modification of an agreed paediatric investigation plan for purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05/ (H5N1) (Pumarix), (EMEA-000178-PIP01-07-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/81/2009 issued on 24 April 2009, and the decision P/48/2011 issued on 4 March 2011,

Having regard to the application submitted by GlaxoSmithKline Biologicals S.A. on 23 April 2012 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 8 June 2012, 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 purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05/ (H5N1) (Pumarix), emulsion and suspension for 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, 25 July 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/478120/2012

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

EMEA-000178-PIP01-07-M02

## Scope of the application

**Active substance(s):**

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

**Invented name:**

Pumarix

**Condition(s):**

Prevention of influenza infection

**Authorised indication(s):**

See Annex II

**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.

**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 23 April 2012 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, and the decision P/48/2011 issued on 4 March 2011.

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

The procedure started on 15 May 2012.

## Scope of the modification

Some measures and timelines 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, 8 June 2012

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 prepandemic 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.<br><br>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.<br><br>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. |

## 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 October 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):**

1. Prevention of influenza infection

Authorised indications:

Prophylaxis of influenza in an officially declared pandemic situation (see sections 4.2 and 5.1).

Pandemic influenza vaccine should be used in accordance with official guidance.

| EU Number | Invented name | Strength | Pharmaceutical form | Route of administration | Packaging | Content (concentration) | Package size |
|---|---|---|---|---|---|---|---|
| EU/1/10/664/001 | Pumarix | | Suspension and emulsion for emulsion for injection | Intramuscular use | suspension (H5N1): vial (glass); emulsion (adjuvant): vial (glass) | suspension: 2.5 ml; emulsion: 2.5 ml | 50 vials (suspension) + 2 x 25 vials (emulsion) |

3.75 µg HA

After mixing, 1 dose (0.5 ml) contains:

Split influenza virus inactivated, containing antigen* equivalent to:

A/Indonesia/05/2005 (H5N1) 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)