EMA/176604/2011

European Medicines Agency decision

P/67/2011

of 11 March 2011

on the acceptance of a modification of an agreed paediatric investigation plan for antigen of pre-pandemic strain A/Vietnam/1203/2004 propagated in Vero cells (EMEA-000156-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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union

European Medicines Agency decision

P/67/2011

of 11 March 2011

on the acceptance of a modification of an agreed paediatric investigation plan for antigen of pre-pandemic strain A/Vietnam/1203/2004 propagated in Vero cells (EMEA-000156-PIP01-07-M02) 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 726/2004[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/25/2009 issued on 23 February 2009, and the decision P/121/2010 issued on 2 July 2010,

Having regard to the application submitted by Baxter Innovations GmbH on 3 December 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan including changes to the granted waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 February 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 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 antigen of pre-pandemic strain A/Vietnam/1203/2004 propagated in Vero cells, suspension for injection, intramuscular use, including changes 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 Baxter Innovations GmbH, Industriestraße 67, 1221 Vienna, Austria.

Done at London, 11 March 2011

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

EMA/PDCO/44037/2011

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

EMEA-000156-PIP01-07-M02

Scope of the application

Active substance(s):

Antigen of pre-pandemic strain A/Vietnam/1203/2004 propagated in Vero cells

Condition(s):

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

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Baxter Innovations GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Baxter Innovations GmbH submitted to the European Medicines Agency on 3 December 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/25/2009 issued on 23 February 2009, and the decision P/121/2010 issued on 2 July 2010.

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

The procedure started on 22 December 2010.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Scope of the modification

Changes in some of the measures of the paediatric investigation plan and a different age range for the waiver.

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 Icelandic and 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.

London, 18 February 2011

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

2. Waiver

2.1. Condition:

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

The waiver applies to:

- Infants and toddlers from birth to less than 6 months,
- for suspension for injection for intramuscular use,
- on the grounds that the specific medicinal product is likely to be ineffective.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

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

3.1.1. Indication targeted by the PIP

Active immunisation against H5N1 subtype of influenza A virus

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 for injection

3.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	1	A partially blinded Study to Assess the Safety and Immunogenicity of a Vero Cell-Derived Whole Virus H5N1 Influenza Vaccine in Healthy Infants, Children and Adolescents Aged 6 Months to less than 18 Years.

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues or efficacy in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	By December 2012
Deferral for one or more studies contained in the paediatric investigation plan:	Yes