EMA/672567/2010

European Medicines Agency decision

P/234/2010

of 26 November 2010

on the acceptance of a modification of an agreed paediatric investigation plan for influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of the following strains: A/Solomon Islands/3/2006 (H1N1) like strain (A/Solomon Islands/3/2006, IVR-145), A/Wisconsin/67/2005 (H3N2) like strain (A/Wisconsin/67/2005, NYMC X161B), B/Malaysia/2506/2004 like strain (B/Malaysia/2506/2004) (Optaflu), (EMEA-000124-PIP01-07-M01) 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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European Medicines Agency decision

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on the acceptance of a modification of an agreed paediatric investigation plan for influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of the following strains: A/Solomon Islands/3/2006 (H1N1) like strain (A/Solomon Islands/3/2006, IVR-145), A/Wisconsin/67/2005 (H3N2) like strain (A/Wisconsin/67/2005, NYMC X161B), B/Malaysia/2506/2004 like strain (B/Malaysia/2506/2004) (Optaflu), (EMEA-000124-PIP01-07-M01) 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/88/2008 issued on 14 October 2008,

Having regard to the application submitted by Novartis Vaccines & Diagnostics GmbH & Co. KG on 26 August 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 October 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.

(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 influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of the following strains: A/Solomon Islands/3/2006 (H1N1) like strain (A/Solomon Islands/3/2006, IVR-145), A/Wisconsin/67/2005 (H3N2) like strain (A/Wisconsin/67/2005, NYMC X161B), B/Malaysia/2506/2004 like strain (B/Malaysia/2506/ 2004) (Optaflu), suspension for injection (in a pre-filled syringe), 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 Novartis Vaccines and Diagnostics GmbH, Emil-von-Behring Str. 76, 35041 – Marburg, Germany.

Done at London, 26 November 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/624789/2010

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

EMEA-000124-PIP01-07-M01

Scope of the application

Active substance(s):

Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of the following strains:

A/Solomon Islands/3/2006 (H1N1) like strain (A/Solomon Islands/3/2006, IVR-145)

A/Wisconsin/67/2005 (H3N2) like strain (A/Wisconsin/67/2005, NYMC X161B)

B/Malaysia/2506/2004 like strain (B/Malaysia/2506/2004)

Invented name:

Optaflu

Condition(s):

Prevention of influenza

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Suspension for injection (in a pre-filled syringe)

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Novartis Vaccines & Diagnostics GmbH & Co. KG

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, Novartis Vaccines & Diagnostics GmbH & Co. KG submitted to the European Medicines Agency on 26 August 2010 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/88/2008 issued on 14 October 2008.
The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 15 September 2010.

Scope of the modification

Some timelines of the original Opinion 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 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 October 2010

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

Not applicable

2. Paediatric Investigation Plan

2.1. Condition

Prevention of influenza

2.1.1. Indication(s) targeted by the PIP

Prevention of seasonal influenza

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Suspension for injection in a pre-filled syringe

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Age appropriate formulation for infants 0 to 36 months of age.
Non-clinical	0	Not applicable.
Clinical	5	Phase II/III, observer-blind, randomised, multi-center study to evaluate safety, tolerability and immunogenicity of trivalent subunit influenza vaccines in healthy children and adolescents aged from 3 to less than 18 years. Phase III, observer-blind, randomised study to evaluate safety of trivalent subunit influenza vaccines in children and adolescents from 3 to less than 18 years of age at risk for influenza complications. Phase I/II, randomised, observer-blind, multicentre, dose-ranging study to evaluate different dosages of Optaflu in healthy children from 6 to less than 36 months of age. Phase III, observer-blind, randomised study to evaluate safety of trivalent subunit influenza vaccines in children aged from 6 to less than 36 months of age at risk for influenza complications. Phase I/II safety and immunogenicity study, active controlled, randomised in infants less than 6 months of age.

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:	No
Date of completion of the paediatric investigation plan:	By July 2016
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

   Authorised indications:

   Prophylaxis of influenza in children and adolescents aged 0 months to 17 years and in adults, especially in those who run an increased risk of associated complications.

   The use of Optaflu should be based on official recommendations.

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)
EU/1/07/394/001	Optaflu	--[1]	Suspension for injection in pre-filled syringe	Intramuscular use	pre-filled syringe (glass)	0.5 ml
EU/1/07/394/002	Optaflu	--[1]	Suspension for injection in pre-filled syringe	Intramuscular use	pre-filled syringe (glass)	0.5 ml
EU/1/07/394/003	Optaflu	--[1]	Suspension for injection in pre-filled syringe	Intramuscular use	pre-filled syringe (glass)	0.5 ml
EU/1/07/394/004	Optaflu	--[1]	Suspension for injection in pre-filled syringe	Intramuscular use	pre-filled syringe (glass)	0.5 ml
EU/1/07/394/005	Optaflu	--[1]	Suspension for injection in pre-filled syringe	Intramuscular use	pre-filled syringe (glass)	0.5 ml
EU/1/07/394/006	Optaflu	--[1]	Suspension for injection in pre-filled syringe	Intramuscular use	pre-filled syringe (glass)	0.5 ml

[1] - Influenza virus surface antigens (haemagglutinin and neuraminidase)*, inactivated, of the following strains:

A/Solomon Islands/3/2006 (H1N1) like strain (A/Solomon Islands/3/2006, IVR-145) 15 micrograms HA**
A/Wisconsin/67/2005 (H3N2) like strain (A/Wisconsin/67/2005, NYMC X161B) 15 micrograms HA**
B/Malaysia/2506/2004 like strain (B/Malaysia/2506/2004) 15 micrograms HA**

per 0.5 ml dose

* propagated in Madin Darby Canine Kidney (MDCK) cells
** haemagglutinin