EMA/501330/2012

European Medicines Agency decision

P/0210/2012

of 28 September 2012

on the acceptance of a modification of an agreed paediatric investigation plan for influenza virus surface antigens (haemagglutinin (HA) and neuraminidase) A/California/7/2009 (H1N1) – like strain used A/Brisbane/10/2010, A/Perth/16/2009 (H3N2) - like strain used NYMC X-187 derived from A/Victoria/210/2009, B/Brisbane/60/2008 (Optaflu), (EMEA-000124-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/88/2008 issued on 14 October 2008, the decision P/234/2010 issued on 26 November 2010,

Having regard to the application submitted by Novartis Vaccines and Diagnostics BV on 25 May 2012 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 17 August 2012,

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 (HA) and neuraminidase) A/California/7/2009 (H1N1) – like strain used A/Brisbane/10/2010, A/Perth/16/2009 (H3N2) - like strain used NYMC X-187 derived from A/Victoria/210/2009, B/Brisbane/60/2008 (Optaflu), suspension 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 Novartis Vaccines and Diagnostics BV, Hullenbergweg 83-85, 1100 DM – Amsterdam, The Netherlands.

Done at London, 28 September 2012

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

EMA/PDCO/476511/2012

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

EMEA-000124-PIP01-07-M02

Scope of the application

Active substance(s):

Influenza virus surface antigens (haemagglutinin (HA) and neuraminidase) A/California/7/2009 (H1N1) – like strain used A/Brisbane/10/2010, A/Perth/16/2009 (H3N2) - like strain used NYMC X-187 derived from A/Victoria/210/2009, B/Brisbane/60/2008

Invented name:

Optaflu

Condition(s):

Prevention of influenza

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Novartis Vaccines and Diagnostics BV

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 and Diagnostics BV submitted to the European Medicines Agency on 25 May 2012 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 decision P/234/2010 issued on 26 November 2010.

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

The procedure started on 19 June 2012.

Scope of the modification

Some 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 Norwegian Paediatric Committee member agrees 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, 17 August 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

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	Study 1: Age appropriate formulation for infants 0 to 36 months of age.
Non-clinical	0	Not applicable.
Clinical	5	Study 2: 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. Study 3: 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. Study 4: 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. Study 5: 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. Study 6: Safety and immunogenicity study, active controlled, randomised in infants less than 6 months of age.

3. Follow-up, completion and deferral of PIP

Concerns on potential long-term safety and efficacy issues in relation to paediatric use:	No.
Date of completion of the paediatric investigation plan:	By July 2017.
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