EMA/374750/2011

European Medicines Agency decision

P/132/2011

of 8 June 2011

on the acceptance of a modification of an agreed paediatric investigation plan for influenza virus surface antigens (H5N1 or H1N1 strains) (Focetria and associated names, Aflunov and associated names, Foclivia and associated names), (EMEA-000599-PIP01-09-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/150/2009 issued on 5 August 2009 and the decision P/211/2010 issued on 29 October 2010,

Having regard to the application submitted by Novartis Vaccines and Diagnostics S.r.l. on 4 February 2011 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 April 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 deferral.

(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.

[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 (H5N1 or H1N1 strains) (Focetria and associated names, Aflunov and associated names, Foclivia and associated names), suspension for injection, intramuscular use, including changes to the deferral, 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 S.r.l., Via Fiorentina 1, 53100 Siena, Italy.

Done at London, 8 June 2011

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

EMA/PDCO/157821/2011

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

EMEA-000599-PIP01-09-M02

Scope of the application

Active substance(s):

Influenza virus surface antigens (H5N1 or H1N1 strains)

Invented name:

Focetria and associated names

Aflunov and associated names

Foclivia and associated names

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 S.r.l.

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 S.r.l. submitted to the European Medicines Agency on 4 February 2011 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/150/2009 issued on 5 August 2009 and decision P/211/2010 issued on 29 October 2010.
The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 23 February 2011.

Scope of the modification

Some measures and/or timelines of the agreed 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 and to the deferral in the scope set out in the Annex I of this opinion.

   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, 20 April 2011

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

The waiver applies to:

- Neonates and infants from birth to less than 2 months of age,
- for suspension for injection, intramuscular use,
- on the grounds that the specific medicinal product is likely to be ineffective.

And to:

- Infants from 2 months to less than 6 months of age,
- for suspension for injection, intramuscular use,
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing measures.

2. Paediatric Investigation Plan

2.1. Condition: Prevention of Influenza

2.1.1. Indication(s) targeted by the PIP

Prevention of influenza.

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)

Suspension for injection, intramuscular use.

2.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	3	A Randomised, Controlled, Observer-blind, Single-center Study to Evaluate the Immunogenicity, Safety and Tolerability of Two Doses of FLUAD H5N1 (Aflunov) Influenza Vaccine in Subjects aged from 6 months to less than 18 years. A Randomised, Controlled, Observer-blind, Multi-center Study to Evaluate the Safety and Immunogenicity of Two Doses of Aflunov or

		Two 0.5mL Doses of MF59 Adjuvanted Vaccine Containing 3.75µg of A/H5N1 Influenza Antigen in Subjects aged from 6 months to less than 18 years. A Randomised, Controlled, Observer-blind Study to Evaluate the Safety and Immunogenicity of Two Doses of Aflunov in 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 issues efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By Mach 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal productCondition(s) and authorised indication(s)

1. Prophylaxis of influenza

Authorised indications:

- Prophylaxis of influenza in an officially declared pandemic situation

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/07/385/001	Focetria	15 µg / ml	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe
EU/1/07/385/002	Focetria	15 µg / ml	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes
EU/1/07/385/004	Focetria	15 µg / ml	Suspension for injection	Intramuscular use	vial (glass)	5.0 ml (1 dose = 0.5 ml)	10 vials (multidose : 10 doses)
EU/1/09/577/001	Foclivia	15 µg/ml	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe
EU/1/09/577/002	Foclivia	15 µg/ml	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes
EU/1/09/577/003	Foclivia	15 µg/ml	Suspension for injection	Intramuscular use	vial (glass)	0.5 ml (1 dose = 0.5ml)	10 vials (monodose)
EU/1/09/577/004	Foclivia	15 µg/ml	Suspension for injection	Intramuscular use	vial (glass)	5.0 ml (1 dose = 0.5 ml)	10 vials (multidose : 10 doses)
EU/1/10/658/001	Aflunov	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe
EU/1/10/658/002	Aflunov	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe

_ _1 Influenza virus surface antigens*, inactivated: A/Vietnam/1194/2004 (H5N1) - like strain used (NIBRG-14) 7.5 micrograms** per 0.5 ml dose

* propagated in eggs

** expressed in microgram haemagglutinin.

Adjuvant MF59C.1 containing:

squalene 9.75 milligrams

polysorbate 80 1.175 milligrams

sorbitan trioleate 1.175 milligrams