European Medicines Agency

Doc. Ref. EMEA/608559/2009
P/198/2009

EUROPEAN MEDICINES AGENCY DECISION

of 9 October 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for A/California/7/2009 influenza-like virus strain (EMEA-000663-PIP01-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 application submitted by Novartis Vaccines & Diagnostics GmbH & Co.KG on 17 July 2009 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 August 2009 in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision agreeing a Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a deferral.

(4) It is therefore appropriate to adopt a Decision granting a 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

A Paediatric Investigation Plan for A/California/7/2009 influenza-like virus strain, suspension for injection, intramuscular use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for A/California/7/2009 influenza-like virus strain, suspension for injection, intramuscular use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for A/California/7/2009 influenza-like virus strain, suspension for injection, intramuscular use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Novartis Vaccines & Diagnostics GmbH & Co. KG, Emil-von-Behring Str. 76, 35041, Marburg, Germany.

Done at London, 9 October 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/516180/2009
EMEA-000663-PIP01-09

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance(s):
A/California/7/2009 influenza-like virus strain

Condition(s):
Influenza

Pharmaceutical form(s):
Suspension for injection

Route(s) of administration:
Intramuscular use

Name/corporate name of the PIP applicant:
Novartis Vaccines & Diagnostics GmbH & Co.KG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Novartis Vaccines & diagnostics GmbH & Co.KG submitted for agreement to the EMEA on 17 July 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 20 August 2009.

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E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;
- to grant a deferral in accordance with Article 21 of said Regulation;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Norwegian Paediatric Committee member does agree with the above-mentioned recommendation of the Paediatric Committee.

2. 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 are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex(es) and appendix.

London, 21 August 2009

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

A. CONDITION(S)

Influenza

B. WAIVER

- **Condition**

  Influenza

  The waiver applies to:

  – Children from birth to less than 2 months;

  – for Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 influenza-like virus, suspension for injection, intramuscular use;

  – on the grounds that the specific medicinal product is likely to be ineffective.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

  Influenza

- **Proposed PIP indication**

  Prevention of infection by pandemic influenza virus (H1N1 strain) in the context of a pandemic

- **Subset(s) of the paediatric population concerned by the paediatric development**

  From 2 months to less than 18 years.

- **Formulation(s)**

  Emulsion for injection, intramuscular use, 3.75 and 7.5 µg of haemagglutinin (HA)

- **Studies**
-

Area	Number of studies	Description
Quality	1	Emulsion for injection
Non-clinical		Not applicable.
Clinical	2	• Immunogenicity and Safety Study of Multiple Formulations of an Intramuscular Inactivated, cell-derived A/H1N1 Influenza Vaccine With and Without Adjuvant in Healthy Subjects Aged 6 months to 17 Years • Immunogenicity and Safety Study of the Intramuscular Inactivated, cell-derived A/H1N1 Influenza Vaccines With and Without Adjuvant in Healthy Subjects Aged 2 to 6 Months

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By May 2011**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**