European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 18 March 2010

on the acceptance of a modification of an agreed Paediatric Investigation Plan for Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), adjuvanted (EMEA-000669-PIP01-09-M01) 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.

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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 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 decision P/196/2009 of the European Medicines Agency on 7 October 2009,

Having regard to the application submitted by Sanofi Pasteur SA on 4 December 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 February 2010, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, and in accordance with Article 12 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 acceptance of changes to an agreed Paediatric Investigation Plan and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an agreed Paediatric Investigation Plan,

(3) It is therefore appropriate to adopt a Decision on the granting of 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

Changes to the agreed Paediatric Investigation Plan for Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), adjuvanted, suspension and emulsion 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, are hereby accepted.

Article 2

A waiver for Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), adjuvanted, suspension and emulsion for injection, intramuscular use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Sanofi Pasteur SA, 2 Avenue Pont Pasteur, 69367 Lyon, France.

Done at London, 18 March 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

19 February 2010
EMA/PDCO/83570/2010

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

EMEA-000669-PIP01-09-M01

Scope of the application

Active substance(s):

Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), adjuvanted

Condition:

Influenza

Pharmaceutical form:

Suspension and emulsion for injection

Route of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Sanofi Pasteur SA

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur SA submitted to the European Medicines Agency on 4 December 2009 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/196/2009 of 7 October 2009. The application for modification proposed changes.

The procedure started on 23 December 2009.

Scope of the modification

The proposed modification is related to change in some measures and timelines of the original opinion and granting of a waiver.

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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 some changes proposed by the applicant regarding the measures of the paediatric investigation plan and the risk management plan,

   And in accordance with Article 12 of Regulation (EC) No 1901/2006 as amended, recommends:

   - to grant a waiver for one or more subsets of the paediatric population on its own motion in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 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.

London, 19 February 2010

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 subsets of the paediatric population and condition covered by the waiver

1. Condition(s)

Influenza

2. Waiver

2.1 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 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), adjuvanted, suspension and emulsion for injection, intramuscular use.

- for suspension and emulsion for injection, intramuscular use.
- on the grounds that the specific medicinal product is likely to be ineffective.

And:

- Children from 2 months to less than 6 months;
- for Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), adjuvanted, suspension and emulsion for injection, intramuscular use.

- for suspension and emulsion for injection, intramuscular use.
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit.

3. Paediatric Investigation Plan

3.1 Condition to be investigated

Influenza

3.2 Indication targeted by the pip

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

3.3 Subset(s) of the paediatric population concerned by the paediatric development

From 6 months to less than 18 years.

3.4 Pharmaceutical form(s)

Suspension and emulsion for injection, 3.8 and 7.5 µg of haemagglutinin (HA).

3.5 Studies

Area	Number of studies	Description
Quality	1	Suspension and emulsion for injection
Non-clinical		Not applicable.
Clinical	2	• Immunogenicity and Safety Study of Multiple Formulations of an Intramuscular Inactivated, Split Virion Swine-Origin A/H1N1 Influenza Vaccine With and Without Adjuvant in Healthy Children and Adolescents Aged 3 to 17 Years (GPF08) • Immunogenicity and Safety Study of Multiple Formulations of an Intramuscular Inactivated, Split Virion Swine-Origin A/H1N1 Influenza Vaccine With and Without Adjuvant in Healthy Infants and Toddlers Aged 6 to 35 Months (GPF09)

4. Follow-up, completion and deferral of pip

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 June 2011**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**