EMA/540825/2010

European Medicines Agency decision

P/184/2010

of 24 September 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, trivalent, (EMEA-000632-PIP01-09) 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.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

P/184/2010

of 24 September 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, trivalent, (EMEA-000632-PIP01-09) 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 application submitted by Abbott Biologicals B.V. on 19 June 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 August 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 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 influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, trivalent, suspension for injection (in a pre-filled syringe), 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 influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, trivalent, suspension for injection (in a pre-filled syringe), 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 influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, trivalent, suspension for injection (in a pre-filled syringe), 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 Abbott Biologicals B.V., C.J. van Houtenlaan 36, 1381 CP – Weesp, The Netherlands.

Done at London, 24 September 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/471522/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-000632-PIP01-09

Scope of the application

Active substance(s):

Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, trivalent

Condition(s):

Prevention of influenza

Pharmaceutical form(s):

Suspension for Injection (in a pre-filled syringe)

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Abbott Biologicals B.V.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Abbott Biologicals B.V. submitted for agreement to the European Medicines Agency on 19 June 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 23 July 2009.

Supplementary information was provided by the applicant on 31 May 2010.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.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 agrees 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 European Medicines Agency, together with its annex(es) and appendix.

London, 6 August 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 subset(s) of the paediatric population and condition(s) covered by the waiver

1. Condition(s)

Prevention of influenza

2. Waiver

2.1. Condition(s)

Prevention of influenza

The waiver applies to:

- Preterm and term newborns and infants (from birth to less than 2 months of age)
- for suspension for injection (in pre-filled syringe), intramuscular route
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing measures.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Prevention of influenza

3.1.1. Indication(s) targeted by the PIP

Prevention of influenza infection

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

From 2 months to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Suspension for injection (in pre-filled syringe), intramuscular route

3.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	4	S203.3.aacc: Randomized, double-blind, multi-center, active-controlled, age-staggered, in-season study in healthy subjects 6 months to less than 18 years of age. S203.3.bbb: Randomized, double-blind, active-controlled, multi-center

		in-season study in subjects either 9 to less than 18 years of age or 3 to less than 9 years of age (primed or unprimed) and at risk for complications from influenza. S203.3.ddd: Partly randomized (in healthy children), partly observer-blind (in at risk children), placebo-controlled, multi-center in-season efficacy study, in both healthy primed or unprimed subjects and subjects at risk for complications from influenza 6 to less than 36 months of age. S203.3.eee: Observer-blind, randomized, placebo-controlled, multi-center in-season study in healthy subjects 2 to less than 6 months of age.

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety or efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By November 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes