European Medicines Agency

Doc. Ref. EMEA/160106/2009
P/64/2009

EUROPEAN MEDICINES AGENCY DECISION

of 31 March 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for Purified diphtheria toxoid / Purified tetanus toxoid / Five component acellular pertussis [Purified Pertussis Toxoid (PT), Purified Filamentous Haemagglutinin (FHA), Purified Fimbriae Types 2 and 3 (FIM), and Purified Pertactin (PRN)] / Inactivated poliomyelitis vaccine (Vero) – Type 1 (Mahoney), Type 2 (MEF-1) and Type 3 (Saukett) / Purified polyribosylribitol phosphate capsular polysaccharide of Haemophilus influenzae type b covalently bound to Tetanus protein (PRP-T) (PEDIACEL) (EMEA-000278-PIP01-08-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)

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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 decision P/108/2008 of the European Medicines Agency on 26 November 2008,

Having regard to the application submitted by Sanofi Pasteur MSD SNC on 17 February 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing a deferral to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 March 2009, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

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 granting of a deferral,

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

A deferral for Purified diphtheria toxoid, Purified diphtheria toxoid / Purified tetanus toxoid / Five component acellular pertussis [Purified Pertussis Toxoid (PT), Purified Filamentous Haemagglutinin (FHA), Purified Fimbriae Types 2 and 3 (FIM), and Purified Pertactin (PRN)] / Inactivated poliomyelitis vaccine (Vero) – Type 1 (Mahoney), Type 2 (MEF-1) and Type 3 (Saukett) / Purified polyribosylribitol phosphate capsular polysaccharide of Haemophilus influenzae type b covalently bound to Tetanus protein (PRP-T), (PEDIACEL), suspension for injection (in a pre-filled syringe), Suspension for injection in a vial, 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 2

This decision, that supersedes previous decision of the European Medicines Agency P/108/2008, is addressed to Sanofi Pasteur MSD SNC, 8 rue Jonas Salk, 69007 Lyon, France.

Done at London, 31 March 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/119767/2009
EMEA-000278-PIP01-08-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
Purified diphtheria toxoid / Purified tetanus toxoid / Five component acellular pertussis [Purified Pertussis Toxoid (PT), Purified Filamentous Haemagglutinin (FHA), Purified Fimbriae Types 2 and 3 (FIM), and Purified Pertactin (PRN)] / Inactivated poliomyelitis vaccine (Vero) – Type 1 (Mahoney), Type 2 (MEF-1) and Type 3 (Saukett) / Purified polyribosylribitol phosphate capsular polysaccharide of Haemophilus influenzae type b covalently bound to Tetanus protein (PRP-T)

(Invented) name
PEDIACEL

Condition(s):
For the active immunisation against infectious diseases caused by Haemophilus influenzae type b, Corynebacterium diphtheriae, Clostridium tetani, Bordetella pertussis and poliovirus types 1, 2 and 3.

Pharmaceutical form(s):
Suspension for injection (in a pre-filled syringe)
Suspension for injection in a vial

Route(s) of administration:
Intramuscular use

Name/corporate name of the PIP applicant:
Sanofi Pasteur MSD SNC

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur MSD SNC submitted to the EMEA on 17 February 2009 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the EMEA decision P/108/2008 of 26 November 2008 proposing a deferral.

The procedure started on 4 March 2009.

Scope of the modification
To grant a deferral

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Opinion
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 grant a deferral

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 Agency, together with its annex(es) and appendix.

London, 6 March 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

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) / DISEASE(S)

Disease caused by Haemophilus influenzae type b, Corynebacterium diphtheriae, Clostridium tetani, Bordetella pertussis and poliovirus types 1, 2 and 3.

B. WAIVER

- **Condition**

Disease caused by Haemophilus influenzae type b, Corynebacterium diphtheriae, Clostridium tetani, Bordetella pertussis and poliovirus types 1, 2 and 3.

  - **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to:

- Newborn and infants from 0 years to less than 6 weeks for suspension for injection, intramuscular use

- Children and adolescents from 4 years to less than 18 years for suspension for injection, intramuscular use

on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

C. PAEDIATRIC INVESTIGATION PLAN

C.1. Condition to be investigated

Haemophilus influenzae type b, Corynebacterium diphtheriae, Clostridium tetani, Bordetella pertussis and poliovirus types 1, 2 and 3.

- **Proposed paediatric plan investigation indication**

Active immunisation against diphtheria, tetanus, pertussis, poliomyelitis, and invasive infections caused by Haemophilus influenzae type b.

- **Subset(s) covered**

Paediatric population from 6 weeks to less than 4 years.

- **Formulation(s)**

Suspension for injection in a pre-filled syringe
Suspention for injection in a vial

- **Studies**

Area	Number of studies	Description
Clinical	1	Randomised, controlled, double blind study of the immunogenicity and safety of PEDIACEL compared to Infanrix –IPV+Hib when both vaccines are given to infants using a three dose immunisation schedule
Clinical	1	Randomised, controlled, single-blind, multi-centre study of the immunogenicity and safety of PEDIACEL compared to Infanrix –IPV+Hib when both vaccines are co-administered with Prevenar to infants and toddlers
Clinical	1	Randomised, controlled, double blind, multi-centre and two-armed study of safety and immunogenicity of booster vaccination with PEDIACEL compared to booster vaccination with Infanrix- hexa when both vaccines are co-administered with Prevenar

Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By June 2009**
Deferral for initiation of some or all studies contained in the paediatric investigation plan:	**No**
Deferral for completion of some or all studies contained in the paediatric investigation plan:	**Yes**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Content (concentration)	Package size
N/A	PEDIACEL	[1)]	Suspension for injection	Intramuscular	N/A	0.5 ml	N/A

[1)] : Strengths:
Vaccinum diphtheriae adsorbatum: not less than 30 international units, Vaccinum poliomyelitidis inactivatum stirpe 2 (MEF 1): 8 D antigen units,
Vaccinum pertussis sine cellulis ex elementis praeparatum adsorbatum (PRN): 3 µg,
Vaccinum tetani adsorbatum: not less than 40 international units, Vaccinum poliomyelitidis inactivatum stirpe 1 (Mahoney): 40 D antigen units,
Vaccinum poliomyelitidis inactivatum stirpe 3 (Saukett): 32 D antigen units,
Vaccinum pertussis sine cellulis ex elementis praeparatum adsorbatum (FHA): 20 µg,
Vaccinum haemophili type b conjugatum: 10 µg H. influenzae type b polysaccharide conjugated to 20 µg of tetanus toxoid,
Vaccinum pertussis sine cellulis ex elementis praeparatum adsorbatum (PT): 20 µg,
Vaccinum pertussis sine cellulis ex elementis praeparatum adsorbatum (FIM): 5 µg