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

Doc. Ref. EMEA/623060/2009
P/168/2009

**EUROPEAN MEDICINES AGENCY DECISION**

**of 9 October 2009**

**on the agreement of a Paediatric Investigation Plan and on the granting of a waiver for purified diphteria toxoid / purified tetanus toxoid / purified pertussis toxoid (PT) / purified filamentous haemagglutinin (FHA) / purified fimbriae types 2 and 3 (FIM) / purified pertactin (PRN) / inactivated type 1 poliovirus (Mahoney) / inactivated type 2 poliovirus (MEF-1) / inactivated type 3 poliovirus (Saukett) / polyribosylribitol phosphate (PRP) from haemophilus influenzae type b as prp-ompc / hepatitis b surface antigen recombinant (HBsAg (EMEA-000394-PIP01-08) 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 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 Sanofi Pasteur MSD SNC on 23 March 2009 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 July 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 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 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 waiver.

HAS ADOPTED THIS DECISION:

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

*Article 1*

A Paediatric Investigation Plan for purified diphteria toxoid / purified tetanus toxoid / purified pertussis toxoid (PT) / purified filamentous haemagglutinin (FHA) / purified fimbriae types 2 and 3 (FIM) / purified pertactin (PRN) / inactivated type 1 poliovirus (Mahoney) / inactivated type 2 poliovirus (MEF-1) / inactivated type 3 poliovirus (Saukett) / polyribosylribitol phosphate (PRP) from haemophilus influenzae type b as prp-ompc / hepatitis b surface antigen recombinant (HBsAg), suspension for injection / suspension for injection in pre-filled syringe, intramuscular route, 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 waiver for **p**urified diphteria toxoid / purified tetanus toxoid / purified pertussis toxoid (PT) / purified filamentous haemagglutinin (FHA) / purified fimbriae types 2 and 3 (FIM) / purified pertactin (PRN) / inactivated type 1 poliovirus (Mahoney) / inactivated type 2 poliovirus (MEF-1) / inactivated type 3 poliovirus (Saukett) / polyribosylribitol phosphate (PRP) from haemophilus influenzae type b as prp-ompc / hepatitis b surface antigen recombinant (HBsAg), suspension for injection / suspension for injection in pre-filled syringe, intramuscular route, 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*

This decision is addressed to Sanofi Pasteur MSD SNC, 8 rue Jonas Salk, 69007 – Lyon, France.

This Decision supersedes previous Decision of the European Medicines Agency Doc Ref. EMEA/513913/2009 of 21 August 2009.

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*

554Doc. Ref. EMEA/PDCO/438388/2009
EMEA-000394-PIP01-08

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

## Scope of the application

Active substance(s):
Purified diphteria toxoid / purified tetanus toxoid / purified pertussis toxoid (PT) / purified filamentous haemagglutinin (FHA) / purified fimbriae types 2 and 3 (FIM) / purified pertactin (PRN) / inactivated type 1 poliovirus (Mahoney) / inactivated type 2 poliovirus (MEF-1) / inactivated type 3 poliovirus (Saukett) / polyribosylribitol phosphate (PRP) from haemophilus influenzae type b as prp-ompc / hepatitis b surface antigen recombinant (HBsAg)

Condition(s):
Active immunisation against infectious diseases caused by Corynebacterium diphtheriae / Clostridium tetani / Bordetella pertussis / poliovirus types 1, 2 and 3 / against invasive disease caused by Haemophilus influenzae type b / infection caused by all known subtypes of hepatitis B virus

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

Route(s) of administration:
Intramuscular route

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

## Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur MSD SNC submitted for agreement to the EMEA on 23 March 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 30 April 2009.

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**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 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population, and 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 members 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 and appendix.

London, 24 July 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)

Active immunisation against infectious diseases caused by Corynebacterium diphtheriae / Clostridium tetani / Bordetella pertussis / poliovirus types 1, 2 and 3 / against invasive disease caused by Haemophilus influenzae type b / infection caused by all known subtypes of hepatitis B virus

## B. WAIVER

- **Condition**

Active immunisation against infectious diseases caused by Corynebacterium diphtheriae / Clostridium tetani / Bordetella pertussis / poliovirus types 1, 2 and 3 / against invasive disease caused by Haemophilus influenzae type b / infection caused by all known subtypes of hepatitis B virus

The waiver applies to:

- Newborn and infants from 0 years to less than 6 weeks for suspension for injection, intramuscular use, and for suspension for injection in pre-filled syringe, intramuscular use on the grounds that the specific medicinal product is likely to be ineffective.

- Children and adolescents from 2 years to less than 18 years for suspension for injection, intramuscular use, and for suspension for injection in pre-filled syringe, intramuscular use on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

## C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Active immunisation against infectious diseases caused by Corynebacterium diphtheriae / Clostridium tetani / Bordetella pertussis / poliovirus types 1, 2 and 3 / against invasive disease caused by Haemophilus influenzae type b / infection caused by all known subtypes of hepatitis B virus

- **Proposed PIP indication**

Active immunisation against diphtheria, tetanus, pertussis, poliomyelitis (caused by poliovirus Types 1, 2 and 3), against invasive disease caused by Haemophilus influenzae type b and infection caused by all known subtypes of hepatitis B virus

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

  From 6 weeks to less than 2 years.

- **Formulation(s)**

Suspension for injection
Suspension for injection in pre-filled syringe

- **Studies**

| Area | Number of studies | Description |
|---|---|---|
| Clinical | 4 | Randomised, active comparator-controlled, open-label, multicenter study in healthy infants to assess the safety, tolerability, and immunogenicity of the investigational vaccine when administered as an infant series at 2, 4, and 6 months.<br><br>Randomised, partial double-blind, multicenter, active comparator-controlled, lot-to-lot consistency study in healthy infants to assess the safety, tolerability, and immunogenicity of the investigational vaccine when administered as an infant series at 2, 4, and 6 months.<br><br>Randomised, modified double-blind, active-comparator controlled, multicenter study to assess the safety, tolerability, and immunogenicity of the hexavalent investigational vaccine in healthy infants at 2, 3, 4, and 12 months.<br><br>Randomised, modified double-blind, active comparator-controlled, multicenter study to assess the safety, tolerability, and immunogenicity of the hexavalent investigational vaccine in healthy infants when administered at 2, 4 and 11-12 months of age. |

| | |
|---|---|
| **Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:** | **Yes** |
| **Date of completion of the paediatric investigation plan:** | **By October 2012** |
| **Deferral for some or all studies contained in the paediatric investigation plan:** | **No** |