EMA/8478/2012

European Medicines Agency decision

P/0034/2012

of 3 February 2012

on the acceptance of a modification of an agreed paediatric investigation plan for inactivated Type 1 Poliovirus (Mahoney) / Purified Fimbriae Types 2 and 3 (FIM) / Purified Tetanus Toxoid / Polyribosylribitol phosphate (PRP) from Haemophilus influenzae type b as PRP-OMPC / Purified Pertussis Toxoid (PT) / Purified Filamentous Haemagglutinin (FHA) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Inactivated Type 3 Poliovirus (Saukett) / Inactivated Type 2 Poliovirus (MEF-1) / Purified Pertactin (PRN) / Purified Diphteria Toxoid (V419) (EMEA-000394-PIP01-08-M01) 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.

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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 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 European Medicines Agency's decision P/168/2009 issued on 9 October 2009,

Having regard to the application submitted by Sanofi Pasteur MSD SNC on 19 October 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 January 2012, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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 inactivated Type 1 Poliovirus (Mahoney) / Purified Fimbriae Types 2 and 3 (FIM) / Purified Tetanus Toxoid / Polyribosylribitol phosphate (PRP) from Haemophilus influenzae type b as PRP-OMPC / Purified Pertussis Toxoid (PT) / Purified Filamentous Haemagglutinin (FHA) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Inactivated Type 3 Poliovirus (Saukett) / Inactivated Type 2 Poliovirus (MEF-1) / Purified Pertactin (PRN) / Purified Diphteria Toxoid (V419), suspension for injection in pre-filled syringe, suspension for injection, intramuscular use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

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

Done at London, 3 February 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/8478/2012

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

EMEA-000394-PIP01-08-M01

Scope of the application

Active substance(s):

Inactivated Type 1 Poliovirus (Mahoney) / Purified Fimbriae Types 2 and 3 (FIM) / Purified Tetanus Toxoid / Polyribosylribitol phosphate (PRP) from Haemophilus influenzae type b as PRP-OMPC / Purified Pertussis Toxoid (PT) / Purified Filamentous Haemagglutinin (FHA) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Inactivated Type 3 Poliovirus (Saukett) / Inactivated Type 2 Poliovirus (MEF-1) / Purified Pertactin (PRN) / Purified Diphteria Toxoid (V419)

Condition(s):

Prevention of 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 and infection caused by all known subtypes of hepatitis B virus

Pharmaceutical form(s):

Suspension for injection in pre-filled syringe

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Sanofi Pasteur MSD SNC

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur MSD SNC submitted to the European Medicines Agency on 19 October 2011 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/168/2009 issued on 9 October 2009.

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The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 16 November 2011.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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 changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   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(es) and appendix.

London, 13 January 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

1.1. Condition: Prevention of 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 and infection caused by all known subtypes of hepatitis B virus

The waiver applies to:

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

And to:

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

2. Paediatric Investigation Plan

2.1. Condition: Prevention of 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 and infection caused by all known subtypes of hepatitis B virus

2.1.1. Indication(s) targeted by the PIP

Active immunisation against diphtheria, tetanus, pertussis, poliomyelitis (cause by poliovirus types 1, 2, and 3), against invasive disease caused by Haemophilius influenzaed type b and infection caused by all known subtypes of hepatitis B virus.

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

From 6 weeks to less than 2 years of age.

2.1.3. Pharmaceutical form(s)

Suspension for injection and suspension for injection in pre-filled syringe.

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	4	Study 1: Randomised, active-controlled, open-label study in healthy infants to assess the safety, tolerability, and immunogenicity of V419 when administered at 2, 4, and 6 months of age followed by a booster dose of DAPTACEL and PedvaxHIB. Study 2: Randomised, active-controlled, partially double-blind (lot-to-lot consistency) study in healthy infants to assess the safety, tolerability, and lot-to-lot consistency and immunogenicity of V419 administered at 2, 4, and 6 months of age followed by a booster dose of PENTACEL. Study 3: Randomised, double-blind, active-controlled study to assess the safety, tolerability, and immunogenicity of V419 in healthy infants. Study 4: Randomised, double-blind, active-comparator controlled study to assess the safety, tolerability, and immunogenicity of V419 in healthy infants.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2014
Deferral for one or more studies contained in the paediatric investigation plan:	No