



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/8126/2012

European Medicines Agency decision P/0015/2012

of 24 January 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for purified Tetanus Toxoid / Inactivated Type 1 Poliovirus (Mahoney) / Inactivated Type 2 Poliovirus (MEF-1) / Inactivated Type 3 Poliovirus (Saukett) / Purified Pertussis Toxoid (PT) / Haemophilus influenzae type b polysaccharide conjugated to tetanus protein / Purified Filamentous Haemagglutinin (FHA) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Purified Diphtheria Toxoid (DTaP-IPV-HepB-PRP-T) (EMEA-001201-PIP01-11) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Sanofi pasteur on 1 September 2011 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 9 December 2011, 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 purified Tetanus Toxoid / Inactivated Type 1 Poliovirus (Mahoney) / Inactivated Type 2 Poliovirus (MEF-1) / Inactivated Type 3 Poliovirus (Saukett) / Purified Pertussis Toxoid (PT) / Haemophilus influenzae type b polysaccharide conjugated to tetanus protein / Purified Filamentous Haemagglutinin (FHA) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Purified Diphtheria Toxoid (DTaP-IPV-HepB-PRP-T), suspension 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, is hereby agreed.

Article 2

A deferral for purified Tetanus Toxoid / Inactivated Type 1 Poliovirus (Mahoney) / Inactivated Type 2 Poliovirus (MEF-1) / Inactivated Type 3 Poliovirus (Saukett) / Purified Pertussis Toxoid (PT) / Haemophilus influenzae type b polysaccharide conjugated to tetanus protein / Purified Filamentous Haemagglutinin (FHA) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Purified Diphtheria Toxoid (DTaP-IPV-HepB-PRP-T), suspension 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, is hereby granted.

Article 3

A waiver for Purified Tetanus Toxoid / Inactivated Type 1 Poliovirus (Mahoney) / Inactivated Type 2 Poliovirus (MEF-1) / Inactivated Type 3 Poliovirus (Saukett) / Purified Pertussis Toxoid (PT) / Haemophilus influenzae type b polysaccharide conjugated to tetanus protein / Purified Filamentous Haemagglutinin (FHA) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Purified Diphtheria Toxoid (DTaP-IPV-HepB-PRP-T), suspension 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, is hereby granted.

Article 4

This decision is addressed to Sanofi Pasteur, 2 avenue Pont Pasteur, 69007 – Lyon, France.

Done at London, 24 January 2012

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/8126/2012

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

EMA-001201-PIP01-11

Scope of the application

Active substance(s):

Purified Tetanus Toxoid / Inactivated Type 1 Poliovirus (Mahoney) / Inactivated Type 2 Poliovirus (MEF-1) / Inactivated Type 3 Poliovirus (Saukett) / Purified Pertussis Toxoid (PT) / Haemophilus influenzae type b polysaccharide conjugated to tetanus protein / Purified Filamentous Haemagglutinin (FHA) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Purified Diphtheria Toxoid (DTaP-IPV-HepB-PRP-T)

Condition(s):

Prevention of infections caused by Corynebacterium diphtheriae, Clostridium tetani, Bordetella pertussis, poliovirus types 1, 2 and 3, Haemophilus influenzae type b and Hepatitis B virus

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Sanofi pasteur



Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Sanofi pasteur submitted for agreement to the European Medicines Agency on 1 September 2011 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 12 October 2011.

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, 9 December 2011

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 infection caused by *Corynebacterium diphtheriae*, *Clostridium tetani*, *Bordetella pertussis*, poliovirus types 1, 2, and 3, *Haemophilus influenzae* type b, and hepatitis B virus.

The waiver applies to:

- Subsets of the paediatric population from birth to less than 6 weeks of age and from 2 years to less than 18 years of age
- for suspension for injection, intramuscular route
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition: Prevention of infection caused by *Corynebacterium diphtheriae*, *Clostridium tetani*, *Bordetella pertussis*, poliovirus types 1, 2, and 3, *Haemophilus influenzae* type b, and hepatitis B virus.

2.1.1. Indication(s) targeted by the PIP

Active immunisation against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive infections caused by *Haemophilus influenzae* type b (such as meningitis, septicaemia, cellulitis, arthritis, epiglottitis, pneumopathy, osteomyelitis)

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

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	15	Study 1 (A3L04): Randomized, controlled, observer-blind, 4-arm, parallel groups trial to assess incidence of fever and immunogenicity of DTaP-IPV-HepB-PRP-T vaccine as compared to Tritanrix HepB/Hib + oral polio vaccine (schedule 2, 4, 6) Study 2 (A3L10): Randomized open-label controlled, 2-arm trial to compare

Area	Number of studies	Description
		immunogenicity against Hep B of DTaP-IPV-HepB-PRP-T vaccine as compared to Pentaxim and Engerix B (schedule 2, 3, 4) Study 3 (A3L22): Open-label extension study of study 2 (A3L10) Study 4 (A3L11): Randomized, observer-blind, controlled, 4-arm, lot-to-lot consistency trial (schedule 2, 4, 6) Study 5 (A3L21): Open-label, extension study of study 4 (A3L11) Study 6 (A3L12): Randomized, observer-blind, controlled study to compare immunogenicity of DTaP-IPV-HepB-PRP-T vaccine to Infanrix Hexa (schedule 2, 4, 6) Study 7 (A3L15): Randomized open-label, controlled, 3-arm trial to compare DTaP-IPV-HepB-PRP-T vaccine to CombAct Hib/Engerix/OPV (schedule 6, 10, 14 weeks) including booster phase at 15-18 months Study 8 (A3L17): Randomized, observer-blind, controlled, 2-arm trial to compare DTaP-IPV-HepB-PRP-T vaccine to Infanrix Hexa (schedule 2, 4, 6) Study 9 (A3L24): Randomized, observer-blind, 4-arm, lot-to-lot consistency trial of DTaP-IPV-HepB-PRP-T vaccine co-administered with Prevenar and Rotarix (schedule 2, 4, 6) Study 10 (A3L26): Randomized, observer-blind extension study of study 7 (A3L15) Study 11 (A3L27): Randomized, observer-blind extension study of study 9 (A3L24) Study 12 (A3L28): Open-label extension study of study 11 (A3L27) Study 13 (A3L38): Randomized, observer-blind, 2-arm trial to compare DTaP-IPV-HepB-PRP-T vaccine to Infanrix Hexa (schedule 3, 5, 12) administered with PCV-13 Study 14 (A3L39): Randomized, observer-blind, 2-arm trial to compare DTaP-IPV-HepB-PRP-T vaccine to Infanrix Hexa (schedule 2, 3, 4) administered with PCV-13 Study 15 (A3L40): Observer-blind extension trial of study 14 (A3L39)

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes