EMA/474586/2012

European Medicines Agency decision

P/0161/2012

of 20 July 2012

on the acceptance of a modification of an agreed paediatric investigation plan for Pneumococcal Polysaccharide Serotype 1 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 4 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 5 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 6B – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 9V – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 14 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 18C – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 19F – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate (Prevenar 13), (EMEA-000036-PIP01-07-M06) 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 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

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on the acceptance of a modification of an agreed paediatric investigation plan for Pneumococcal Polysaccharide Serotype 1 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 4 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 5 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 6B – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 9V – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 14 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 18C – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 19F – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate (Prevenar 13), (EMEA-000036-PIP01-07-M06) 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 European Medicines Agency's decision P/34/2008 of 24 June 2008, the decision P/81/2008 of 26 September 2008, the decision P/66/2009 of 20 April 2009, the decision P/15/2010 of 5 February 2010, the decision P/83/2010 of 1 June 2010, and the decision P/73/2011 of 5 April 2011,

Having regard to the application submitted by Pfizer Ltd on 20 April 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 July 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.

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

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for Pneumococcal Polysaccharide Serotype 1 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 4 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 5 – Diphtheria CRM197 Conjugate,Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 6B – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 9V – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 14 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 18C – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 19F – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate (Prevenar 13), 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 Pfizer Ltd, Ramsgate Road, CT13 9NJ - Sandwich, United Kingdom.

Done at London, 20 July 2012

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

EMA/PDCO/273017/2012

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

EMEA-000036-PIP01-07-M06

Scope of the application

Active substance(s):

Pneumococcal Polysaccharide Serotype 1 – Diphtheria CRM197 Conjugate

Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate

Pneumococcal Polysaccharide Serotype 4 – Diphtheria CRM197 Conjugate

Pneumococcal Polysaccharide Serotype 5 – Diphtheria CRM197 Conjugate

Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate

Pneumococcal Polysaccharide Serotype 6B – Diphtheria CRM197 Conjugate

Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate

Pneumococcal Polysaccharide Serotype 9V – Diphtheria CRM197 Conjugate

Pneumococcal Polysaccharide Serotype 14 – Diphtheria CRM197 Conjugate

Pneumococcal Polysaccharide Serotype 18C – Diphtheria CRM197 Conjugate

Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate

Pneumococcal Polysaccharide Serotype 19F – Diphtheria CRM197 Conjugate

Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate

Invented name:

Prevenar 13

Condition(s):

Disease caused by streptococcus pneumoniae

Authorised indication(s):

See Annex II

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

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Pfizer Ltd

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Ltd submitted to the European Medicines Agency on 20 April 2012 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/34/2008 of 24 June 2008, the decision P/81/2008 of 26 September 2008, the decision P/66/2009 of 20 April 2009, the decision P/15/2010 of 5 February 2010, the decision P/83/2010 of 1 June 2010, and the decision P/73/2011 of 5 April 2011.

The procedure started on 15 May 2012.

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 Norwegian Paediatric Committee member agrees 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 annexes and appendix.

Langen, Germany, 6 July 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:

Disease caused by Streptococcus pneumoniae

The waiver applies to:

- infants below 2 months;
- for suspension for injection, intramuscular use.
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition:

Disease caused by Streptococcus pneumoniae

2.1.1. Indication(s) targeted by the PIP

Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants and children from 6 weeks to less than 18 years.

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

From 2 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Suspension for injection, intramuscular use

2.1.4. Studies

Area	Subarea	Description
Clinical	Safety, Immunogenicity 6096A1-006	Phase 3, Comparative Safety, Tolerability, Immunogenicity and Routine Pediatric Vaccinations Infants 2 months
Clinical	Safety, Immunogenicity 6096A1-500	Phase 3 Safety, immunogenicity and concomitant vaccines Infants 3 months
Clinical	Safety, Immunogenicity 6096A1-501	Phase 3 Safety, immunogenicity and concomitant vaccines Infants 2 months

Clinical	Safety, Immunogenicity 6096A1-008	Phase 3 Safety, immunogenicity and concomitant vaccines Infants 2 months
Clinical	Safety, Immunogenicity 6096A1-007	Phase 3 Safety, immunogenicity and concomitant vaccines Infants 2 months
Clinical	Safety, Immunogenicity 6096A1-009	Phase 3 Safety, immunogenicity +/- polysorbate 80 (P80) and Routine Pediatric Vaccinations Infants 2 months
Clinical	Safety, Immunogenicity 6096A1-3000	Phase 3 Final manufacturing lot study Infants 2 months
Clinical	Safety, Immunogenicity 6096A1-3002	Phase 3 Safety and immunogenicity Infants 7 – below 12 months and children 1 to below 5 years
Clinical	Safety, Immunogenicity 6096A1-3007	Phase 3 Safety, immunogenicity and concomitant vaccines Infants 2 months
Clinical	Impact on naso-pharyngeal colonization 6096A1-3006	Phase 3 Evaluation of the impact of 13vPnC on nasopharyngeal colonisation Infants 2 months
Clinical	Safety, Immunogenicity 6115A-1-3002	Phase 3, Safety, Tolerability, and Immunogenicity in HIV Infected Individuals aged 6 years and older
Clinical	Safety, Immunogenicity 6096A1-3014	Phase 3, Safety, Tolerability And Immunogenicity In Children with Sickle Cell Disease 6 to 18 years of age.
Clinical	Safety, Immunogenicity 6096A1-3010	Phase 3, Safety, Immunogenicity in Alaska Native Infants and Children 2 months to ≤ 60 months of age
Clinical	Safety, Immunogenicity 6096A1-4001-EU	Safety, Tolerability, and Immunogenicity in premature infants born at less than 37 weeks gestation

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

Disease caused by streptococcus pneumoniae

Authorised indication:

Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants and children from 6 weeks to 5 years of age.

EU Number	Invented name Name	Strength	Pharma-ceutical form	Route of administration	Packaging	Content (concentration)	Package size
EMEA/H/C/001104	Prevenar 13	2µg/0.5ml dose of each of the 13 pneumo-coccal polysaccharide sero-type - diphtheria CRM 197 conjugates contained in the vaccine, except Pneumo-coccal polysaccharide sero-type 6B - diphtheria CRM 197 conjugate, which contains 4µg/0.5ml	Solution for injection	Intra-muscular use	pre-filled syringe (glass)	Suspension for injection	pre-filled syringe; 1 pre-filled syringe with separate needle; 10 pre-filled syringes;10 pre-filled syringes with separate needles; 50 pre-filled syringes;50 pre-filled syringes with separate needles