EMA/871501/2022

European Medicines Agency decision

P/0485/2022

of 2 December 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 8 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15C – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 16F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 24F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 17F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 33F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 10A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 12F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 20 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 31 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 35B – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 22F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 9N – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 11A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23B – Diphtheria CRM197 Conjugate (V116) (EMEA-003155-PIP01-21) 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.

European Medicines Agency decision

P/0485/2022

of 2 December 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 8 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15C – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 16F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 24F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 17F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 33F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 10A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 12F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 20 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 31 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 35B – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 22F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 9N – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 11A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23B – Diphtheria CRM197 Conjugate (V116) (EMEA-003155-PIP01-21) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Merck Sharp & Dohme (Europe) Inc on 14 December 2021 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 14 October 2022, in accordance with Article 17 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,

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

Has adopted this decision:

Article 1

A paediatric investigation plan for Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 8 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15C – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 16F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 24F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 17F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 33F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 10A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 12F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 20 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 31 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 35B – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 22F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 9N – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 11A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23B – Diphtheria CRM197 Conjugate (V116), solution for injection in pre-filled syringe, 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 Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 8 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15C – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 16F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 24F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 17F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 33F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 10A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 12F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 20 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 31 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 35B – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate / Pneumococcal

Polysaccharide Serotype 22F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 9N – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 11A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23B – Diphtheria CRM197 Conjugate (V116), solution for injection in pre-filled syringe, 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 Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 8 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15C – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 16F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 24F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 17F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 33F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 10A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 12F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 20 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 31 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 35B – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 22F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 9N – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 11A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23B – Diphtheria CRM197 Conjugate (V116), solution for injection in pre-filled syringe, 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 Merck Sharp & Dohme (Europe), Inc., Clos du Lynx 5, 1200 – Brussels, Belgium.

EMA/PDCO/649667/2022
Amsterdam, 14 October 2022

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

EMEA-003155-PIP01-21

Scope of the application

Active substance(s):

Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 8 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15C – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 15A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 16F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 24F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 17F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 33F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 10A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 12F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 20 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 31 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 35B – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 22F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 9N – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 11A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23B – Diphtheria CRM197 Conjugate (V116)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of disease caused by *Streptococcus pneumoniae*

Pharmaceutical form(s):

Solution for injection in pre-filled syringe

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Merck Sharp & Dohme (Europe) Inc

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe) Inc submitted for agreement to the European Medicines Agency on 14 December 2021 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 31 January 2022.

Supplementary information was provided by the applicant on 27 June 2022. The applicant proposed modifications to the paediatric investigation plan.

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 17(1) 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)(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 Paediatric Committee member of Norway 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 and appendix.

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 (PIP)

1. Waiver

1.1. Condition:

Prevention of disease caused by *Streptococcus pneumoniae*

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- solution for injection in pre-filled syringe, intramuscular use;
- on the grounds that the specific medicinal product is likely to be ineffective.

The waiver applies to:

- the paediatric population from 6 months to less than 2 years of age;
- solution 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.

2. Paediatric investigation plan

2.1. Condition:

Prevention of disease caused by *Streptococcus pneumoniae*

2.1.1. Indication(s) targeted by the PIP

Active immunization for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in patients ≥2 years of age and older

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection in pre-filled syringe

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1** Double-blind, randomised, active-controlled trial to evaluate safety, tolerability and immunogenicity of V116 compared to pneumococcal polysaccharide vaccine (PPSV23) in children from 2 years to less than 18

	years of age who have completed a primary pneumococcal vaccination regimen and who are at increased risk of pneumococcal disease.
Modelling and simulation studies	Not applicable
Other studies	Not applicable
Extrapolation plan	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By February 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.