EMA/554379/2023

European Medicines Agency decision

P/0510/2023

of 29 December 2023

on the acceptance of a modification of an agreed 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 20A – 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-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.

European Medicines Agency decision

P/0510/2023

of 29 December 2023

on the acceptance of a modification of an agreed 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 20A – 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-M01) 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 European Medicines Agency's decision P/0485/2022 issued on 2 December 2022,

Having regard to the application submitted by Merck Sharp & Dohme (Europe), Inc. on 4 August 2023 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 10 November 2023, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 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.

Has adopted this decision:

Article 1

Changes to the agreed 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 20A – 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, 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 Merck Sharp & Dohme (Europe), Inc., 25 Boulevard du Souverain, 1170 – Bruxelles, Belgium.

EMA/PDCO/365471/2023
Amsterdam, 10 November 2023

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

EMEA-003155-PIP01-21-M01

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 20A – 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 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe), Inc. submitted to the European Medicines Agency on 4 August 2023 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/0485/2022 issued on 2 December 2022.

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

The procedure started on 11 September 2023.

Scope of the modification

Some measures 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 Paediatric Committee member of Norway 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.

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.