MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept changes to the agreed paediatric investigation plan (MHRA-100920-PIP01-23) and to the deferral

MHRA-100920-PIP01-23-M01

Scope of the Application

Active Substance(s)

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

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 (UK) Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Ltd submitted to the licensing authority on 07/08/2024 05:16 BST an application for a Modification

The procedure started on 06/09/2024 15:34 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100920-PIP01-23-M01

Of 04/11/2024 21:57 GMT

On the adopted decision for Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 22F – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 33F – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 8 – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 9N – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 10A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 11A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 12F – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 17F – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 20A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 15A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 15C – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 16F – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 23A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 23B – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 24F – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 31 – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 35B – Diphtheria CRM197 Conjugate (MHRA-100920-PIP01-23-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 22F – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 33F – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 8 – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 9N – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 10A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 11A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 12F – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 17F – Diphtheria CRM197 Conjugate;

Pneumococcal Polysaccharide Serotype 20A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 15A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 15C – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 16F – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 23A – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 23B – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 24F – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 31 – Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 35B – Diphtheria CRM197 Conjugate, Solution for injection in pre-filled syringe. , INTRAMUSCULAR USE .

This decision is addressed to Merck Sharp & Dohme (UK) Ltd, 120 Moorgate, London, UNITED KINGDOM, EC2M 6UR

ANNEX I

1. Waiver

1.1 Condition:

Prevention of disease caused by Streptococcus pneumoniae The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Solution for injection in pre-filled syringe. Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: For the paediatric population from birth to less than 6 months of age: - on the grounds that the specific medicinal product is likely to be ineffective. For the paediatric population from 6 months to less than 2 years of age: - 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(s):

Prevention of disease caused by Streptococcus pneumoniae

2.2 Indication(s) targeted by the PIP:

Active immunisation for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in patients $\geq$ 2 years of age and older.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection in pre-filled syringe.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	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.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	31/05/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes