MHRA
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Canary Wharf
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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100161-PIP01-21-M01

Scope of the Application

Active Substance(s)

Pneumococcal Polysaccharide Serotype 1 - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 3 - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 4 - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 5 - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 6A - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 6B - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 7F - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 9V - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 14 - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 18C - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 19A - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 19F - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 22F - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 23F - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 33F - Diptheria CRM197 Conjugate

Condition(s)

Prevention of disease caused by Streptococcus pneumoniae

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

Intramuscular use

Name / Corporate name of the PIP applicant

Merck Sharp & Dohme (UK) Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Limited submitted to the licensing authority on 19/07/2021 01:05 BST an application for a Modification

The procedure started on 18/10/2021 12:32 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-100161-PIP01-21-M01

Of 19/10/2021 21:22 BST

On the adopted decision for 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 22F - Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 23F - Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 33F - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 33F - Diphtheria CRM197 Conjugate; 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 (MHRA-100161-PIP01-21-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 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 22F - Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 23F - Diphtheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 33F - Diptheria CRM197 Conjugate; Pneumococcal Polysaccharide Serotype 33F - Diphtheria CRM197 Conjugate; 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, Suspension for injection , Intramuscular use .

This decision is addressed to Merck Sharp & Dohme (UK) Limited, 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): All subsets of the paediatric population from birth to less than 6 weeks of age Pharmaceutical form(s): Suspension for injection Route(s) of administration: Intramuscular use Reason for granting waiver: on the grounds that the specific medicinal product is likely to be ineffective.

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, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants, children and adolescents from 6 weeks to less than 18 years of age

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

The paediatric population from 6 weeks to less than 18 years of age

2.4 Pharmaceutical Form(s):

Suspension for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	4	Study 1 Double-blind, randomised, active-controlled trial to evaluate safety, tolerability and immunogenicity of 15-valent pneumococcal polysaccharide

		conjugate vaccine (V114) compared to Prevenar-13 in healthy infants from 42 to less than 90 days of age at enrolment (infant study). Study 2 Double-blind, randomised, active-controlled trial to evaluate safety, tolerability and immunogenicity of 15-valent pneumococcal polysaccharide conjugate vaccine (V114) compared to Prevenar-13 in healthy children from 7 months to less than 6 years of age, who are pneumococcal vaccine naïve or who have previously received Synflorix (catch-up study). Study 3 Double-blind, randomised, active-controlled trial to evaluate safety, tolerability and immunogenicity of 4-dose schedules of 15-valent pneumococcal polysaccharide conjugate vaccine (V114) or Prevenar-13 compared to mixed schedules which begin with Prevenar-13 and change to V114 at Dose 2, 3 or 4 in healthy infants from 6 to less than 15 weeks of age at enrolment (interchangeability study). Study 4 Double-blind, randomised, active-controlled trial to evaluate safety, tolerability and immunogenicity of 15-valent pneumococcal polysaccharide conjugate vaccine (V114) compared to Prevenar-13 in HIV-infected children and adolescents from 6 to less than 18 years (HIV-infected subjects study).
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:	31/05/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes