

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

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100236-PIP01-21-M02) and to the deferral

MHRA-100236-PIP01-21-M03

Scope of the Application

Active Substance(s)

Pneumococcal Polysaccharide Serotype 6A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 14 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 3 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 12F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 23F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate ; Pneumococcal Polysaccharide Serotype 33F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 5 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 7F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 6B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 19A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 19F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 8 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 11A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 15B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 1 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 22F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 4 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 9V conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 10A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 18C conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate

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

Pfizer Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pfizer Limited submitted to the licensing authority on 27/02/2023 09:11 GMT an application for a Modification

The procedure started on 15/06/2023 12:30 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-100236-PIP01-21-M03

Of 10/08/2023 13:56 BST

On the adopted decision for Pneumococcal Polysaccharide Serotype 6A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 14 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 3 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 12F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 23F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate ; Pneumococcal Polysaccharide Serotype 33F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 5 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 7F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 6B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 19A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 19F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 8 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 11A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 15B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 1 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 22F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 4 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 9V conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 10A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 18C conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate (MHRA-100236-PIP01-21-M03) 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 6A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide

Serotype 14 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 3 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 12F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 23F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate ; Pneumococcal Polysaccharide Serotype 33F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 5 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 7F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 6B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 19A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 19F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 8 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 11A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 15B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 1 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 22F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 4 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 9V conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 10A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate; Pneumococcal Polysaccharide Serotype 18C conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate, Suspension for injection , INTRAMUSCULAR USE .

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, Kent, UNITED KINGDOM, CT139NJ

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 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	6	Study 1 (B7471003) Randomised, active-controlled trial to evaluate safety, tolerability and immunogenicity of a 20-valent pneumococcal polysaccharide conjugate vaccine (20vPnC) compared to 13-valent pneumococcal polysaccharide conjugate vaccine (13vPnC) in healthy infants from 42 to 98 days of age at enrolment. Study 2 (B7471011) Randomised, double-blind active-controlled trial to evaluate safety, tolerability, and immunogenicity of a 20-valent pneumococcal polysaccharide conjugate vaccine (20vPnC) compared to 13-valent pneumococcal polysaccharide conjugate vaccine (13vPnC) in healthy infants from 42 to 98 days of age at enrolment. Study 3 (B7471012) Randomised, double-blind active-controlled trial to evaluate safety, tolerability, and immunogenicity, of 20-valent pneumococcal polysaccharide conjugate vaccine (20vPnC) compared to 13-valent pneumococcal polysaccharide conjugate vaccine (13vPnC) in healthy infants from 42 to 112 days of age at enrolment. Study 4 (B7471013) Randomised, double-blind active-controlled trial to evaluate safety of 20-valent pneumococcal polysaccharide

		conjugate vaccine (20vPnC) compared to 13-valent pneumococcal polysaccharide conjugate vaccine (13vPnC) in healthy infants from 42 to 98 days of age at enrolment. Study 5 (B7471014) Single arm trial to evaluate safety and immunogenicity of 20-valent pneumococcal polysaccharide conjugate vaccine (20vPnC) in healthy children from 15 months to less than 18 years of age. Study 6 (B7471027) (Added during procedure MHRA-100236-PIP01-21-M01) Randomised, active-controlled trial to evaluate safety and immunogenicity, of 20-valent pneumococcal polysaccharide conjugate vaccine (20vPnC) compared to 13-valent pneumococcal polysaccharide conjugate vaccine (13vPnC) in healthy infants from 12 months to less than 24 months of age.
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:	31/07/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes