MHRA
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a waiver

MHRA-101954-PIP01-25

Scope of the Application

Active Substance(s)

N. meningitidis serogroup Y polysaccharide conjugated to Corynebacterium diphtheriae (C. diphtheriae) CRM197 protein; N. meningitidis serogroup W polysaccharide conjugated to Corynebacterium diphtheriae (C. diphtheriae) CRM197 protein; N. meningitidis serogroup X polysaccharide conjugated to Purified Tetanus Toxoid; N. meningitidis serogroup C polysaccharide conjugated to Corynebacterium diphtheriae (C. diphtheriae) CRM197 protein; Neisseria meningitidis (N. meningitidis) serogroup A polysaccharide conjugated to Purified Tetanus Toxoid

Condition(s)

Prevention of invasive meningococcal disease

Pharmaceutical Form(s)

Powder and solvent for solution for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Serum Institute of India Pvt. Ltd.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Serum Institute of India Pvt. Ltd. submitted to the licensing authority on 20/06/2025 16:21 BST an application for a Paediatric Investigation Plan

The procedure started on 17/07/2025 22:11 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 agree a paediatric investigation plan and grant a waiver

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-101954-PIP01-25

Of 13/03/2026 08:17 GMT

On the adopted decision for N. meningitidis serogroup Y polysaccharide conjugated to Corynebacterium diphtheriae (C. diphtheriae) CRM197 protein; N. meningitidis serogroup W polysaccharide conjugated to Corynebacterium diphtheriae (C. diphtheriae) CRM197 protein; N. meningitidis serogroup X polysaccharide conjugated to Purified Tetanus Toxoid; N. meningitidis serogroup C polysaccharide conjugated to Corynebacterium diphtheriae (C. diphtheriae) CRM197 protein; Neisseria meningitidis (N. meningitidis) serogroup A polysaccharide conjugated to Purified Tetanus Toxoid (MHRA-101954-PIP01-25) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for N. meningitidis serogroup Y polysaccharide conjugated to Corynebacterium diphtheriae (C. diphtheriae) CRM197 protein; N. meningitidis serogroup W polysaccharide conjugated to Corynebacterium diphtheriae (C. diphtheriae) CRM197 protein; N. meningitidis serogroup X polysaccharide conjugated to Purified Tetanus Toxoid; N. meningitidis serogroup C polysaccharide conjugated to Corynebacterium diphtheriae (C. diphtheriae) CRM197 protein; Neisseria meningitidis (N. meningitidis) serogroup A polysaccharide conjugated to Purified Tetanus Toxoid, Powder and solvent for solution for injection , INTRAMUSCULAR USE .

This decision is addressed to Serum Institute of India Pvt. Ltd., 212/2 Hadapsar, Off Soli-Poonawalla Road, Pune 411028, Maharashtra, India, Pune, INDIA, 411028

ANNEX I

1. Waiver

1.1 Condition:

Prevention of invasive meningococcal disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 9 months of age Pharmaceutical form(s): Powder and solvent for solution for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of invasive meningococcal disease

2.2 Indication(s) targeted by the PIP:

Active immunisation against invasive meningococcal disease caused by N. meningitidis serogroups A, C, W, Y and X.

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

The paediatric population from 9 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder and solvent for solution 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	3	Study 1 (ACYWX-02; CVIA058) Randomised, observer-blind, active controlled study to evaluate the safety and immunogenicity of two formulations of meningococcal groups ACYWX conjugate vaccine compared to a licensed meningococcal serogroups ACYW conjugate vaccine, in healthy children from 12 months to 16 months of age. Study 2 (ACYWX-03; CVIA 071) Randomised, observer-blind, active controlled study to evaluate the safety and immunogenicity of meningococcal groups ACYWX conjugate vaccine compared to a licensed meningococcal serogroups ACYW conjugate vaccine in healthy

		children from 2 years to less than 18 years of age (and adults). Study 3 (DMID 20-0024) Randomised, observer-blind, active controlled study to evaluate the safety, immunogenicity and non-interference with concomitant routine vaccines, of meningococcal groups ACYWX conjugate vaccine compared to MenACWY-TT conjugate vaccine in healthy children from 9 months and 15 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:	28/02/2025
Deferral of one or more studies contained in the paediatric investigation plan:	No