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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100701-PIP01-22-M01

Scope of the Application

Active Substance(s)

Outer Membrane Vesicles (OMV) from N. meningitidis Strain NZ 98/254; Recombinant Neisseria meningitis group B Protein 936-741; Meningococcal group W-135 oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein; Meningococcal group A oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein; Meningococcal group C oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein; Recombinant Neisseria meningitis group B Protein 287- 953; Recombinant Neisseria meningitis group B Protein 961c; Meningococcal group Y oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein

Condition(s)

Prevention of meningococcal meningitis

Pharmaceutical Form(s)

Powder and suspension for suspension for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

GlaxoSmithKline UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GlaxoSmithKline UK Limited submitted to the licensing authority on 27/09/2022 13:57 BST an application for a

The procedure started on 28/02/2023 12:43 GMT

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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100701-PIP01-22-M01

Of 28/03/2023 12:21 BST

On the adopted decision for Outer Membrane Vesicles (OMV) from N. meningitidis Strain NZ 98/254; Recombinant Neisseria meningitis group B Protein 936-741; Meningococcal group W-135 oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein; Meningococcal group A oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein; Meningococcal group C oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein; Recombinant Neisseria meningitis group B Protein 287- 953; Recombinant Neisseria meningitis group B Protein 961c; Meningococcal group Y oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein (MHRA-100701-PIP01-22-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 a deferral)

This decision applies to a for Outer Membrane Vesicles (OMV) from N. meningitidis Strain NZ 98/254; Recombinant Neisseria meningitis group B Protein 936-741; Meningococcal group W-135 oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein; Meningococcal group A oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein; Meningococcal group C oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein; Recombinant Neisseria meningitis group B Protein 287- 953; Recombinant Neisseria meningitis group B Protein 961c; Meningococcal group Y oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein, Powder and suspension for suspension for injection , INTRAMUSCULAR .

This decision is addressed to GlaxoSmithKline UK Limited , 980 Great West Road, Brentford, UNITED KINGDOM, TW8 9GS

ANNEX I

1. Waiver

1.1 Condition:

Prevention of Meningococcal Meningitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 months of age Pharmaceutical form(s): Powder and suspension for suspension for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product

cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of meningococcal meningitis.

2.2 Indication(s) targeted by the PIP:

Active immunization against invasive disease caused by N. meningitidis group A, B, C, Y, and W-135 of individuals from 2 months of age and older.

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

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

2.4 Pharmaceutical Form(s):

Powder and suspension for suspension for injection.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	2	Study 1 (AB04984) Intramuscular dose range-finding developmental toxicity study in rabbit (pilot study). Study 2 Pivotal reproductive and peri/post-natal developmental toxicity study in the rabbit.
Clinical Studies	16	Study 3 (V102_02), Study 4 (V102_02E1), Study 5 (V102_03), Study 6 (V102_03E1), Study 7-9 deleted, Study 10 (V102_08), Study 11 (V102_11), Study 12 (V102_12), Study 13 (V102_14), Study 14 (V102_15) , Study 15 (V102_15E1) , Study 16 (V102_16), Study 17 (V102_16E1), Study 18 (V72_72)
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:	31/12/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes