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 and to the deferral.

MHRA-100701-PIP01-22-M02

Scope of the Application

Active Substance(s)

Recombinant Neisseria meningitis group B protein 936-741; Meningococcal group W-135 oligosaccharides conjugated to Corynebacterium diptheriae CRM197 protein; Meningococcal group A oligosaccharides conjugated to Corynebacterium diptheriae CRM197 protein; Recombinant Neisseria meningitis group B Protein 287-953; Recombinant Neisseria meningitis group B Protein 961c; Meningococcal group Y oligosaccharides conjugated to Corynebacterium diptheriae CRM197 protein; Outer Membrane Vesicles (OMV) from N. meningitidis Strain NZ 98/254; Meningococcal group C 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 17/04/2024 11:59 BST an application for a Modification

The procedure started on 01/07/2024 12:51 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-100701-PIP01-22-M02

Of 05/07/2024 16:50 BST

On the adopted decision for Recombinant Neisseria meningitis group B protein 936-741; Meningococcal group W-135 oligosaccharides conjugated to Corynebacterium diptheriae CRM197 protein; Meningococcal group A oligosaccharides conjugated to Corynebacterium diptheriae CRM197 protein; Recombinant Neisseria meningitis group B Protein 287-953; Recombinant Neisseria meningitis group B Protein 961c; Meningococcal group Y oligosaccharides conjugated to Corynebacterium diptheriae CRM197 protein; Outer Membrane Vesicles (OMV) from N. meningitidis Strain NZ 98/254; Meningococcal group C oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein (MHRA-100701-PIP01-22-M02) 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 Recombinant Neisseria meningitis group B protein 936-741; Meningococcal group W-135 oligosaccharides conjugated to Corynebacterium diptheriae CRM197 protein; Meningococcal group A oligosaccharides conjugated to Corynebacterium diptheriae CRM197 protein; Recombinant Neisseria meningitis group B Protein 287-953; Recombinant Neisseria meningitis group B Protein 961c; Meningococcal group Y oligosaccharides conjugated to Corynebacterium diptheriae CRM197 protein; Outer Membrane Vesicles (OMV) from N. meningitidis Strain NZ 98/254; Meningococcal group C oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein, Powder and suspension for suspension for injection , INTRAMUSCULAR USE .

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 (AB20847) Pivotal reproductive and peri/post-natal developmental toxicity study in the rabbit.
Clinical Studies	13	exceed word limit
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