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

MHRA-102032-PIP01-25-M01

Scope of the Application

Active Substance(s)

Neisseria meningitidis group B fHBP protein subfamily A; Neisseria meningitidis group B fHBP protein subfamily B

Condition(s)

Prevention of invasive meningococcal disease caused by Neisseira meningitidis serogroup B

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 29/08/2025 10:24 BST an application for a Modification

The procedure started on 09/10/2025 16:26 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 waiver and 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-102032-PIP01-25-M01

Of 17/10/2025 13:26 BST

On the adopted decision for Neisseria meningitidis group B fHBP protein subfamily A; Neisseria meningitidis group B fHBP protein subfamily B (MHRA-102032-PIP01-25-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 Neisseria meningitidis group B fHBP protein subfamily A; Neisseria meningitidis group B fHBP protein subfamily B, 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 invasive meningococcal disease caused by Neisseira meningitidis serogroup B. The waiver applies / applied to: - Paediatric Subset(s): The paediatric population from birth to less than 6 months of age. Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe. - Paediatric Subset(s): The paediatric population from 6 months to 1 year of age. Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments. Pharmaceutical form(s): Suspension for injection Route(s) of administration: INTRAMUSCULAR USE

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of invasive meningococcal disease caused by Neisseira meningitidis serogroup B

2.2 Indication(s) targeted by the PIP:

Active immunisation to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroup B

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

The paediatric population from 1 year 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	9	exceed 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:	31/05/2020
Deferral of one or more studies contained in the paediatric investigation plan:	Yes