MHRA
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Canary Wharf
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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-100470-PIP01-22) and to the waiver and to the deferral

MHRA-100470-PIP01-22-M01

Scope of the Application

Active Substance(s)

Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein Neisseria meningitidis serogroup B fHbp subfamily A Neisseria meningitidis serogroup B fHbp subfamily B Neisseria meningitidis group C polysaccharide conjugated to tetanus toxoid carrier protein Neisseria meningitidis group W-135 polysaccharide conjugated to tetanus toxoid carrier protein Neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid carrier protein

Condition(s)

Prevention of invasive disease caused by Neisseria meningitidis group A, B, C, W and Y

Pharmaceutical Form(s)

Powder and suspension for 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 17/10/2022 06:34 BST an application for a Modification

The procedure started on 23/03/2023 11:04 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 to the waiver 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-100470-PIP01-22-M01

Of 21/09/2023 16:03 BST

On the adopted decision for Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein Neisseria meningitidis serogroup B fHbp subfamily A Neisseria meningitidis serogroup B fHbp subfamily B Neisseria meningitidis group C polysaccharide conjugated to tetanus toxoid carrier protein Neisseria meningitidis group W-135 polysaccharide conjugated to tetanus toxoid carrier protein Neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid carrier protein (MHRA-100470-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 modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein Neisseria meningitidis serogroup B fHbp subfamily A Neisseria meningitidis serogroup B fHbp subfamily B Neisseria meningitidis group C polysaccharide conjugated to tetanus toxoid carrier protein Neisseria meningitidis group W-135 polysaccharide conjugated to tetanus toxoid carrier protein Neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid carrier protein , Powder and suspension for suspension for injection , INTRAMUSCULAR USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Prevention of invasive disease caused by Neisseria meningitidis group A, B, C, W and Y The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 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 the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of invasive disease caused by Neisseria meningitidis group A, B, C, W and Y

2.2 Indication(s) targeted by the PIP:

Active immunisation against invasive disease caused by Neisseria meningitidis group A, B, C, W and Y from 6 months of age

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

The paediatric population from 6 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	0	Not applicable.
Clinical Studies	4	Study 1 (B1971057) Randomised, controlled, observer-blinded study to evaluate immunogenicity, safety and tolerability of bivalent rLP2086 (Trumenba) and immunogenicity, safety and tolerability of MenABCWY compared to meningococcal groups A, C, Y and W-135 Conjugate Vaccine (MenACWY-CRM) (Menveo) and to bivalent rLP2086 (Trumenba) for the respective meningococcal group strains in children from 10 years to less than 18 years of age (and adults). Study 2 (C3511001) Randomised, controlled, observer-blinded immunogenicity and safety study to demonstrate that the immune response for N meningitidis group A (MenA), MenC, MenW, and MenY induced by 2 doses of MenABCWY is non-inferior to the immune response induced by 1 dose of the

		licensed meningococcal group A, C, W-135 and Y conjugate vaccine (MenACWY-CRM) (Menveo), and that the immune response for 4 primary MenB test strains induced by 2 doses of MenABCWY is non-inferior to the immune response induced by 2 doses of meningococcal group B vaccine (recombinant, adsorbed) (bivalent rLP2086) (Trumenba). Study 3 (C3511002) and Study 4 (C351100X) were deleted during procedure MHRA-100470-PIP01-22-M01. Study 5 (C3511006) Randomised, active-controlled, open-label trial to evaluate immunogenicity, safety and tolerability of 2 doses of MenABCWY in children from 12 months to less than 10 years of age. Study 6 (C351100Z) Added during procedure MHRA-100470-PIP01-22-M01. Randomised, controlled, immunogenicity, safety and tolerability study of MenABCWY in healthy infants 6 months of age. -To evaluate the immune response for MenA, MenC, MenW, MenY induced by MenABCWY compared to the immune response induced by MenACWY-TT after 2 primary vaccinations and after a booster dose. -To evaluate the immune response for MenB induced by MenABCWY compared to the immune response induced by Bexsero after 2 primary vaccinations and after a booster dose.
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:	31/12/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes