MHRA
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Canary Wharf
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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100470-PIP01-22

Scope of the Application

Active Substance(s)

Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein, 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, Neisseria meningitidis serogroup B fHbp subfamily A, Neisseria meningitidis serogroup B fHbp subfamily B,

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 07/03/2022 16:07 GMT an application for a Paediatric Investigation Plan

The procedure started on 08/03/2022 09:04 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 agree a paediatric investigation plan and grant a deferral 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-100470-PIP01-22

Of 30/03/2022 16:36 BST

On the adopted decision for Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein, 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, Neisseria meningitidis serogroup B fHbp subfamily A, Neisseria meningitidis serogroup B fHbp subfamily B, (MHRA-100470-PIP01-22) 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 Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein, 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, Neisseria meningitidis serogroup B fHbp subfamily A, Neisseria meningitidis serogroup B fHbp subfamily B, , Powder and suspension for suspension for injection , INTRAMUSCULAR .

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, Kent, 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 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 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 2 months of age

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	0	Not applicable
Clinical Studies	5	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 Trumenba for the respective meningococcal group strains in children from 10 years <18 years of age (and adults) Stage 1: evaluation of primary vaccination responses Stage 2: evaluation of persistence of immunity and responses to a booster vaccination. 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 vaccine 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 Trumenba. Study 3 (C3511002) Open label, controlled, immunogenicity, safety and tolerability study of MenABCWY and Trumenba vaccines when co-administered with Vaxelis and Prevnar13 to infants 6 months of age (sentinel stage) and 2 months of age (expanded stage) Study 4 (C351100X) Randomised, controlled, observer-blinded, immunogenicity, safety and tolerability study of MenABCWY in infants aged 2 months. To evaluate the immune response for MenA, MenC, MenW, MenY induced by MenABCWY compared to the immune response induced by MenACWY-TT (Nimenrix) 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. 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 < 10 years 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:	Yes
Date of completion of the paediatric investigation plan:	30/04/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes