MHRA
10 South Colonnade
Canary Wharf
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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100851-PIP01-23) and to the deferral

MHRA-100851-PIP01-23 -M01

Scope of the Application

Active Substance(s)

NEISSERIA MENINGITIDIS GROUP C POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN; NEISSERIA MENINGITIDIS GROUP A 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; Recombinant Neisseria meningitidis serogroup B protein 1; Recombinant Neisseria meningitidis serogroup B protein 2; Recombinant Neisseria meningitidis serogroup B Protein-based active substance; Recombinant Neisseria meningitidis serogroup B protein 3

Condition(s)

Prevention of meningococcal disease (serogroups A, B, C, W and Y)

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Sanofi Pasteur

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Sanofi Pasteur submitted to the licensing authority on 26/09/2024 14:39 BST an application for a Modification

The procedure started on 05/11/2024 08:23 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.

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Final Decision Letter

MHRA-100851-PIP01-23 -M01

Of 04/02/2025 07:54 GMT

On the adopted decision for NEISSERIA MENINGITIDIS GROUP C POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN; NEISSERIA MENINGITIDIS GROUP A 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; Recombinant Neisseria meningitidis serogroup B protein 1; Recombinant Neisseria meningitidis serogroup B protein 2; Recombinant Neisseria meningitidis serogroup B Protein-based active substance; Recombinant Neisseria meningitidis serogroup B protein 3 (MHRA-100851-PIP01-23 -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 C POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN; NEISSERIA MENINGITIDIS GROUP A 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; Recombinant Neisseria meningitidis serogroup B protein 1; Recombinant Neisseria meningitidis serogroup B protein 2; Recombinant Neisseria meningitidis serogroup B Protein-based active substance; Recombinant Neisseria meningitidis serogroup B protein 3, Suspension for injection , INTRAMUSCULAR USE .

This decision is addressed to Sanofi Pasteur, 14 Espace Henry Vallée, Lyon, FRANCE, 69007

ANNEX I

1. Waiver

1.1 Condition:

Prevention of meningococcal disease (serogroups 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): 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 disease (serogroups A, B, C, W and Y)

2.2 Indication(s) targeted by the PIP:

Active immunisation of individuals from 6 weeks of age against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, B, C, W and Y

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):

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 (VAN00010) Dose finding study to evaluate safety and immunogenicity of MenPenta vaccine in children and adolescents from 10 years to less than 18 years of age (and adults). Study 2 (VAN00011) Double-blind randomised trial to evaluate safety and immunogenicity of MenPenta vaccine compared to a licensed alternative administered concomitantly with routine vaccines in children and adolescents from 10

		years to less than 18 years of age (and adults). Study 3 (VAN00013) Partially blinded study to evaluate the safety and immunogenicity of the MenPenta vaccine in children from 2 months to less than 10 years of age. Study 4 (VAN00014) Double-blind randomised placebo-controlled trial to evaluate safety and immunogenicity of MenPenta vaccine compared to a licensed alternative administered concomitantly with routine paediatric vaccines to healthy children from 2 months to less than 24 months of age. Study 5 (VAN00018) Open-label follow-up trial of study VAN00010 (PIP study 1) to evaluate antibody persistence safety and immunogenicity of a booster dose of MenPenta vaccine in adolescents 3-4 years post- priming.
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:	31/12/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes