MHRA
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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-100475-PIP01-22-M02

Scope of the Application

Active Substance(s)

Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid; Neisseria meningitidis serogroup C polysaccharide conjugated to tetanus toxoid; Neisseria meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid; Neisseria meningitidis serogroup W polysaccharide conjugated to tetanus toxoid

Condition(s)

Prevention of invasive meningococcal disease

Pharmaceutical Form(s)

Solution 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 03/01/2025 15:27 GMT an application for a Modification

The procedure started on 18/02/2025 10:47 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-100475-PIP01-22-M02

Of 25/03/2025 08:30 GMT

On the adopted decision for Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid; Neisseria meningitidis serogroup C polysaccharide conjugated to tetanus toxoid; Neisseria meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid; Neisseria meningitidis serogroup W polysaccharide conjugated to tetanus toxoid (MHRA-100475-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 Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid; Neisseria meningitidis serogroup C polysaccharide conjugated to tetanus toxoid; Neisseria meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid; Neisseria meningitidis serogroup W polysaccharide conjugated to tetanus toxoid, Solution for injection , INTRAMUSCULAR .

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

ANNEX I

1. Waiver

1.1 Condition:

Prevention of invasive meningococcal disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 weeks of age. Pharmaceutical form(s): Solution for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: On the grounds the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of invasive meningococcal disease

2.2 Indication(s) targeted by the PIP:

Active immunisation to prevent invasive meningococcal disease caused by N. meningitidis serogroups A, C, W, and Y.

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

The paediatric population from 6 weeks to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Solution 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	15	Study 1 (MET50) An open-label, randomised, parallel-group, controlled, multi-centre study to evaluate the immunogenicity and safety profile of a single dose of MenACYW conjugate vaccine when given alone compared to that of the licensed Meningococcal (Groups A, C, Y and W-135) Diphtheria Conjugate Vaccine (Menveo), and when MenACYW conjugate vaccine is given concomitantly with diphtheria, pertussis, and tetanus (Tdap) vaccine and human papilloma virus (HPV) vaccine in paediatric subjects from 10 to less than 18 years of age. Study 2 (MET54) A randomised, active-controlled, open-label study to evaluate the immunogenicity and safety profile of a single dose of MenACYW conjugate vaccine when given alone compared to that of a licensed meningococcal group A, C, W-135 and Y conjugate vaccine (Nimenrix)

		in 12 to 23 months old paediatric subjects. Study 3 (MET51) A modified double-blind, randomised, parallel-group, active controlled, multi-centre trial to compare the immunogenicity and describe the safety of a single dose of MenACYW conjugate vaccine to a single dose of licensed quadrivalent meningococcal polysaccharide groups A, C, W-135, and Y conjugate vaccine (MenACWY-Tetanus Toxoid [TT], Nimenrix) in paediatric subjects from 12 to less than 24 months old in the European Union (EU) who were either meningococcal vaccine naïve or had received monovalent MenC vaccination during infancy. Study 4 (MET57) Open-label, randomised, parallel-group, active-controlled, multicentre study to describe the immunogenicity and safety of a single dose of MenACYW conjugate vaccine when administered alone and when administered concomitantly with other paediatric vaccine(s) in paediatric subjects from 12 to less than 24 months old.
Extrapolation, Modeling & Simulation Studies	0	Clinical Studies Continued... Study 5 (MET35) A double-blind, randomised, parallel-group, active-controlled, trial to evaluate the immunogenicity and describe the safety of MenACYW conjugate vaccine compared to Meningococcal (Groups A, C, Y and W-135) Diphtheria Conjugate Vaccine (Menveo) in paediatric subjects 2 to 9 years of age in the United States. Study 6 (MET52) Open-label, randomised, parallel-group, active-controlled, multicentre study to evaluate the immunogenicity and describe the safety of MenACYW conjugate vaccine when administered concomitantly with Men B vaccine and other routine paediatric vaccines as part of the National Immunisation Schedule in the 2nd year of life to healthy paediatric subjects in the United Kingdom. Study 7 (MET58) Partially modified double-blind (open-label for some of the

		vaccines/study groups), randomised, parallel-group, active-controlled, multicentre study to compare the immunogenicity and describe the safety of MenACYW conjugate vaccine to a licensed quadrivalent meningococcal polysaccharide groups A, C, W-135, and Y conjugate vaccine (Nimenrix) when administered concomitantly with routine paediatric vaccines to healthy paediatric subjects from 6 weeks old in EU. Study 8 (MET42) Partially modified double-blind, randomised, parallel-group, active-controlled, multicentre study to compare the immunogenicity and describe the safety of MenACYW conjugate vaccine and Meningococcal (Groups A, C, Y and W-135) Diphtheria Conjugate Vaccine (Menveo) when administered concomitantly with routine paediatric vaccines to paediatric subjects 6 weeks old in the United States. Study 9 (MET41) Modified double-blind, randomised, parallel-group, active-controlled, study to describe the safety of MenACYW conjugate vaccine when administered concomitantly with routine paediatric vaccines given to healthy infants and toddlers in the United States and Puerto Rico.
Other Studies	0	Clinical Studies Continued... Study 10 (MET33) Open-label, randomised, parallel-group, active-controlled, multi-centre study to describe the immunogenicity and safety of a 3-dose immunisation schedule of MenACYW conjugate vaccine or a 4-dose immunisation schedule of a licensed quadrivalent meningococcal conjugate vaccine (Menveo) when administered concomitantly with routine paediatric vaccines in healthy infants and toddlers in Mexico and to describe the immunogenicity and safety of a 3-dose immunisation schedule of MenACYW conjugate vaccine when administered concomitantly with routine paediatric vaccines in healthy infants and toddlers in

		the Russian Federation. Study 11 (MET61) Modified double-blind, randomised, parallel-group, active-controlled, multicentre study to compare the immunogenicity and describe the safety of MenACYW conjugate vaccine and Menveo or Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (Menactra) when administered concomitantly with or without routine paediatric vaccines to paediatric subjects 6 to 19 months old, in the United States. Study 12 (MET43) Modified double-blind, randomised, parallel-group, active-controlled, multi-centre study to evaluate immune lot consistency of MenACYW conjugate vaccine, evaluate the immune non-inferiority versus Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (Menactra), and describe the safety and additional immunogenicity of study vaccines in paediatric patients 10 to less than 18 years old. Study 13 (MET56) Double-blind, randomised, parallel-group, active-controlled, multicentre trial to compare the immunogenicity and describe the safety of a booster dose of MenACYW conjugate vaccine compared to Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (Menactra) in paediatric subjects from 15 to less than 18 years old.
Other Measures	0	Clinical Studies Continued... Study 14 (MET62) Open-label, multi-centre study to describe the immune persistence of the priming dose and describe the immunogenicity and safety of a booster dose of MenACYW conjugate vaccine in children in Finland who had been vaccinated 3 years earlier as toddlers with either MenACYW conjugate vaccine or quadrivalent meningococcal polysaccharide groups A, C, W-135, and Y

		conjugate vaccine (Nimenrix) as part of the MET54 study (Study 2) in paediatric subjects 4 to 5 years old. Study 15 (MET59) Open-label, multi-centre study to describe the immune persistence of the priming dose and describe the immunogenicity and safety of a booster dose of MenACYW conjugate vaccine, when co-administered along with MenB vaccines in adolescents (and adults) in USA who had been vaccinated 5 years earlier as adolescents with either MenACYW conjugate vaccine or Meningococcal (Groups A, C, Y and W-135) Diphtheria Conjugate Vaccine (Menveo) as part of the MET50 study (Study 1).

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:	30/09/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes