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-100064-PIP01-21-M01)

MHRA-100475-PIP01-22-M01

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 11/03/2022 14:15 GMT an application for a Modification

The procedure started on 14/11/2022 08:32 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

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-M01

Of 03/04/2023 15:12 BST

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-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 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 USE .

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 that 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, Y, and W-135

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: Study MET50 Study 2: Study MET54 Study 3: Study MET51 Study 4: Study MET57 Study 5: Study MET35 Study 6: Study MET52 Study 7: Study MET58 Study 8: study MET42 Study 9: Study MET41. Study 10: Study MET33 Study 11: Study MET61 Study 12: Study MET43 Study 13: Study MET56 Study 14: Study MET62 Study 15: Study MET59
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:	30/09/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes