MHRA
10 South Colonnade
Canary Wharf
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United Kingdom

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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-100239-PIP01-21

Scope of the Application

Active Substance(s)

multivalent pneumococcal polysaccharide conjugate vaccine

Condition(s)

Prevention of disease caused by Streptococcus pneumoniae

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 08/10/2021 22:04 BST an application for a Paediatric Investigation Plan

The procedure started on 04/05/2022 07:27 BST

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-100239-PIP01-21

Of 06/09/2022 17:34 BST

On the adopted decision for multivalent pneumococcal polysaccharide conjugate vaccine (MHRA-100239-PIP01-21) 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 multivalent pneumococcal polysaccharide conjugate vaccine, 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 disease caused by Streptococcus pneumoniae The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 42 days of age Pharmaceutical form(s): Suspension for injection Route(s) of administration: Intramuscular use Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of disease caused by Streptococcus pneumoniae

2.2 Indication(s) targeted by the PIP:

Active immunisation for the prevention of invasive disease, pneumonia, and acute otitis media caused by Streptococcus pneumoniae (or pneumococcus) in infants, children and adolescents from 42 days to less than 18 years of age.

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

The paediatric population from 42 days 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	6	Study 1 (PSK00008) Randomised, single (observed) blind, active-controlled study to evaluate immunogenicity and safety in healthy toddlers and infants of three different SP0202 formulations in order to identify the lead formulation for the confirmatory safety and immunogenicity studies. Study 2 (PSK03) Randomised single (observer) blind, parallel-group, active-controlled, confirmatory study to evaluate the safety and immunogenicity of SP0202 versus the comparator vaccine (Prevenar 13) in healthy infants from 42 days to less than 90 days of age at the time of enrolment Study 3 (PSK04) Randomised single (observer) blind, parallel-group, active-controlled, confirmatory study to evaluate the safety and immunogenicity of SP0202 versus the comparator vaccine (Prevenar 13) in healthy infants from 42 days to less than 90 days of age at the time of enrolment. Study 4 (PSK05) Randomised, single (observer) blind, active-controlled study to evaluate the safety of SP0202 administered as a primary series and booster schedule in healthy infants from

		42 days to less than 90 days of age at the time of enrolment. Study 5 (PSK00010) Randomised single (observer) blind, parallel group, active-controlled study to evaluate the immune response and safety profile of SP0202 and Prevnar 13 one month after vaccination in healthy toddlers from 12 months to less than 24 months of age and healthy children/ adolescents from 2 years to less than 18 years of age Study 6 Randomised, single (observer) blind, active-controlled study to evaluate the immune response and the safety profile of SP0202 and the comparator in children at increased risk of pneumococcal disease, from 6 years to less than 18 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:	No
Date of completion of the paediatric investigation plan:	31/12/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes