MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100239-PIP01-21-M01) and to the deferral

MHRA-100239-PIP01-21-M02

Scope of the Application

Active Substance(s)

Multivalent pneumococcal polysaccharide conjugate to carrier protein

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 18/10/2024 16:26 BST an application for a Modification

The procedure started on 05/11/2024 10:11 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-100239-PIP01-21-M02

Of 17/12/2024 08:27 GMT

On the adopted decision for Multivalent pneumococcal polysaccharide conjugate to carrier protein (MHRA-100239-PIP01-21-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 Multivalent pneumococcal polysaccharide conjugate to carrier protein, Suspension for injection , INTRAMUSCULAR USE .

This decision is addressed to Sanofi Pasteur, 14 Espace Henry Vallee, 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 PCV21 versus the comparator vaccine 20vPCV (20-valent PCV, Prevenar 20) 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 PCV21 versus the comparator vaccine 15vPCV (15 valent PCV, Vaxneuvance) in healthy infants from 42 days to less than 113 days of age at the time of enrolment. Study 4 (PSK05) Randomised, single (observer) blind,

		active-controlled study to evaluate the safety of PCV21 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 PCV21 and the comparator vaccine (20vPCV) one month after the last vaccination in healthy naïve children from 7 months to less than 12 months of age, in healthy children aged from 12 months to less than 24 months and in healthy naïve, or with partial or full regimen with other PCVs, children from 2 years to less than 18 years of age. Study 6 (PSK00026) Randomised, single (observer) blind, active-controlled study to evaluate the immune response and the safety profile of PCV21 and the comparator in children at increased risk of pneumococcal disease, from 2 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:	31/05/2027
Deferral of one or more studies contained in the paediatric investigation plan:	No