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:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-101616-PIP01-24

Scope of the Application

Active Substance(s)

Multivalent pneumococcal polysaccharide vaccine

Condition(s)

Prevention of pneumococcal disease caused by S. pneumoniae

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

GlaxoSmithKline UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GlaxoSmithKline UK Limited submitted to the licensing authority on 12/09/2024 17:50 BST an application for a Paediatric Investigation Plan

The procedure started on 29/10/2024 14:52 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 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-101616-PIP01-24

Of 02/04/2026 10:11 BST

On the adopted decision for Multivalent pneumococcal polysaccharide vaccine (MHRA-101616-PIP01-24) 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 vaccine, Suspension for injection , INTRAMUSCULAR USE .

This decision is addressed to GlaxoSmithKline UK Limited, 980 Great West Road , Brentford, UNITED KINGDOM, TW8 9GS

ANNEX I

1. Waiver

1.1 Condition:

Prevention of pneumococcal disease caused by S. pneumoniae The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 weeks 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 is likely to be ineffective.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of pneumococcal disease caused by S. pneumoniae

2.2 Indication(s) targeted by the PIP:

Active immunisation for prevention of invasive pneumococcal disease (IPD), pneumonia and acute otitis media (AOM) caused by the S. pneumoniae serotypes contained in the vaccine in children from 6 weeks to less than 18 years of age

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):

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 Randomised, observer-blind, active-controlled, single-dose study to evaluate the safety, reactogenicity and immunogenicity of multivalent pneumococcal polysaccharide (Pn-MAPS30plus) vaccine in healthy children from 12 months to 15 months of age who have previously completed a primary vaccination schedule. Study 2 Randomised, observer-blind, active-controlled, dose selection study to evaluate the safety, reactogenicity and immunogenicity of Pn-MAPS30plus vaccine in healthy children from 6 weeks of age receiving 3-dose primary vaccination series followed by a booster dose at 12 to 15 months. Study 3 Randomised, observer-blind, active-controlled study to evaluate immunogenicity, safety and reactogenicity of Pn-MAPS30plus in healthy children from 6 weeks of age compared to active PCV control. Study 4 Randomised, observer-blind, active-controlled study to evaluate safety, reactogenicity and immunogenicity of age-appropriate vaccination with Pn-MAPS30plus

		in healthy children from 7 months to less than 6 years of age with or without previous PCV vaccination, based on an age-appropriate catch-up schedule. Study 5 Randomised, observer-blind, active-controlled trial to evaluate the safety, reactogenicity and immunogenicity of a single dose of Pn-MAPS30plus in children from 6 years to less than 18 years of age at high-risk for invasive pneumococcal disease.
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:	30/06/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes