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 waiver

MHRA-101980-PIP01-25

Scope of the Application

Active Substance(s)

Streptococcus agalactiae, serotype Ia, capsular polysaccharide, conjugated to CRM197 Streptococcus agalactiae, serotype Ib, capsular polysaccharide, conjugated to CRM197 Streptococcus agalactiae, serotype II, capsular polysaccharide, conjugated to CRM197 Streptococcus agalactiae, serotype III, capsular polysaccharide, conjugated to CRM197 Streptococcus agalactiae, serotype IV, capsular polysaccharide, conjugated to CRM197 Streptococcus agalactiae, serotype V, capsular polysaccharide, conjugated to CRM197

Condition(s)

Prevention of Group B Streptococcus invasive disease via maternal immunisation.

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Intramuscular use

Name / Corporate name of the PIP applicant

Pfizer Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pfizer Limited submitted to the licensing authority on 23/06/2025 17:00 BST an application for a Paediatric Investigation Plan

The procedure started on 24/07/2025 19:57 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 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-101980-PIP01-25

Of 04/08/2026 08:33 BST

On the adopted decision for Group B Streptococcus 6-valent polysaccharide conjugate vaccine (GBS6) (MHRA-101980-PIP01-25) 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 Group B Streptococcus 6-valent polysaccharide conjugate vaccine (GBS6), Solution for injection , INTRAMUSCULAR USE .

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, Kent, UNITED KINGDOM, CT13 9NJ

ANNEX I

1. Waiver

1.1 Condition:

Prevention of Group B Streptococcus invasive disease via maternal immunisation The waiver applies / applied to: Paediatric Subset(s): Males and non-pregnant females from birth to less than 18 years Pharmaceutical form(s): Solution for injection Route(s) of administration: Intramuscular use Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of Group B Streptococcus invasive disease via maternal immunisation

2.2 Indication(s) targeted by the PIP:

Active immunisation of pregnant adolescents for the prevention of Group B Streptococcus invasive disease caused by Streptococcus agalactiae serotypes Ia, Ib, II, III, IV and V in infants from birth through 90 days of age.

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

Pregnant females from menarche 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	1	Study 1 (C1091009) Randomised, placebo-controlled, double-blinded study to assess the safety, tolerability, and immunogenicity of Group B Streptococcus 6-valent polysaccharide conjugate vaccine (GBS6), in healthy pregnant adolescents (and adult females) and their infants.
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:	31/08/2029
Deferral of one or more studies contained in the paediatric investigation plan:	No