

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-102231-PIP01-25

Scope of the Application

Active Substance(s)

13 Grass Aqueous Extract

Condition(s)

Treatment of allergic rhinitis / rhino-conjunctivitis

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Allergy Therapeutics (UK) Ltd.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Allergy Therapeutics (UK) Ltd. submitted to the licensing authority on 21/11/2025 09:02 GMT an application for a Paediatric Investigation Plan

The procedure started on 09/12/2025 12:46 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:

The agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of 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-102231-PIP01-25

Of 24/08/2026 08:09 BST

On the adopted decision for 13 Grass Aqueous Extract (MHRA-102231-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 13 Grass Aqueous Extract, Suspension for injection , SUBCUTANEOUS USE .

This decision is addressed to Allergy Therapeutics (UK) Ltd., Dominion Way, Worthing, UNITED KINGDOM, BN14 8SA

ANNEX I

1. Waiver

1.1 Condition:

Treatment of allergic rhinitis or rhino-conjunctivitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years of age Pharmaceutical form(s): Suspension for injection Route(s) of administration: Subcutaneous 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):

Treatment of allergic rhinitis or rhino-conjunctivitis

2.2 Indication(s) targeted by the PIP:

Subcutaneous hyposensitisation treatment of allergic rhinitis or rhino-conjunctivitis caused by an IgE-mediated allergy to grass pollen

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

The paediatric population from 5 years 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	1	Study 1 (PQGrass308/G308) Randomised, double blind, placebo-controlled, two part trial to evaluate efficacy, safety and tolerability of 13 Grass Aqueous Extract (PQ Grass) in children and adolescents from 5 years to less than 18 years of age with seasonal allergic rhinitis or rhino-conjunctivitis due to grass pollen.
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:	30/09/2033
Deferral of one or more studies contained in the paediatric investigation plan:	Yes

