MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
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-102114-PIP01-25

Scope of the Application

Active Substance(s)

Standardised allergen extract of peanut kernels (Arachis hypogaea)

Condition(s)

Treatment of peanut allergy

Pharmaceutical Form(s)

Sublingual lyophilisate

Route(s) of Administration

SUBLINGUAL USE

Name / Corporate name of the PIP applicant

ALK-Abelló A/S

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, ALK-Abelló A/S submitted to the licensing authority on 18/09/2025 20:07 BST an application for a Paediatric Investigation Plan

The procedure started on 25/09/2025 18:46 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-102114-PIP01-25

Of 08/07/2026 16:38 BST

On the adopted decision for Standardised allergen extract of peanut kernels (Arachis hypogaea) (MHRA-102114-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 Standardised allergen extract of peanut kernels (Arachis hypogaea) , Sublingual lyophilisate , SUBLINGUAL USE .

This decision is addressed to ALK-Abelló A/S, Bøge Allé 6-8, Hørsholm, DENMARK, 2970

ANNEX I

1. Waiver

1.1 Condition:

Treatment of peanut allergy The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Sublingual lyophilisate Route(s) of administration: Sublingual use Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s)

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of peanut allergy

2.2 Indication(s) targeted by the PIP:

Treatment of patients from 6 months to less than 18 years old with a diagnosis of peanut allergy

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

The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Sublingual lyophilisate

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	4	Study 1 (PT-01) A 3-part trial to assess the safety, tolerability, and efficacy of Arachis hypogaea (peanut) SLIT tablet in children from 4 years to less than 18 years of age (and adults) with peanut allergy, including two open label non-randomised parts followed by a double blind randomised placebo controlled part. Study 2 (PT-02) Open-label, uncontrolled trial to evaluate long term safety of Arachis hypogaea (peanut) SLIT tablet in children from 6 months to less than 18 years of age (and adults) with peanut allergy. Study 3 (PT-03) Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of Arachis hypogaea (peanut) SLIT tablet in children from 6 months to less than 18 years of age with peanut allergy. Study 4 (PT-04) Double-blind, randomised, placebo-controlled trial to evaluate safety of Arachis hypogaea (peanut) SLIT tablet in children from 6 months to less than 18 years of age with peanut allergy.
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:	30/06/2029
Deferral of one or more studies contained in the paediatric investigation plan:	No