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

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100989-PIP01-23-M01

Scope of the Application

Active Substance(s)

DERMATOPHAGOIDES FARINAE; DERMATOPHAGOIDES PTERONYSSINUS

Condition(s)

Treatment of asthma, Treatment of allergic rhinitis

Pharmaceutical Form(s)

Oral 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 09/08/2023 08:52 BST an application for a Modification

The procedure started on 04/12/2023 07:40 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-100989-PIP01-23-M01

Of 18/12/2023 18:14 GMT

On the adopted decision for DERMATOPHAGOIDES FARINAE; DERMATOPHAGOIDES PTERONYSSINUS (MHRA-100989-PIP01-23-M01) 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 DERMATOPHAGOIDES FARINAE; DERMATOPHAGOIDES PTERONYSSINUS, Oral 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:

Condition 1: Treatment of asthma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years of age Pharmaceutical form(s): Oral lyophilisate Route(s) of administration: SUBLINGUAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments Reason for Refusing Waiver: Not Applicable Condition 2: Treatment of allergic rhinitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years of age The paediatric population from 12 to less than 18 years of age Pharmaceutical form(s): Oral lyophilisate Route(s) of administration: SUBLINGUAL USE Reason for granting waiver: For the paediatric population from birth to less than 5 years of age - on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments For the paediatric population from 12 to less than 18 years of age - on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered

2. Paediatric Investigation Plan:

2.1 Condition(s):

Condition 1: Treatment of asthma Condition 2:Treatment of allergic rhinitis

2.2 Indication(s) targeted by the PIP:

Condition 1:Treatment of allergic asthma due to house dust mites Condition 2: Treatment of allergic rhinitis due to house dust mites

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

For Condition 1: The paediatric population from birth 5 years to less than 18 years of age For Condition 2: The paediatric population from 5 years to less than 12 years of age

2.4 Pharmaceutical Form(s):

For both Conditions: Oral lyophilisate

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 Deleted during procedure EMEA-001258-PIP01-11-M03. Study 3 (MT-11) Added during procedure EMEA-001258-PIP01-11-M03 Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of the house dust mite (HDM) sublingual immunotherapy (SLIT) tablet compared to placebo in children from 5 years to less than 18 years with HDM-induced allergic asthma.Study 1 Deleted during procedure EMEA-001258-PIP01-11-M05. Study 4 (MT-12) Added during procedure EMEA-001258-PIP01-11-M05 Double-blind, randomised, placebo-controlled trial to evaluate the efficacy and safety of the house dust mite (HDM)

		sublingual immunotherapy (SLIT) oral lyophilisate compared to placebo in children from 5 to less than 12 years of age with HDM-induced allergic rhinitis / rhinoconjunctivitis.
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:	30/06/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes