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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100700-PIP01-22-M01

Scope of the Application

Active Substance(s)

BIRCH POLLEN

Condition(s)

Treatment of allergic rhinitis/ rhino-conjunctivitis

Pharmaceutical Form(s)

Oral lyophilisate

Route(s) of Administration

SUBLINGUAL USE

Name / Corporate name of the PIP applicant

ALK ABELLO A/S

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, ALK ABELLO A/S submitted to the licensing authority on 30/03/2023 17:13 BST an application for a

The procedure started on 11/08/2023 17:15 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 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-100700-PIP01-22-M01

Of 29/08/2023 13:40 BST

On the adopted decision for BIRCH POLLEN (MHRA-100700-PIP01-22-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 for BIRCH POLLEN, Oral lyophilisate , SUBLINGUAL USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of allergic rhinitis/ 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): 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.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of allergic rhinitis/ rhino-conjunctivitis

2.2 Indication(s) targeted by the PIP:

Treatment of tree pollen allergic rhinitis/ rhino-conjunctivitis

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):

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 1 (TT-04) Randomised, placebo-controlled, double-blind parallel-group trial to evaluate efficacy and safety of the SQ tree SLIT-tablet in adolescents (and adults) with allergenic rhinitis/ Rhino-conjunctivitis due to birch pollen. Study 2 (TT-06) Randomised, placebo-controlled, double-blind parallel-group trial to evaluate efficacy and safety of SQ tree SLIT-tablet in children 5 to less than 18 years of age with allergic rhinitis/ rhino-conjunctivitis due to birch 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:	30/09/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes