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 (MHRA-100105-PIP01-21-M02)

MHRA-100105-PIP01-21-M03

Scope of the Application

Active Substance(s)

ALPRAZOLAM

Condition(s)

Treatment of epileptic seizures

Pharmaceutical Form(s)

Inhalation powder

Route(s) of Administration

INHALATION USE

Name / Corporate name of the PIP applicant

UCB Pharma Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, UCB Pharma Limited submitted to the licensing authority on 22/07/2026 07:14 BST an application for a Modification

The procedure started on 04/08/2026 15:13 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

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-100105-PIP01-21-M03

Of 13/10/2026 14:53 BST

On the adopted decision for ALPRAZOLAM (MHRA-100105-PIP01-21-M03) 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 ALPRAZOLAM, Inhalation powder , Inhalation use .

This decision is addressed to UCB Pharma Limited, 208 Bath Road, Slough, UNITED KINGDOM, SL1 3WE

ANNEX I

1. Waiver

1.1 Condition:

Treatment of epileptic seizures The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age. Pharmaceutical form(s): Inhalation powder Route(s) of administration: Inhalation 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 epileptic seizures

2.2 Indication(s) targeted by the PIP:

Rapid cessation of seizures in patients with stereotypical prolonged seizures from 12 years to less than 18 years of age

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

The paediatric population from 12 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Inhalation powder

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	3	Study 1 (UP0100) Open-label, uncontrolled trial to evaluate the pharmacokinetics (PK), safety, and tolerability of alprazolam for inhalation use in adolescent from 12 years to less than 18 years of age with an established diagnosis of focal, generalised, or focal and generalised epilepsy, and to contribute to modelling of the PK. Study 2 (EP0162) Double-blind, randomised, placebo-controlled, study to evaluate the efficacy and safety of alprazolam for inhalation use in adolescents from 12 years to less than 18 years of age (and adults) with epilepsy with stereotypical prolonged seizures, to demonstrate superiority over placebo. Study 3 (EP0165) Open-label, uncontrolled extension study to evaluate safety, tolerability, and activity of alprazolam for inhalational use in adolescents from 12 years to less than 18 years of age (and adults) with stereotypical prolonged seizures.
Extrapolation, Modeling & Simulation Studies	2	Study 4 (CL0498 Part 2) Modelling and simulation population pharmacokinetic (PK) study to

		confirm the dose of alprazolam for inhalation use in the treatment of prolonged stereotypical seizures in adolescents from 12 years to less than 18 years of age. Study 5 (M1) Modelling and simulation population pharmacokinetic (PK) study to support dosing recommendation of alprazolam for inhalation use in adolescents from 12 years to less than 18 years of age for treatment of prolonged stereotypical seizures by matching exposure between adolescent and adult patients with epilepsy.
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:	Yes