

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-101849-PIP01-25

Scope of the Application

Active Substance(s)

lemborexant

Condition(s)

Treatment of chronic insomnia

Pharmaceutical Form(s)

Film-coated tablet; Age-appropriate oral formulation

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Eisai Europe Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Eisai Europe Limited submitted to the licensing authority on 16/05/2025 17:34 BST an application for a Paediatric Investigation Plan

The procedure started on 10/10/2025 14:50 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 deferral 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-101849-PIP01-25

Of 15/06/2026 14:16 BST

On the adopted decision for lemborexant (MHRA-101849-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 lemborexant, Film-coated tablet; Age-appropriate oral formulation , ORAL USE .

This decision is addressed to Eisai Europe Limited, European Knowledge Centre, Mosquito Way, Hatfield, UNITED KINGDOM, AL10 9SN

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic insomnia The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Film-coated tablet Age appropriate oral dosage form Route(s) of administration: ORAL 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 chronic insomnia

2.2 Indication(s) targeted by the PIP:

Treatment of chronic insomnia with neurodevelopmental/psychiatric disorders (NDPDs)

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

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet Age appropriate oral dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate formulation for children from 2 years of age.
Non-Clinical Studies	2	Study 2 Dose range-finding juvenile toxicity study. Study 3 Definitive juvenile toxicity study.
Clinical Studies	2	Study 4 Open-label, multiple-dose, study to evaluate PK and safety of lemborexant in children from 2 years to less than 18 years of age with chronic insomnia and neurodevelopmental and psychiatric disorders (NDPDs). Study 5 Double-blind, placebo-controlled, randomised withdrawal design study to evaluate the safety and efficacy of lemborexant in children from 2 years to less than 18 years of age with chronic insomnia and NDPDs who have failed an adequate behavioural intervention.
Extrapolation, Modeling & Simulation Studies	1	Study 6 Population pharmacokinetic (PopPK) model to determine the paediatric dose.
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:	28/02/2035
Deferral of one or more studies contained in the paediatric investigation plan:	Yes