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-100044-PIP01-21-M02

Scope of the Application

Active Substance(s)

seltorexant

Condition(s)

Treatment of major depressive disorder.

Pharmaceutical Form(s)

Film-coated tablet; Age-appropriate dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Janssen-Cilag Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Limited submitted to the licensing authority on 02/07/2024 17:57 BST an application for a Modification

The procedure started on 09/09/2024 15:47 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-100044-PIP01-21-M02

Of 18/09/2024 11:08 BST

On the adopted decision for seltorexant (MHRA-100044-PIP01-21-M02) 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 seltorexant, Film-coated tablet; Age-appropriate dosage form , ORAL USE .

This decision is addressed to Janssen-Cilag Limited, 50-100 Holmers Farm Way , High Wycombe, UNITED KINGDOM, HP124EG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of major depressive disorder The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age Pharmaceutical form(s): Film-coated tablet; Age-appropriate dosage form Route(s) of administration: ORAL USE Reason for granting waiver: For the paediatric population from birth to less than 7 years of age on the grounds the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s). For the paediatric population from 7 years to less than 12 years of age on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of major depressive disorder.

2.2 Indication(s) targeted by the PIP:

Adjunctive treatment of MDD with insomnia symptoms in adolescents (12 years to less than 18 years of age) who have responded inadequately to antidepressant (SSRI) medication and psychotherapy.

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):

Film-coated tablet Age-appropriate dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of a lower strength, age-appropriate formulation.
Non-Clinical Studies	1	Study 2 (TOX14339) Assessment of seltorexant on postnatal maturation and reproductive development in female juvenile rats.
Clinical Studies	3	Study 3 (42847922MDD1016) Randomised, placebo-controlled, double-blind study to assess the safety, tolerability and pharmacokinetics (PK) of seltorexant as adjunctive therapy to antidepressants in adolescents from 12 years to less than 18 years of age with major depressive disorder without psychotic features, with or without insomnia symptoms, who have had an inadequate response to selective serotonin reuptake inhibitor (SSRI) monotherapy, and psychotherapy in the current depressive episode. Study 4 (42847922MDD3007) Randomised, placebo-controlled, double-blind study to assess the efficacy of seltorexant as adjunctive therapy

		to antidepressants in terms of superiority versus placebo in adolescents from 12 to less than 18 years of age with major depressive disorder with insomnia symptoms, who have responded inadequately to SSRI monotherapy, and psychotherapy, followed by an open-label extension to evaluate long term efficacy and safety. Study 5 (42847922MDD3008) Randomised, placebo-controlled, double-blind study with extension to assess the efficacy and safety of seltorexant as adjunctive therapy to antidepressants in terms of superiority versus placebo in adolescents from 12 years to less than 18 years of age with major depressive disorder with insomnia symptoms, who have responded inadequately to SSRI monotherapy and psychotherapy.
Extrapolation, Modeling & Simulation Studies	1	Study 6 Modelling and simulation study to support paediatric dosing.
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:	Yes
Date of completion of the paediatric investigation plan:	28/02/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes