EMA/98632/2024

European Medicines Agency decision

P/0104/2024

of 12 April 2024

on the acceptance of a modification of an agreed paediatric investigation plan for seltorexant (EMEA-002746-PIP01-20-M03) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

European Medicines Agency decision

P/0104/2024

of 12 April 2024

on the acceptance of a modification of an agreed paediatric investigation plan for seltorexant (EMEA-002746-PIP01-20-M03) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0079/2021 issued on 17 March 2021, the decision P/0291/2021 issued on 13 August 2021, and the decision P/0479/2023 issued on 1 December 2023,

Having regard to the application submitted by Janssen-Cilag International NV on 17 November 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 February 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for seltorexant, film-coated tablet, age-appropriate dosage form, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Janssen-Cilag International NV, Turnhoutseweg 30, 2340 – Beerse, Belgium.

EMA/PDCO/542260/2023
Amsterdam, 23 February 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002746-PIP01-20-M03

Scope of the application

Active substance(s):

Seltorexant

Invented name and authorisation status:

See Annex II

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 International NV

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International NV submitted to the European Medicines Agency on 17 November 2023 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0079/2021 issued on 17 March 2021, the decision P/0291/2021 issued on 13 August 2021, and the decision P/0479/2023 issued on 1 December 2023.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 3 January 2024.

A meeting with the Paediatric Committee took place on 21 February 2024.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of major depressive disorder

The waiver applies to:

- the paediatric population from birth to less than 7 years of age;
- film-coated tablet, age-appropriate dosage form, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s);

  and

- the paediatric population from 7 years to less than 12 years of age;
- film-coated tablet, age-appropriate dosage form, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of major depressive disorder

2.1.1. Indication(s) targeted by the PIP

Adjunctive treatment of major depressive disorder (MDD) with insomnia symptoms in adolescents (12 to <18 years of age) who have responded inadequately to antidepressant (SSRI) medication and psychotherapy

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 12 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Age-appropriate dosage form

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of a lower strength age-appropriate formulation.

Non-clinical studies	**Study 2 *(*TOX14339)** Assessment of seltorexant on postnatal maturation and reproductive development in female juvenile rats.
Clinical studies	**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 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 to less than 18 years of age with major depressive disorder with insomnia symptoms, who have responded inadequately to SSRI monotherapy and psychotherapy.
Extrapolation, modelling and simulation studies	**Study 6** Modelling and simulation study to support paediatric dosing.
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By February 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.