EMA/94275/2021

European Medicines Agency decision

P/0079/2021

of 17 March 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for seltorexant (EMEA-002746-PIP01-20) 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.

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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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Janssen-Cilag International NV on 24 March 2020 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 January 2021, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

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

Has adopted this decision:

Article 1

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

Article 2

A deferral for seltorexant, film-coated tablet, age-appropriate dosage form, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for seltorexant, film-coated tablet, age-appropriate dosage form, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

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

EMA/PDCO/703016/2020 Corr
Amsterdam, 29 January 2021

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-002746-PIP01-20

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 International NV

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International NV submitted for agreement to the European Medicines Agency on 24 March 2020 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 30 April 2020.

Supplementary information was provided by the applicant on 26 October 2020. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 12 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population, and Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

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

2. The measures and timelines of the agreed 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 annex 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 (MDD)

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 (MDD)

2.1.1. Indication(s) targeted by the PIP

Adjunctive treatment of 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	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a lower strength age-appropriate formulation.

Area	Number of measures	Description
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 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	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 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 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes