EMADOC-1700519818-2037057

European Medicines Agency decision

EMA/PE/0000233864

of 16 April 2025

on the acceptance of a modification of an agreed paediatric investigation plan for daridorexant (Quviviq) 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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on the acceptance of a modification of an agreed paediatric investigation plan for daridorexant (Quviviq) 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/0131/2020 issued on 15 April 2020, the decision P/0116/2022 issued on 13 April 2022 and the decision P/0054/2024 issued on 8 March 2024,

Having regard to the application submitted by Idorsia Pharmaceuticals Deutschland GmbH on 21 November 2024 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 28 February 2025, 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 and to the deferral.

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

[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 daridorexant (Quviviq), including changes to the deferral, 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 Idorsia Pharmaceuticals Deutschland GmbH, 8 Marie-Curie-Strasse, 79539 Loerrach, Germany.

EMADOC-1700519818-1801572
Amsterdam, 28 February 2025

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

EMA/PE/0000233864

Scope of the application

Active substance(s):

Daridorexant

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of insomnia

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate oral solid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Idorsia Pharmaceuticals Deutschland GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Idorsia Pharmaceuticals Deutschland GmbH submitted to the European Medicines Agency on 21 November 2024 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/0131/2020 issued on 15 April 2020, the decision P/0116/2022 issued on 13 April 2022 and the decision P/0054/2024 issued on 8 March 2024.

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

The procedure started on 2 January 2025.

Scope of the modification

Some timelines 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 and to the deferral 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 insomnia

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- film-coated tablet, age-appropriate oral solid dosage form, oral use;
- 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:

Treatment of insomnia

2.1.1. Indication(s) targeted by the PIP

Treatment of insomnia in children with comorbid neurodevelopmental and psychiatric disorders

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Age-appropriate oral solid dosage form

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of an age-appropriate oral solid pharmaceutical form (mini-tablets)
Non-clinical studies	**Study 2** Definitive juvenile toxicity study in rats
Clinical studies	**Study 3** Multi-centre, double-blind, randomised, placebo-controlled, parallel-group polysomnography dose-finding study assessing the efficacy, safety, and pharmacokinetics of a multiple-dose oral administration of daridorexant in paediatric subjects aged from 10 years to less than 18 years of age with insomnia. (ID-078A205)

	Study 4 Multi-centre, 3-period study assessing the efficacy, safety and tolerability of oral treatment with daridorexant in paediatric subjects from 2 to less than 18 years of age with insomnia disorder with comorbid neurodevelopmental and psychiatric disorders (NDPDs) **Study 5** Multi-centre, open-label extension study assessing the long-term safety and tolerability of daridorexant in paediatric subjects from 2 to less than 18 years of age with insomnia disorder with comorbid neurodevelopmental and psychiatric disorders (NDPDs) **Study 6** Added in EMEA-002121-PIP03-19-M01 Multi-centre, double-blind, randomised, placebo-controlled, crossover, polysomnography study assessing the efficacy, safety, and pharmacokinetics of a single-dose oral administration of daridorexant in paediatric subjects aged 2 years to < 10 years with insomnia disorder associated with neurodevelopmental disorders (attention deficit hyperactivity disorder or autism spectrum disorder)
Extrapolation, modelling and simulation studies	Not applicable
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:	No
Date of completion of the paediatric investigation plan:	By May 2032
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:

Condition(s) and authorised indication(s)

1. Treatment of insomnia

Authorised indication(s):

- Treatment of adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning
  - Invented name(s): Quviviq
  - Authorised pharmaceutical form(s): Film-coated tablet
  - Authorised route(s) of administration: Oral use
  - Authorised via centralised procedure