

EMA/177631/2023

European Medicines Agency decision

P/0175/2023

of 15 May 2023

on the acceptance of a modification of an agreed paediatric investigation plan for lasmiditan (Rayvow), (EMA-002166-PIP01-17-M07) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0167/2018 issued on 15 June 2018, the decision P/0358/2018 issued on 7 December 2018, the decision P/0291/2019 issued on 14 August 2019, the decision P/0299/2020 issued on 12 August 2020 and the decision P/0056/2021 issued on 29 January 2021 and the decision P/0291/2022 issued on 11 August 2022,

Having regard to the application submitted by Eli Lilly and Company Limited on 15 December 2022 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 31 March 2023, 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 lasmiditan, (Rayvow), tablet, 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 Eli Lilly and Company Limited, 8 Arlington Square West, Downshire Way, RG12 1PU – Bracknell, United Kingdom.

EMA/PDCO/3583/2023 Corr¹
Amsterdam, 31 March 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002166-PIP01-17-M07

Scope of the application

Active substance(s):

Lasmiditan

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of migraine headaches

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Eli Lilly and Company Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company Limited submitted to the European Medicines Agency on 15 December 2022 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/0167/2018 issued on 15 June 2018, the decision P/0358/2018 issued on 7 December 2018, the decision P/0291/2019 issued on 14 August 2019, the decision P/0299/2020 issued on 12 August 2020 and the decision P/0056/2021 issued on 29 January 2021 and the decision P/0291/2022 issued on 11 August 2022.

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

The procedure started on 30 January 2023.

¹ 8 May 2023

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 migraine headaches

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- tablet, oral use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric investigation plan

2.1. Condition:

Treatment of migraine headaches

2.1.1. Indication(s) targeted by the PIP

Acute treatment of migraine with and without aura

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

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

2.1.4. Measures

Area	Description
Quality-related studies	Study 1 Study deleted in EMEA-002166-PIP01-17-M06
Non-clinical studies	Study 2 Definitive juvenile toxicity study in rats (353404)
Clinical studies	Study 3 Open-label, single dose pharmacokinetic and tolerability study of lasmiditan in paediatric subjects from 6 years to less than 18 years of age with a history of migraine headache (H8H-MC-LAHX) Study 4 Randomized, double-blind, placebo-controlled, parallel-group study to assess efficacy and safety of lasmiditan in paediatric subjects from 6 years to less than 18 years of age with migraine (H8H-MC-LAHV)

	Study 5 Open label, long-term safety study of lasmiditan in paediatric subjects from 6 years to less than 18 years of age with migraine with or without aura who have completed Study 3 or 4 (H8H-MC-LAHW)
Extrapolation, modelling and simulation studies	Study 6 Modelling and simulation study for initial paediatric dose finding
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 March 2026
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 migraine headaches

Authorised indication(s):

- RAYVOW is indicated for the acute treatment of the headache phase of migraine attacks, with or without aura in adults.
 - Invented name(s): RAYVOW.
 - Authorised pharmaceutical form(s): tablets.
 - Authorised route(s) of administration: oral use.
 - Authorised via centralised procedure.