



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/366138/2018

European Medicines Agency decision

P/0167/2018

of 15 June 2018

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for lasmiditan (EMEA-002166-PIP01-17) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the application submitted by Eli Lilly and Company Ltd on 9 June 2017 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 27 April 2018, 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 lasmiditan, tablet, orodispersible tablet, 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 lasmiditan, tablet, orodispersible tablet, 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 lasmiditan, tablet, orodispersible tablet, 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 Eli Lilly and Company Limited, Lilly Research Centre, Erl Wood Manor, Sunninghill Road, GU20 6PH - Windlesham, United Kingdom.

EMA/PDCO/124961/2018 **Corr**

London, 27 April 2018

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

EMA-002166-PIP01-17

Scope of the application

Active substance(s):

Lasmiditan

Condition(s):

Treatment of migraine headaches

Pharmaceutical form(s):

Tablet

Orodispersible tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Eli Lilly and Company Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company Ltd submitted for agreement to the European Medicines Agency on 9 June 2017 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 18 July 2017.

Supplementary information was provided by the applicant on 5 January 2018. 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 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.

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 migraine headaches

The waiver applies to:

- the paediatric population from birth to less than 6 years;
- tablet, orodispersible 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

Orodispersible tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Development of a bioequivalent orodispersible tablet with effective taste mask.
Non-clinical studies	1	Study 2 Definitive juvenile toxicity study in rats (353404).
Clinical studies	3	Study 3 Open-label, single dose pharmacokinetic and tolerability study of lasmiditan in paediatric subjects from 6 to less than 18 years old 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 to less than 18 years old with migraine (H8H-MC-LAHV). Study 5 Open label, long-term safety study of lasmiditan in paediatric subjects from 6 to less than 18 years of age with migraine with or without aura who have completed Study 3 or 4 (H8H-MC-LAHV).
Extrapolation, modelling and simulation studies	1	Study 6 Modelling and simulation study for initial paediatric dose finding.
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:	No
Date of completion of the paediatric investigation plan:	By November 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes