

EMA/465562/2018

European Medicines Agency decision

P/0210/2018

of 17 July 2018

on the acceptance of a modification of an agreed paediatric investigation plan for mexiletine (hydrochloride) (EMA-002012-PIP01-16-M01) 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 European Medicines Agency's decision P/0155/2017 issued on 2 June 2017,

Having regard to the application submitted by Lupin (Europe) Ltd. on 12 March 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 1 June 2018, 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.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for mexiletine (hydrochloride), capsule, hard, oral solution, oral use, gastric 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 Lupin (Europe) Ltd., Victoria Court, Bexton Road, WA16 0PF - Knutsford, United Kingdom.

EMA/PDCO/166696/2018

London, 1 June 2018

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

EMA-002012-PIP01-16-M01

Scope of the application

Active substance(s):

Mexiletine (hydrochloride)

Condition(s):

Treatment of myotonic disorders

Pharmaceutical form(s):

Capsule, hard

Oral solution

Route(s) of administration:

Oral use

Gastric use

Name / corporate name of the PIP applicant:

Lupin (Europe) Ltd.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Lupin (Europe) Ltd. submitted to the European Medicines Agency on 12 March 2018 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0155/2017 issued on 2 June 2017.

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

The procedure started on 3 April 2018.

Scope of the modification

Some measures and 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 in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the paediatric investigation plan 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition

Treatment of myotonic disorders

2.1.1. Indication(s) targeted by the PIP

Symptomatic treatment of myotonic disorders

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Capsule, hard

Oral solution

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	2	Study 1 Development of age appropriate solid formulation (capsule, not containing erythrosine as colorant) in lower strengths appropriate to the paediatric population Study 2 Development of an age appropriate oral liquid formulation (oral solution)
Non-clinical studies	1	Study 3 11-week toxicity study in juvenile rats with a 4-week recovery period
Clinical studies	4	Study 4 Open-label, non-comparative study to evaluate the PK, safety and efficacy of mexiletine in children and adolescents 6 to less than 18 years of age with clinical symptoms or signs of myotonic disorders Study 5 Open-label, non-comparative study to evaluate the PK, safety and efficacy of mexiletine in children from birth to less than 6 years of age with clinical symptoms or signs of myotonic disorders

		Study 6 deleted in procedure EMEA-002012-PIP01-16-M01 Study 7 Open-label follow-up study evaluating the long-term safety and efficacy of mexiletine in children with myotonic disorders who have completed the initial paediatric studies
Extrapolation, modelling and simulation studies	1	Study 8 PK modelling study to support dosing recommendations in children
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 September 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes