EMA/327869/2019

European Medicines Agency decision

P/0221/2019

of 17 June 2019

on the acceptance of a modification of an agreed paediatric investigation plan for terbinafine (hydrochloride) (EMEA-001259-PIP02-13-M02) 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 European Medicines Agency's decision P/0144/2013 issued on 3 July 2013 and the decision P/0015/2017 issued on 31 January 2017,

Having regard to the application submitted by Polichem, S.A. on 14 February 2019 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 29 May 2019, 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 terbinafine (hydrochloride), medicated nail lacquer, topical 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 Polichem, S.A., 50, Val Fleuri, 1526 – Luxembourg, Luxembourg.

EMA/PDCO/173588/2019
Amsterdam, 29 May 2019

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

EMEA-001259-PIP02-13-M02

Scope of the application

Active substance(s):

Terbinafine (hydrochloride)

Condition(s):

Treatment of onychomycosis

Pharmaceutical form(s):

Medicated nail lacquer

Route(s) of administration:

Topical use

Name/corporate name of the PIP applicant:

Polichem, S.A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Polichem, S.A. submitted to the European Medicines Agency on 14 February 2019 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/0144/2013 issued on 3 July 2013 and the decision P/0015/2017 issued on 31 January 2017.

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

The procedure started on 1 April 2019.

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 Norwegian Paediatric Committee member 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 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 onychomycosis

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- medicated nail lacquer, topical use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition

Treatment of onychomycosis

2.1.1. Indication(s) targeted by the PIP

Treatment of onychomycosis

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Medicated nail lacquer for topical use

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	2	**Study 1** In vitro study, comparing permeation through bovine hoof membranes with a thickness corresponding to adult toenails and half the thickness for child toenails. **Study 2** In silico study to estimate systemic absorption of terbinafine in children following topical application of P-3058 on finger- & toenails.

Clinical studies	1	**Study 3** Open-label, multi-centre study to evaluate tolerability, safety and to provide dosing recommendations for topical terbinafine.
Extrapolation, modelling and simulation studies	0	Not applicable
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 December 2018
Deferral for one or more measures contained in the paediatric investigation plan:	Yes