



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/241957/2023

## European Medicines Agency decision P/0203/2023

of 13 June 2023

on the acceptance of a modification of an agreed paediatric investigation plan for efinaconazole (EMA-001627-PIP01-14-M03) 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.**



# European Medicines Agency decision

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on the acceptance of a modification of an agreed paediatric investigation plan for efinaconazole (EMA-001627-PIP01-14-M03) 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<sup>1</sup>,

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<sup>2</sup>,

Having regard to the European Medicines Agency's decision P/0047/2015 issued on 6 March 2015 and the decision P/0195/2022 issued on 10 June 2022,

Having regard to the application submitted by Almirall, S.A. on 23 January 2023 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 26 April 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 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.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1, as amended.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

**Article 1**

Changes to the agreed paediatric investigation plan for efinaconazole, cutaneous solution, cutaneous use, 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 Almirall, S.A., Ctra. Laureà Miró, 408-410, 08980 - Sant Feliu de Llobregat, Spain.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/51234/2023  
Amsterdam, 26 April 2023

## Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001627-PIP01-14-M03

### Scope of the application

**Active substance(s):**

Efinaconazole

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of onychomycosis

**Pharmaceutical form(s):**

Cutaneous solution

**Route(s) of administration:**

Cutaneous use

**Name/corporate name of the PIP applicant:**

Almirall, S.A.

### Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Almirall, S.A. submitted to the European Medicines Agency on 23 January 2023 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 P/0047/2015 issued on 6 March 2015 and the decision P/0195/2022 issued on 10 June 2022.

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

The procedure started on 27 January 2023.



## 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 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 onychomycosis

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- cutaneous solution, cutaneous 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 6 years to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Cutaneous solution

### 2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	<b>Study 1</b> Study deleted in procedure EMEA-001627-PIP01-14-M02) <b>Study 2</b> Study deleted in procedure EMEA-001627-PIP01-14-M02) <b>Study 3</b> Study added in procedure EMEA-001627-PIP01-14-M02) Open-label, pharmacokinetic (PK), safety and activity study in children from 6 years to less than 18 years of age with mild to moderate onychomycosis of the toenails

	<b>Study 4</b> Study deleted in procedure EMEA-001627-PIP01-14-M03
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 January 2019
Deferral for one or more measures contained in the paediatric investigation plan:	No



## **Annex II**

### **Information about the authorised medicinal product**

***Information provided by the applicant:***

**The product is not authorised anywhere in the European Community.**