



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/666639/2017

## European Medicines Agency decision

P/0338/2017

of 10 November 2017

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for crisorole (EMA-002065-PIP01-16) 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<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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>2</sup>,

Having regard to the application submitted by Pfizer Ltd on 24 October 2016 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 31 October 2017, in accordance with Article 17(1) 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, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) of Regulation (EC) No 1901/2006, 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.

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

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

Has adopted this decision:

**Article 1**

A paediatric investigation plan for crisaborole, ointment, topical 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 crisaborole, ointment, topical 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 crisaborole, ointment, topical 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 Pfizer Ltd, Ramsgate Road, CT13 9NJ - Sandwich, Kent, United Kingdom.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/654355/2017  
London, 31 October 2017

## Final opinion of the Paediatric Committee on the agreement of a Paediatric Investigation plan and a deferral and a waiver

EMA-002065-PIP01-16

### Scope of the application

**Active substance(s):**

Crisaborole

**Condition(s):**

Treatment of atopic dermatitis

**Pharmaceutical form(s):**

Ointment

**Route(s) of administration:**

Topical use

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

Pfizer Ltd

### Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Pfizer Ltd submitted for agreement to the European Medicines Agency on 24 October 2016 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.

An Opinion was adopted by the Paediatric Committee on 15 September 2017 for the above mentioned product. Pfizer Ltd received the Paediatric Committee Opinion on 22 September 2017.

On 6 October 2017 Pfizer Ltd submitted to the European Medicines Agency a written request, including detailed grounds for re-examination of the Opinion.

The re-examination procedure started on 7 October 2017.



## Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

1.1. to maintain its opinion and

- 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)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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 atopic dermatitis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 1 month of age;
- ointment, 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 atopic dermatitis

### 2.1.1. Indication(s) targeted by the PIP

Treatment of mild to moderate atopic dermatitis in patients 1 month of age and older

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

From 1 month to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Ointment

### 2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	3	<b>Study 1</b> 4-week definitive juvenile toxicity study in rats with a 1-week recovery period to evaluate food consumption, sexual maturation, functional observational battery, motor activity, acoustic startle response, clinical pathology, necropsy findings, organ weights and histopathology <b>Study 2</b> 4-week definitive juvenile dermal toxicity study in Gottingen minipigs with a 1-week recovery period to evaluate clinical signs, body weight, food consumption, growth rate, clinical pathology, ECG and ophthalmoscopy

		<p><b>Study 3</b></p> <p>4-week definitive juvenile toxicity study in rats with a 2-week recovery period to evaluate systemic safety, body weight, food consumption, motor activity, acoustic startle habituation, clinical pathology, including haematology and clinical chemistry, macroscopic and microscopic pathology</p>
Clinical studies	5	<p><b>Study 4</b></p> <p>Double-blind, randomised, vehicle-controlled trial to evaluate safety and efficacy of crisaborole ointment, 2% compared to vehicle in children from 2 to less than 18 years of age (and adults) with mild-to-moderate atopic dermatitis.</p> <p><b>Study 5</b></p> <p>Double-blind, randomised, vehicle-controlled trial to evaluate safety and efficacy of crisaborole ointment, 2% compared to vehicle in children from 2 to less than 18 years of age (and adults) with mild-to-moderate atopic dermatitis.</p> <p><b>Study 6</b></p> <p>Open-label, uncontrolled, extension study to evaluate long-term safety of crisaborole ointment, 2% in children from 2 to less than 18 years of age (and adults) with mild-to-moderate atopic dermatitis.</p> <p><b>Study 7</b></p> <p>Double-blind, randomised, vehicle-controlled trial to evaluate safety and efficacy of crisaborole ointment, 2% compared to vehicle in children from 1 month to less than 24 months of age with mild-to-moderate atopic dermatitis.</p> <p><b>Study 8</b></p> <p>Double-blind, randomised, active- and emollient-controlled study to evaluate efficacy and safety of crisaborole ointment, 2% compared to topical corticosteroid (TCS) and emollient in children from 2 to less than 18 years of age with mild to moderate atopic dermatitis. Treatments in all the arms must be administered on top of an emollient.</p>
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 August 2021
Deferral for one or more measures contained in the paediatric investigation plan:	Yes