EMA/698088/2011

European Medicines Agency decision

P/217/2011

of 16 September 2011

on the agreement of a paediatric investigation plan and on the refusal of a deferral and on the granting of a waiver for prednicarbate / octenidine dihydrochloride, (EMEA-000993-PIP01-10) 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 application submitted by Almirall Hermal GmbH on 7 June 2010 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 12 August 2011, in accordance with Article 18 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 refusal 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 refusing 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 prednicarbate / octenidine dihydrochloride, cream, cutaneous 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 prednicarbate / octenidine dihydrochloride, cream, cutaneous 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 refused.

Article 3

A waiver for prednicarbate / octenidine dihydrochloride, cream, cutaneous 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 Almirall Hermal GmbH, Scholzstrasse 3, 21465 Reinbek, Germany.

Done at London, 16 September 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/698088/2011

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

EMEA-000993-PIP01-10

Scope of the application

Active substance(s):

Prednicarbate / octenidine dihydrochloride

Condition(s):

Treatment of dermatomycosis

Treatment of atopic dermatitis

Pharmaceutical form(s):

Cream

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Almirall Hermal GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Almirall Hermal GmbH submitted for agreement to the European Medicines Agency on 7 June 2010 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 15 July 2010.

Supplementary information was provided by the applicant on 27 May 2011.

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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 18 of said Regulation,
   - to refuse 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 said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients..

   The Icelandic and the Norwegian Paediatric Committee members agree 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(es) and appendix.

London, 12 August 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

1. Waiver

1.1. Condition: Treatment of dermatomycosis

The waiver applies to:

- Infants and toddlers from birth to less than 12 years of age
- for cream, cutaneous use
- on the grounds of lack of significant benefit as studies are of no benefit.

1.2. Condition: Treatment of atopic dermatitis

The waiver applies to:

- Newborns from birth to less than 28 days of age
- for cream, cutaneous use
- on the grounds of lack of significant benefit as studies are of no benefit.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of dermatomycosis

2.1.1. Indication(s) targeted by the PIP

Treatment of inflamed acute dermatophytosis

Treatment of inflamed cutaneous candidiasis

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

From 12 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Cream, cutaneous use

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Extrapolation from adult data in children from 12 to less than 18 years of age supported by review of the literature and by analysis of results from the adult program and PK/safety study in children with atopic dermatitis

2.2. Condition: Treatment of Atopic Dermatitis

2.2.1. Indication(s) targeted by the PIP

Treatment of infected atopic dermatitis

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

From 1 month to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Cream, topical use

2.2.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	Open-label, single arm, single and multiple dose PK and tolerability study in infants and children from 1 month to less than 4 years of age. Extrapolation from adult data in children 4 to less than 18 years of age, supported by review of the literature and by analysis of the results from the adult program.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No.
Date of completion of the paediatric investigation plan:	By October 2014.
Deferral for one or more studies contained in the paediatric investigation plan:	No.

3.1. Refusal of deferral

The PDCO denied a deferral on the grounds that the agreed study will be conducted in parallel to the adult development.