EMA/335299/2010

European Medicines Agency decision

P/87/2010

of 1 June 2010

on the agreement of a paediatric investigation plan and on the granting of a waiver for clindamycin (phosphate) / bituminosulphonate (sodium) (EMEA-000532-PIP01-09) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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 Ichthyol - Gesellschaft Cordes, Hermanni & Co. (GmbH & Co.) KG on 29 January 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 April 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, 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 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 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 clindamycin (phosphate) / bituminosulphonate (sodium), solution, 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 waiver for clindamycin (phosphate) / bituminosulphonate (sodium), solution, 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 3

This decision is addressed to Ichthyol - Gesellschaft Cordes, Hermanni & Co. (GmbH & Co.) KG, Sportallee 85, 22335 Hamburg, Germany.

Done at London, 1 June 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/216200/2010

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

EMEA-000532-PIP01-09

Scope of the application

Active substance(s):

Clindamycin (phosphate) / bituminosulphonate (sodium)

Condition(s):

Acne vulgaris

Pharmaceutical form(s):

Solution

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Ichthyol - Gesellschaft Cordes, Hermanni & Co. (GmbH & Co.) KG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Ichthyol - Gesellschaft Cordes, Hermanni & Co. (GmbH & Co.) KG submitted for agreement to the European Medicines Agency on 29 January 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 20 August 2009.

Supplementary information was provided by the applicant on 28 January 2010.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 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 Articles 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   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 subsets of the paediatric population and condition 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, 16 April 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

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

1. Condition(s)

Acne vulgaris

2. Waiver

2.1. Condition

Acne vulgaris

The waiver applies to:

- the paediatric population from birth to less than 10 years of age
- for solution for cutaneous use
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Acne vulgaris

3.2. Indication targeted by the pip

Treatment of acne vulgaris

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

From 10 to less than 18 years of age.

3.4. Pharmaceutical form(s)

Solution for cutaneous use

3.5. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	1	Study 1) Double-blind, randomized, vehicle-controlled, active-controlled, multi-centre study to evaluate the efficacy and tolerability of clindamycin phosphate, sodium bituminosulfonate solution versus placebo in mild to moderate acne

Area	Number of studies	Description
		vulgaris in paediatric patients and adults from 10 to less than 46 years of age.

4. Follow-up, completion and deferral of pip

Measures to address long term follow-up in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By November 2010
Deferral for one or more studies contained in the paediatric investigation plan:	No