EMA/335351/2010

European Medicines Agency decision

P/90/2010

of 1 June 2010

on the agreement of a paediatric investigation plan and on the granting of a waiver for bisoctrizole / titanium dioxide (EMEA-000585-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.

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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 Orfagen on 19 June 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 bisoctrizole / titanium dioxide, 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 waiver for bisoctrizole / titanium dioxide, 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 3

This decision is addressed to Orfagen, Parc Technologique du Canal, 4, rue Marie Curie, BP 22132, 31521 Ramonville Saint Agne, France.

Done at London, 1 June 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/216470/2010

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

EMEA-000585-PIP01-09

Scope of the application

Active substance(s):

Bisoctrizole / titanium dioxide

Condition(s):

Solar urticaria

Pharmaceutical form(s):

Cream

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Orfagen

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Orfagen submitted for agreement to the European Medicines Agency on 19 June 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 23 July 2009.

Supplementary information was provided by the applicant on 22 January 2010.

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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 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, 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)

Solar urticaria

2. Waiver

2.1. Condition

Solar urticaria

The waiver applies to:

- the paediatric population from birth to less than 11 years of age
- for cream for cutaneous use
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Solar urticaria

3.2. Indication targeted by the pip

Prevention of solar urticaria

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

From 12 to less than 18 years of age.

3.4. Pharmaceutical form(s)

Cream for cutaneous use

3.5. Studies

Area	**Number of studies**	**Description**
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	1	Study 1) Single blind, randomised, multicentre, active controlled trial to evaluate the efficacy, tolerability and improvement of life quality of bisoctrizole, titanium dioxide cream in children from 12 to less than 18 of age and in adults with idiopathic solar urticaria.

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 December 2011
Deferral for one or more studies contained in the paediatric investigation plan:	No