EMA/725996/2012

European Medicines Agency decision

P/0281/2012

of 21 November 2012

on the granting of a product specific waiver for brimonidine tartrate (EMEA-001239-PIP01-11) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 Galderma International on 5 December 2011 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 5 October 2012 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.

(2) 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 waiver for brimonidine tartrate, gel, 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 2

This decision is addressed to Galderma International, Tour Europlaza, 20 avenue André Prothin, La Défense 4, 92927 Cedex, France.

Done at London, 21 November 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/562799/2012

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-001239-PIP01-11

Scope of the application

Active substance(s):

Brimonidine tartrate

Condition(s):

Treatment of rosacea

Pharmaceutical form(s):

Gel

Route(s) of administration:

Topical use

Name/corporate name of the PIP applicant:

Galderma International

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GALDERMA International submitted for agreement to the European Medicines Agency on 5 December 2011 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 15 February 2012.

Supplementary information was provided by the applicant on 16 July 2012.

The applicant withdrew its proposed paediatric investigation plan and requested a product-specific waiver and proposed to extend the scope of the waiver to cover all subsets of the paediatric population.

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Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population, 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 Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

London, 5 October 2012

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

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition: Treatment of rosacea

The waiver applies to:

- All subsets of the paediatric population from birth to less than 12 years of age;
- for gel, topical use;
- on the grounds that the specific medicinal product is likely to be unsafe.

The waiver applies to:

- The paediatric population from 12 to less than 18 years of age;
- for gel, topical 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.