EMA/583062/2010

European Medicines Agency decision

P/185/2010

of 24 September 2010

on the granting of a product specific waiver for afamelanotide (EMEA-000737-PIP01-09) 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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on the granting of a product specific waiver for afamelanotide (EMEA-000737-PIP01-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 Clinuvel UK Limited on 19 October 2009 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 August 2010 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 afamelanotide, implant, subcutaneous 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 Clinuvel UK Limited, C/- Reed Smith, Broadgate Tower, Third Floor, 20 Primrose Street, London, EC2A 2 RS, United Kingdom.

Done at London, 24 September 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/499747/2010

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

EMEA-000737-PIP01-09

Scope of the application

Active substance(s):

Afamelanotide

Condition(s):

Treatment of congenital erythropoietic porphyria

Treatment of solar urticaria

Treatment of polymorphic light eruption

Prevention of drug phototoxic response

Prevention of actinic keratosis

Pharmaceutical form(s):

Implant

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Clinuvel UK Limited

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Clinuvel UK Limited submitted to the European Medicines Agency on 19 October 2009 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 19 November 2009.

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

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A meeting with the Paediatric Committee took place on 4 August 2010.

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 all the above mentioned condition(s) in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations and 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(s) agree(s) 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, 6 August 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Grounds for the granting of the waiver

1.1. Condition

Treatment of congenital erythropoietic porphyria (CEP)

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age
- for implant, subcutaneous use
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

1.2. Condition

Treatment of solar urticaria

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age
- for implant, subcutaneous use
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

1.3. Condition

Treatment of polymorphic light eruption

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age
- for implant, subcutaneous use
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

1.4. Condition

Prevention of drug phototoxic response

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age
- for implant, subcutaneous use
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets.

1.5. Condition

Prevention of actinic keratosis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age
- for implant, subcutaneous use
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets.