EMA/316665/2013

European Medicines Agency decision

P/0150/2013

of 3 July 2013

on the granting of a product specific waiver for zolpidem tartrate (EMEA-001444-PIP01-13) 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 zolpidem tartrate (EMEA-001444-PIP01-13) 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 Transcept Pharmaceuticals, Inc on 8 February 2013 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 17 May 2013 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 zolpidem tartrate, sublingual tablet, sublingual 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 Transcept Pharmaceuticals, Inc, 1003 West Cutting Boulevard, CA 94804 - Point Richmont, USA.

Done at London, 3 July 2013

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

EMA/PDCO/113333/2013

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

EMEA-001444-PIP01-13

Scope of the application

Active substance(s):

Zolpidem (tartrate)

Condition(s):

Treatment of insomnia

Pharmaceutical form(s):

Sublingual tablet

Route(s) of administration:

Sublingual use

Name/corporate name of the PIP applicant:

Transcept Pharmaceuticals, Inc

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Transcept Pharmaceuticals, Inc submitted to the European Medicines Agency on 8 February 2013 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 20 March 2013.

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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 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.

   The Icelandic and the Norwegian Paediatric Committee members agree 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, 17 May 2013

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 insomnia

The waiver applies to:

- The paediatric population from birth to less than 18 years;
- for sublingual tablet, sublingual use;
- on the grounds that the specific medicinal product is likely to be ineffective;
- on the grounds that the specific medicinal product is likely to be unsafe.