EMA/221083/2011

European Medicines Agency decision

P/71/2011

of 4 April 2011

on the granting of a product specific waiver for iloperidone (EMEA-000995-PIP01-10) 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 iloperidone (EMEA-000995-PIP01-10) 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 Vanda Pharmaceuticals Ltd. on 2 July 2010 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 18 February 2011 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 iloperidone, suspension for injection, tablet, intramuscular use, oral 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 Vanda Pharmaceuticals Limited, 81 Oxford Street, W1D 2EU London, United Kingdom.

Done at London, 4 April 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/45543/2011

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

EMEA-000995-PIP01-10

Scope of the application

Active substance(s):

Iloperidone

Condition(s):

Treatment of schizophrenia

Pharmaceutical form(s):

Suspension for injection

Tablet

Route(s) of administration:

Intramuscular use

Oral use

Name/corporate name of the PIP applicant:

Vanda Pharmaceuticals Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Vanda Pharmaceuticals Ltd. submitted for agreement to the European Medicines Agency on 2 July 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of Said Regulation.

The procedure started on 15 September 2010.

Supplementary information was provided by the applicant on 6 December 2010. The applicant withdrew its proposed paediatric investigation plan and its request for a deferral and changed the scope of the requested waiver.

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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)(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, 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 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, 18 February 2011

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 schizophrenia

The waiver applies to:

- All subsets of the paediatric population from birth to less than 12 years of age,
- for suspension for injection for intramuscular use and for tablets for oral use,
- 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 waiver applies to:

- Adolescents from 12 to less than 18 years of age,
- for suspension for injection for intramuscular use and for tablets for oral use,
- on the grounds that the specific medicinal product is likely to be unsafe, and on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.