



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/779528/2012

European Medicines Agency decision

P/0007/2013

of 21 January 2013

on the granting of a product specific waiver for morphine / oxycodone (EMEA-001281-PIP01-12) 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 morphine / oxycodone (EMEA-001281-PIP01-12) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by QRxPharma Inc on 10 April 2012 Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 7 December 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 morphine / oxycodone, capsule, hard, 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 QRxPharma Inc, 1430 US Highway 206, Suite 230, Bedminster, NJ 07921 - Bedminster, New Jersey, United States.

Done at London, 21 January 2013

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

EMA/PDCO/660271/2012

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

EMA-001281-PIP01-12

Scope of the application

Active substance(s):

Morphine / oxycodone

Condition(s):

Treatment of pain

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

QRxPharma Inc

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, QRxPharma Inc submitted to the European Medicines Agency on 10 April 2012 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 May 2012.

Supplementary information was provided by the applicant on 3 September 2012.

The applicant withdrew its proposed paediatric investigation plan and withdrew its request for a deferral and proposed to extend the scope of the waiver to cover all subsets of the paediatric population.

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)(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, 7 December 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 pain

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for capsule, hard for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.