EMA/800821/2010

European Medicines Agency decision

P/16/2011

of 21 January 2011

on the granting of a product specific waiver for nepafenac (Nevanac) (EMEA-000913-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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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 Alcon Laboratories (UK) Ltd. on 9 August 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 10 December 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 nepafenac (Nevanac), eye drops, suspension, ocular 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 Alcon Laboratories (UK) Ltd., Pentagon Park, Boundary Way, HP2 7UD Hemel Hempstead, Herts, United Kingdom.

Done at London, 21 January 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director

(Signature on file)

EMA/PDCO/661059/2010

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

EMEA-000913-PIP01-10

Scope of the application

Active substance(s):

Nepafenac

Invented name:

Nevanac

Condition(s):

Prevention of post operative pain and inflammation associated with cataract surgery

Treatment of post operative pain and inflammation associated with cataract surgery

Prevention of post surgical macular oedema

Authorised indication(s): see Annex II

Pharmaceutical form(s):

Eye drops, suspension

Route(s) of administration:

Ocular use

Name/corporate name of the PIP applicant:

Alcon Laboratories (UK) Ltd.

Information about the authorised medicinal product: see Annex II

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Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Alcon Laboratories (UK) Ltd. submitted to the European Medicines Agency on 9 August 2010 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 13 October 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 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, 10 December 2010

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: Prevention of post-operative pain and inflammation associated with cataract surgery

The waiver applies to:

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

1.2. Condition: Treatment of post-operative pain and inflammation associated with cataract surgery

The waiver applies to:

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

1.3. Condition: Prevention of post-surgical macular oedema

The waiver applies to:

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

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of post operative pain and inflammation associated with cataract surgery

   Authorised indications:

   Prevention and treatment of post operative pain and inflammation associated with cataract surgery

2. Treatment of post operative pain and inflammation associated with cataract surgery

   Authorised indications:

   Prevention and treatment of post operative pain and inflammation associated with cataract surgery

3. Prevention of post surgical macular oedema

   Authorised indication:

   None

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/07/433/001	Nevanac	1 mg/ml	Eye drops, suspension	Ocular use	bottle (LDPE/LDPE)	5 ml	1 x 5 ml