European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 15 May 2009

on the granting of a product specific waiver for bromfenac sodium sesquihydrate (EMEA-000269-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 Croma Pharma GmbH on 1 May 2008 under Article 13 of Regulation (EC) No 1901/2006 as amended,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 30 April 2009 in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee has given, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) of Regulation (EC) No 1901/2006 as amended 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 bromfenac sodium sesquihydrate, eye drops, solution, 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 Croma Pharma GmbH, Stockerauerstrasse 181, 2100 – Korneuburg, Austria.

Done at London, 15 May 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/267259/2009
EMEA-000269-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE GRANTING OF A PRODUCT SPECIFIC WAIVER (AFTER RE-EXAMINATION)

Scope of the application

Active substance(s):
Bromfenac sodium sesquihydrate

Condition(s):
Postoperative ocular inflammation

Pharmaceutical form(s):
Eye drops, solution

Route(s) of administration:
Ocular use

Name/corporate name of the waiver applicant:
Croma Pharma GmbH

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Croma Pharma GmbH submitted for agreement to the EMEA on 1 May 2008 an application for a product-specific waiver on the grounds set out in Article 11(1) of said Regulation for the above mentioned medicinal product.

An Opinion was adopted by the Paediatric Committee on 6 March 2009, recommending the refusal of a waiver for all subsets of the paediatric population and the above mentioned condition(s) for the above mentioned product. Croma Pharma GmbH received the Paediatric Committee Opinion on 11 March 2009.

Croma Pharma GmbH submitted written notice including detailed grounds to the EMEA on 7 April 2009 to request a re-examination of the Opinion.

The re-examination procedure started on 8 April 2009.

A meeting with the Paediatric Committee took place on 29 April 2009.

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Final Opinion

The Paediatric Committee, having assessed the detailed grounds for re-examination request in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, revises its opinion and 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 Agency, together with its annex and appendix.

London, 30 April 2009

On behalf of the Paediatric Committee,
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

GROUNDS FOR THE GRANTING OF THE WAIVER

GROUNDS FOR THE GRANTING OF THE WAIVER

The waiver applies to:

- **Condition**

Postoperative ocular inflammation

Paediatric subsets:

All subsets of the paediatric population from birth to less than 18 of age for

eye drops, solution for ocular use

on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.