European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 19 September 2008

on the application for product specific waiver for naproxen, esomeprazole magnesium trihydrate, EMEA-000268-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 AstraZeneca AB on 22 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 29 August 2008 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 a positive opinion,

(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 naproxen, esomeprazole magnesium trihydrate, tablet, oral the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 2

This decision is addressed to AstraZeneca AB, S-15185 Sodertalje, Sweden.

Done at London, 19 September 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

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

EMEA/PDCO/445230/2008
EMEA-000268-PIP01-08

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A PRODUCT-SPECIFIC WAIVER FOR

Scope of the application

Active substance:
Naproxen, esomeprazole magnesium trihydrate

Condition(s):
Rheumatoid arthritis;
Primary generalised osteoarthritis;
Ankylosing spondylitis

Pharmaceutical form(s):
Tablet

Route(s) of administration:
Oral

Name/corporate name of the waiver applicant:
AstraZeneca AB

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted for agreement to the EMEA on 22 May 2008 an application for a waiver on the grounds set out in Article 11 of Regulation (EC) No 1901/2006 as amended for the above mentioned medicinal product.

The procedure started on 1 July 2008.

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Opinion
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 waiver for all subsets of the paediatric population and all above mentioned conditions in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, 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.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its appendix.

London, 29 August 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)