EMA/202139/2010

European Medicines Agency decision

P/59/2010

of 29 March 2010

on the granting of a product specific waiver for esomeprazole magnesium/acetylsalisylic acid (EMEA-000682-PIP01-09) 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 AstraZeneca AB on 14 July 2009 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 19 March 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, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) of Regulation (EC) No 1901/2006, 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 Esomeprazole magnesium/acetylsalisylic acid, capsule, 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 AstraZeneca AB, S-151 85 Södertälje, Sweden.

Done at London, 29 March 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/177942/2010

Opinion of the Paediatric Committee on the granting of a product specific waiver (after re-examination)

EMEA-000682-PIP01-09

Scope of the application

Active substance(s):

Esomeprazole magnesium/acetylsalisylic acid

Condition(s):

Gastric Ulcer

Duodenal Ulcer

Pharmaceutical form(s):

Capsule

Route(s) of administration:

Oral use

Name/corporate name of the PIP 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 European Medicines Agency on 14 July 2009 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 15 January 2010, recommending the refusal of a waiver for all subsets of the paediatric population and all the above mentioned condition(s) for the above mentioned product. AstraZeneca AB received the Paediatric Committee Opinion on 19 January 2010.

AstraZeneca AB submitted written notice including detailed grounds to the European Medicines Agency on 17 February 2010 to request a re-examination of the Opinion.

The re-examination procedure started on 18 February 2010.

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Final Opinion

1. 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 all 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 Norwegian Paediatric Committee member agrees 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(s) and the Executive Director of the European Medicines Agency, together with its annex and appendix.

London, 19 March 2010

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

(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Grounds for the granting of the waiver

1.1. Condition

Gastric ulcer

Duodenal ulcer

The waiver applies to:

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

for capsule, oral use

on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.