EMA/195552/2014

European Medicines Agency decision

P/0121/2014

of 7 May 2014

on the granting of a product specific waiver for amlodipine / rosuvastatin (EMEA-001578-PIP01-13) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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 Krka, d.d., Novo mesto on 12 December 2013 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 21 March 2014 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 amlodipine / rosuvastatin, film-coated tablet, 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 Krka, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, 8501 - Novo mesto, Slovenia.

Done at London, 7 May 2014

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

EMA/PDCO/94701/2014

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

EMEA-001578-PIP01-13

Scope of the application

Active substance(s):

Amlodipine / rosuvastatin

Condition(s):

Treatment of dyslipidaemia

Treatment of hypertension

Treatment of ischemic coronary artery disorders

Prevention of cardiovascular events

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Krka, d.d., Novo mesto

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Krka, d.d., Novo mesto submitted to the European Medicines Agency on 12 December 2013 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 21 January 2014.

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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 all the above mentioned conditions 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, 21 March 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition: treatment of dyslipidaemia

The waiver applies to:

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

1.2. Condition: treatment of hypertension

The waiver applies to:

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

1.3. Condition: treatment of ischemic coronary artery disorders

The waiver applies to:

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

1.4. Condition: prevention of cardiovascular events

The waiver applies to:

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