EMA/259616/2014

European Medicines Agency decision

P/0157/2014

of 18 June 2014

on the granting of a product specific waiver for clarithromycin (in combination with amoxicillin + metronidazole + pantoprazole), (EMEA-001614-PIP01-13) 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 Mayoly-Spindler on 13 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 25 April 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 clarithromycin (in combination with amoxicillin + metronidazole + pantoprazole), orodispersible tablet, film-coated tablet, gastro-resistant tablet, 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 agreed PIP covers all conditions, indications, pharmaceutical forms, routes of administration for the combination of active substances, as agreed in the decision P/0156/2014 issued on 18 June 2014, the decision P/0158/2014 issued on 18 June 2014, and the decision P/0159/2014 issued on 18 June 2014 including subsequent modifications thereof.

Article 3

This decision is addressed to Mayoly-Spindler, 6 avenue de l'Europe, 78401 – Chatou, France

Done at London, 18 June 2014

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

EMA/PDCO/254728/2014 Corr

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

EMEA-001614-PIP01-13

Scope of the application

Active substance(s):

Clarithromycin (in combination with amoxicillin + metronidazole + pantoprazole)

Condition(s):

Treatment of *Helicobacter spp.* infections

Pharmaceutical form(s):

Orodispersible tablet

Film-coated tablet

Gastro-resistant tablet

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Mayoly-Spindler

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Mayoly-Spindler submitted to the European Medicines Agency on 13 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 used in combination.

The procedure started on 26 February 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 the above mentioned condition(s) in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product used in combination 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 and the Executive Director of the European Medicines Agency, together with its annex and appendix.

London, 25 April 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 Helicobacter spp. infections

The waiver applies to:

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