EMA/642067/2014

European Medicines Agency decision

P/0308/2014

of 24 November 2014

on the granting of a product specific waiver for macrogol 3350 (EMEA-001668-PIP01-14) 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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An agency of the European Union

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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 7 July 2014 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 10 October 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 macrogol 3350, oral powder, 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 MAYOLY SPINDLER, 6 avenue de l'europe BP 51, 78401 - CHATOU Cedex, France.

Done at London, 24 November 2014

For the European Medicines Agency
Zaide Frias
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/481207/2014

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

EMEA-001668-PIP01-14

Scope of the application

Active substance(s):

Macrogol 3350

Condition(s):

Treatment of constipation

Pharmaceutical form(s):

Oral powder

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 7 July 2014 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 13 August 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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population, 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, 10 October 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 constipation

The waiver applies to:

- the paediatric population from birth to less than 2 months;
- oral powder, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s);

  and to:

- the paediatric population from 2 months to less than 2 years;
- oral powder, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible;

  and to:

- the paediatric population from 2 years to less than 18 years;
- oral powder, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.