



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/104847/2016

European Medicines Agency decision

P/0089/2016

of 22 March 2016

on the granting of a product specific waiver for azithromycin / miconazole / sulfamethoxazole (EMEA-001769-PIP01-15) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Lukács és Társa Gyógyszerkereskedelmi Bt. on 4 June 2015 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 29 January 2016 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 azithromycin / miconazole / sulfamethoxazole, ointment, topical 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 Lukács és Társa Gyógyszerkereskedelmi Bt., Mártírok u. 53., 8725 - Iharosberény, Hungary.

Done at London, 22 March 2016

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

EMA/PDCO/747440/2015
London, 29 January 2016

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

EMA-001769-PIP01-15

Scope of the application

Active substance(s):

Azithromycin / Miconazole / Sulfamethoxazole

Condition(s):

Treatment of burns

Pharmaceutical form(s):

Ointment

Route(s) of administration:

Topical use

Name / corporate name of the PIP applicant:

Lukács és Társa Gyógyszerkereskedelmi Bt.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Lukács és Társa Gyógyszerkereskedelmi Bt. submitted for agreement to the European Medicines Agency on 4 June 2015 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 14 July 2015.

Supplementary information was provided by the applicant on 4 November 2015

The applicant withdrew its proposed paediatric investigation plan and requested a product-specific waiver.

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 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 and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition

Treatment of burns

The waiver applies to:

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