



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/513787/2011

European Medicines Agency decision P/166/2011

of 6 July 2011

on the granting of a product specific waiver for ciclosporin (EMEA-001007-PIP01-10) 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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on the granting of a product specific waiver for ciclosporin (EMEA-001007-PIP01-10) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 Allergan Pharmaceuticals Ireland on 07 June 2010 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 20 May 2011 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 ciclosporin, eye drops, solution, ocular 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 Allergan Pharmaceuticals Ireland, Castlebar Road, County Mayo, Westport, Ireland.

Done at London, 6 July 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)



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EMA/PDCO/259165/2011

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

EMA-001007-PIP01-10

Scope of the application

Active substance(s):

Ciclosporin

Condition(s):

Treatment of atopic keratoconjunctivitis

Pharmaceutical form(s):

Eye drops, solution

Route(s) of administration:

Ocular use

Name/corporate name of the PIP applicant:

Allergan Pharmaceuticals Ireland

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Allergan Pharmaceuticals Ireland submitted for agreement to the European Medicines Agency on 07 June 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 15 July 2010.

Supplementary information was provided by the applicant on 3 March 2011. The applicant withdrew its proposed paediatric investigation plan and requested a waiver for all subsets of the paediatric population.



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, and 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, 20 May 2011

(Signature on file)

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition: Treatment of atopic keratoconjunctivitis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 4 years of age;
- for eye drops (solution), ocular use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets.

The waiver applies to:

- All subsets of the paediatric population from 4 years to less than 18 years of age;
- for eye drops (solution), ocular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.