EMA/329833/2012

European Medicines Agency decision

P/0089/2012

of 29 May 2012

on the granting of a product specific waiver for bimatoprost (Lumigan), (EMEA-000917-PIP02-11) 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 Allergan Pharmaceuticals Ireland on 6 January 2012 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 13 April 2012 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 bimatoprost (Lumigan), cutaneous solution, cutaneous 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as granted in the decision P/56/2011 issued on 4 March 2011, including subsequent modifications thereof.

Article 3

This decision is addressed to Allergan Pharmaceuticals Ireland, Castlebar Road, County Mayo, Westport, United Kingdom.

Done at London, 29 May 2012

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

EMA/329833/2012

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

EMEA-000917-PIP02-11

Scope of the application

Active substance(s):

Bimatoprost

Invented name:

Lumigan

Condition(s):

Treatment of androgenic alopecia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Cutaneous solution

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Allergan Pharmaceuticals Ireland

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Allergan Pharmaceuticals Ireland submitted to the European Medicines Agency on 6 January 2012 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 15 February 2012.

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 for 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, 13 April 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition: Treatment of androgenic alopecia

The waiver applies to:

- Pre-pubertal children and post-menarcheal girls;
- for cutaneous solution, cutaneous 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.

And to:

- Post-pubertal boys;
- for cutaneous solution, cutaneous use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of glaucoma

   Authorised indications:

   Reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults (as monotherapy or as adjunctive therapy to beta-blockers).

EU Number	Invented name	Strength	Pharmaceutical Form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/02/205/001	Lumigan	0.3 mg/ml	Eye Drops, solution	Ocular use	Bottle (LDPE)	3 ml	1 bottle
EU/1/02/205/002	Lumigan	0.3 mg/ml	Eye Drops, solution	Ocular use	Bottle (LDPE)	3 ml	3 bottles
EU/1/02/205/003	Lumigan	0.1 mg/ml	Eye Drops, solution	Ocular use	Bottle (LDPE)	3 ml	1 bottle
EU/1/02/205/004	Lumigan	0.1 mg/ml	Eye Drops, solution	Ocular use	Bottle (LDPE)	3 ml	3 bottles