EMA/624333/2014

European Medicines Agency decision

P/0293/2014

of 30 October 2014

on the acceptance of a modification of an agreed paediatric investigation plan for bimatoprost (Lumigan and associated names) (EMEA-000917-PIP01-10-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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European Medicines Agency decision

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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 European Medicines Agency's decision P/56/2011 issued on 4 March 2011, the decision P/0125/2012 issued on 4 July 2012, the decision P/0065/2013 issued on 26 March 2013 and the decision P/0076/2014 issued on 2 April 2014,

Having regard to the application submitted by Allergan Pharmaceuticals Ireland on 23 June 2014 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 September 2014, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral and to the waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral and the 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

Changes to the agreed paediatric investigation plan for bimatoprost (Lumigan and associated names), eye drops, solution, cutaneous solution, ophthalmic insert, ocular use, cutaneous use, intraocular use, including changes to the deferral, and the waiver, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

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

Done at London, 30 October 2014

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

EMA/PDCO/428771/2014

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-000917-PIP01-10-M04

Scope of the application

Active substance(s):

Bimatoprost

Invented name:

Lumigan and associated names

Condition(s):

Treatment of glaucoma

Treatment of non-scarring hair loss

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Eye drops, solution

Cutaneous solution

Ophthalmic Insert

Route(s) of administration:

Ocular use

Cutaneous use

Intraocular use

Name/corporate name of the PIP applicant:

Allergan Pharmaceuticals Ireland

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Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Allergan Pharmaceuticals Ireland submitted to the European Medicines Agency on 23 June 2014 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/56/2011 issued on 4 March 2011, the decision P/0125/2012 issued on 4 July 2012, the decision P/0065/2013 issued on 26 March 2013 and the decision P/0076/2014 issued on 2 April 2014.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and changes to the waiver to cover the remaining subsets of the paediatric population.

The procedure started on 16 July 2014.

Scope of the modification

A waiver has been extended to cover all paediatric subsets.

Opinion

The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree to changes to the paediatric investigation plan and to the deferral and to amend the scope of the waiver 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, set out in the Annex I of the opinion.

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

London, 12 September 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition

Treatment of glaucoma

The waiver applies to:

- the paediatric population from birth to less than 18 years of age;
- for solution for ocular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for ophthalmic insert for intraocular use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

1.2. Condition

Treatment of non-scarring hair loss

The waiver applies to:

- the paediatric population from birth to less than 18 years of age;
- for solution for cutaneous use and for eye drops, solution for ocular use and for ophthalmic insert for intraocular 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).

Authorised pharmaceutical form(s):

Eye drops, solution

Authorised route(s) of administration:

Ocular use