



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/113584/2014

European Medicines Agency decision

P/0076/2014

of 2 April 2014

on the acceptance of a modification of an agreed paediatric investigation plan for bimatoprost (Lumigan and associated names), (EMA-000917-PIP01-10-M03) 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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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 European Medicines Agency's decision P/56/2011 issued on 4 March 2011, the decision P/0125/2012 issued on 4 July 2012, and the decision P/0065/2013 issued on 26 March 2013,

Having regard to the application submitted by Allergan Pharmaceuticals Ireland on 20 November 2013 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 14 February 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 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 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 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, 2 April 2014

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



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EMA/PDCO/731290/2013

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMA-000917-PIP01-10-M03

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

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 20 November 2013 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, and the decision P/0065/2013 issued on 26 March 2013.

The application for modification proposed changes to the agreed paediatric investigation plan and to the waiver.

The procedure started on 18 December 2013.

Scope of the modification

The scope of the waiver was modified.

Opinion

1. 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 waiver in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

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

London, 14 February 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

1. Waiver

1.1. Condition: treatment of glaucoma

The waiver applies to:

- the paediatric population from birth to less than 2 months of age;
- for solution for ocular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

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.

2. Paediatric Investigation Plan

2.1. Condition: treatment of glaucoma

2.1.1. Indication(s) targeted by the PIP

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 2 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for ocular use.

2.1.4. Studies

Area	Number of studies	Description
Quality related studies		Not applicable.
Non-clinical studies		Not applicable.
Clinical studies	1	Study 1 Identifier 192024-056 Randomised, parallel group, multicentre, active controlled, double masked non-inferiority trial to evaluate efficacy of bimatoprost 0.03% preservative-free ophthalmic solution compared to timolol.

The date of completion of the paediatric investigation plan corresponds to the timeline for completion of the latest measure(s) reported below.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By October 2015
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

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