EMA/78091/2011

European Medicines Agency decision

P/56/2011

of 4 March 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for bimatoprost (LUMIGAN 0.1 mg/ml eye drops, solution, LUMIGAN 0.3 mg/ml eye drops, solution) (EMEA-000917-PIP01-10) 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 726/2004[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 12 April 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 January 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) 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 paediatric investigation plan for bimatoprost (LUMIGAN 0.1 mg/ml eye drops, solution, LUMIGAN 0.3 mg/ml eye drops, solution), eye drops, cutaneous solution, ocular use, 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 agreed.

Article 2

A deferral for bimatoprost (LUMIGAN 0.1 mg/ml eye drops, solution, LUMIGAN 0.3 mg/ml eye drops, solution), eye drops, cutaneous solution, ocular use, 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 3

A waiver for bimatoprost (LUMIGAN 0.1 mg/ml eye drops, solution, LUMIGAN 0.3 mg/ml eye drops, solution), eye drops, cutaneous solution, ocular use, 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 4

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

Done at London, 4 March 2011

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

EMA/PDCO/711020/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-000917-PIP01-10

Scope of the application

Active substance(s):

Bimatoprost

Invented name:

LUMIGAN 0.1 mg/ml eye drops, solution

LUMIGAN 0.3 mg/ml eye drops, solution

Condition(s):

Treatment of glaucoma

Treatment of non-scarring hair loss

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Eye drops

Cutaneous solution

Route(s) of administration:

Ocular use

Cutaneous 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 16(1) of Regulation (EC) No 1901/2006 as amended, Allergan Pharmaceuticals Ireland submitted for agreement to the European Medicines Agency on 12 April 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 20 May 2010.

Supplementary information was provided by the applicant on 8 November 2010. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation,
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded 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 measures and timelines of the agreed paediatric investigation plan and the subsets of the paediatric population and conditions 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 annex(es) and appendix.

London, 14 January 2011

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

Annex I

The subsets of the paediatric population and conditions 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.

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
- 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		Not applicable.
Non-clinical		Not applicable.
Clinical	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.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By November 2014
Deferral for one or more studies 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:

   Treatment of elevated intraocular pressure in patients with 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