EMA/647635/2013

# European Medicines Agency decision

P/0298/2013

of 29 November 2013

on the acceptance of a modification of an agreed paediatric investigation plan for travoprost (Travatan) (EMEA-001271-PIP01-12-M01) 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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An agency of the European Union

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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/0267/2012 issued on 20 November 2012,

Having regard to the application submitted by Alcon Laboratories (UK) Ltd. on 22 July 2013 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 October 2013, 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.

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

[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 travoprost (Travatan), eye drops, solution, ocular use, 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 Alcon Laboratories (UK) Ltd., Park View, Riverside Way, GU15 3YL – Camberley, United Kingdom.

Done at London, 29 November 2013

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

EMA/PDCO/450608/2013

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

EMEA-001271-PIP01-12-M01

## Scope of the application

**Active substance(s):**

Travoprost

**Invented name:**

Travatan

**Condition(s):**

Treatment of glaucoma

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Eye drops, solution

**Route(s) of administration:**

Ocular use

**Name/corporate name of the PIP applicant:**

Alcon Laboratories (UK) Ltd.

**Information about the authorised medicinal product:**

See Annex II

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## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Alcon Laboratories (UK) Ltd. submitted to the European Medicines Agency on 22 July 2013 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0267/2012 issued on 20 November 2012.

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

The procedure started on 15 August 2013.

## Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been 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 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, 11 October 2013

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 eye drops, solution, ocular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

# 2. Paediatric Investigation Plan

## *2.1. Condition: Treatment of glaucoma*

### 2.1.1. Indication(s) targeted by the PIP

Treatment of elevated intraocular pressure (IOP) in patients with open-angle glaucoma.

### 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)

Eye drops, solution, ocular use.

### 2.1.4. Studies

| Area | Number of studies | Description |
|---|---|---|
| Quality | 0 | Not applicable. |
| Non-clinical | 0 | Not applicable. |
| Clinical | 2 | **Study 1:** An Open-Label, PK and safety study of travoprost eye drops solution in paediatric population.<br>**Study 2:** 12-week, randomized double-masked, safety and efficacy study of travoprost eye drops compared to timolol in paediatric patients with glaucoma. |

## 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Concerns on potential long term safety and efficacy issues in relation to paediatric use: | No. |
| Date of completion of the paediatric investigation plan: | By April 2014. |
| Deferral for one or more studies contained in the paediatric investigation plan: | No. |

# Annex II

# Information about the authorised medicinal product

## Condition(s) and authorised indication(s):

1. Treatment of glaucoma

   Authorised indication(s):

   - Decrease of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma

## Authorised pharmaceutical form(s):

Eye drops, solution

## Authorised route(s) of administration:

Ocular use