EMA/380528/2016

European Medicines Agency decision

P/0159/2016

of 15 June 2016

on the refusal of a modification of an agreed paediatric investigation plan for tafluprost (Taflotan and associated names) (EMEA-001187-PIP01-11-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 726/2004[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/0132/2012 issued on 4 July 2012, the decision P/0174/2014 issued on 11 July 2014 and the decision P/0216/2015 issued on 2 October 2015,

Having regard to the application submitted by Santen Oy on 3 February 2016 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 29 April 2016, 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 refusal of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the refusal 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 tafluprost (Taflotan and associated names), eye drops, solution, ocular 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, are hereby refused.

Article 2

This decision is addressed to Santen Oy, Niittyhaankatu 20, 33720 – Tampere, Finland.

Done at London, 15 June 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/287960/2016 corr
London, 29 April 2016

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

EMEA-001187-PIP01-11-M03

Scope of the application

Active substance(s):

Tafluprost

Invented name:

Taflotan and associated names

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:

Santen Oy

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Santen Oy submitted to the European Medicines Agency on 3 February 2016 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0132/2012

issued on 4 July 2012, the decision P/0174/2014 issued on 11 July 2014 and the decision P/0216/2015 issued on 2 October 2015.

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

The procedure started on 29 March 2016.

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 refuse the changes proposed by the applicant regarding the paediatric investigation plan.

   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 subset(s) of the paediatric population and condition(s) covered by the waiver remain unchanged and are set out in the Annex I.

3. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

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

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

Condition: treatment of glaucoma

The waiver applies to:

- the paediatric population from birth to less than 1 month of age;
- eye drops, solution, ocular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies 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 in paediatric patients 1 month post-natal to less than18 years of age.

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

From 1 month to less than 18 years of age.

2.2. Pharmaceutical form(s)

Eye drops, solution.

2.3. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Development of lower strength.
Non-clinical studies	0	Not applicable.
Clinical studies	2	Study 2 Open-label PK and safety/tolerability study of tafluprost in paediatric patients with glaucoma or ocular hypertension. Study 3 12-week, double-blinded, parallel-group study assessing the safety and efficacy of tafluprost versus timolol in paediatric patients with glaucoma or ocular hypertension.

Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2017
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

Treatment of glaucoma

Authorised indication(s):

Reduction of elevated intraocular pressure in open angle glaucoma and ocular hypertension as monotherapy in patients:

- who would benefit from preservative free eye drops
- insufficiently responsive to first line therapy
- intolerant or contra-indicated to first line therapy

As adjunctive therapy to beta-blockers.

Authorised pharmaceutical form(s):

Eye drops, solution in single-dose container

Eye drops, solution

Authorised route(s) of administration:

Ocular use