EMA/314400/2014

European Medicines Agency decision

P/0174/2014

of 11 July 2014

on the acceptance of a modification of an agreed paediatric investigation plan for tafluprost (Taflotan and associated names), (EMEA-001187-PIP01-11-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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on the acceptance of a modification of an agreed paediatric investigation plan for tafluprost (Taflotan and associated names), (EMEA-001187-PIP01-11-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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,

Having regard to the application submitted by Merck Sharp & Dohme (Europe), Inc. on 2 March 2014 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 23 May 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.

(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 tafluprost (Taflotan and associated names), 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 Merck Sharp & Dohme (Europe), Inc., 5 Clos du Lynx, Lynx Binnenhof 5, B-1200 – Brussels, Belgium.

Done at London, 11 July 2014

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

EMA/PDCO/130592/2014

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

EMEA-001187-PIP01-11-M01

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:

Merck Sharp & Dohme (Europe), Inc.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe), Inc. submitted to the European Medicines Agency on 2 March 2014 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.

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

The procedure started on 25 March 2014.

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 Icelandic and the Norwegian Paediatric Committee members agree 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, 23 May 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 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.

2.1.3. Pharmaceutical form(s)

Eye drops, solution.

2.1.4. 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):

1. 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