EMA/414428/2012

European Medicines Agency decision

P/0132/2012

of 4 July 2012

on the agreement of a paediatric investigation plan and on the granting of a waiver for tafluprost (Taflotan and associated names), (EMEA-001187-PIP01-11) 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 Merck Sharp & Dohme (Europe), Inc. on 11 July 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 May 2012, in accordance with Article 18 of Regulation (EC) No 1901/2006, 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 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 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 tafluprost (Taflotan and associated names), eye drops, solution, Eye drops, solution in single-dose container, 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, is hereby agreed.

Article 2

A waiver for tafluprost (Taflotan and associated names), eye drops, solution, Eye drops, solution in single-dose container, 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, is hereby granted.

Article 3

This decision is addressed to Merck Sharp & Dohme (Europe), Inc., 5 Clos du Lynx / Lynx Binnenhof 5, 1200 – Brussels, Belgium.

Done at London, 4 July 2012

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

EMA/414428/2012

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

EMEA-001187-PIP01-11

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

Eye drops, solution in single-dose container

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

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe), Inc. submitted for agreement to the European Medicines Agency on 11 July 2011 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 16 August 2011.

Supplementary information was provided by the applicant on 27 February 2012 and on 7 May 2012. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a deferral.

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 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 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 annex(es) and appendix.

London, 16 May 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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,
- for solution for 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

Tafluprost preservative-free is indicated for the treatment of elevated intraocular pressure in paediatric patients 1 month post-natal to less 18 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, single-dose container.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1: Development of lower strength.
Non-clinical	0	Not applicable.
Clinical	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.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	No.
Date of completion of the paediatric investigation plan:	By September 2017.
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 indications: 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.

Invented name	**Strength**	**Pharmaceutical form**	**Route of administration**
Taflotan and associated names	15 µg/ml	Eye drops, solution in single-dose container Eye drops, solution	Ocular use