European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 23 December 2008

on the refusal of a Paediatric Investigation Plan and on the refusal of a deferral and on the granting of a waiver for travoprost / brinzolamide (EMEA-000368-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 Alcon Laboratories (UK) Limited on 21 August 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 November 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency, has given an opinion on the refusal of a Paediatric Investigation Plan and on the refusal of a deferral and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision refusing a Paediatric Investigation Plan,

(3) It is therefore appropriate to adopt a Decision refusing 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 travoprost / brinzolamide, suspension, eye drops, 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 refused.

Article 2

A deferral for travoprost / brinzolamide, suspension, eye drops, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby refused.

Article 3

A waiver for travoprost / brinzolamide, suspension, eye drops, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Alcon Laboratories (UK) Limited, Pentagon Park, Boundary Way, Hemel Hempstead, Herts, HP2 7UD, United Kingdom

Done at London, 23 December 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

EMEA/PDCO/608859/2008
EMEA-000368-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE REFUSAL OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND ON THE GRANTING OF A PRODUCT-SPECIFIC WAIVER

Scope of the application

Active substance:
Travoprost / Brinzolamide

Condition(s):
Ocular hypertension
Glaucoma

Pharmaceutical form(s):
Suspension

Route(s) of administration:
Eye drops

Name/corporate name of the PIP applicant:
Alcon Laboratories (UK) Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Alcon Laboratories (UK) Limited submitted for agreement to the EMEA on 21 August 2008 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 25 September 2008.

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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 refuse the paediatric investigation plan in accordance with Article 18 of said Regulation as the measures and the timelines are not appropriate to ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or some subsets, nor to adapt a paediatric formulation or does not bring expected significant therapeutic benefit,

- to refuse a deferral in accordance with Article 21 of said Regulation,

- to grant a product-specific waiver for all 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 Icelandic and the Norwegian Paediatric Committee members do agree with the above-mentioned recommendation of the Paediatric Committee.

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

London, 14 November 2008

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