European Medicines Agency

Doc. Ref. EMEA/688850/2009
P/220/2009

EUROPEAN MEDICINES AGENCY DECISION

of 3 November 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for latanoprost (Xalatan and associated names) (EMEA-000011-PIP01-07-M03) 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 decision P/169/2009 of the European Medicines Agency on 12 August 2009,

Having regard to the application submitted by Pfizer Global Research & Development on 6 August 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 September 2009, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

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 acceptance of changes to an agreed Paediatric Investigation,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an 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 latanoprost (Xalatan 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 accepted.

Article 2,

This decision, that supersedes previous decision of the European Medicines Agency P/169/2009, is addressed to Pfizer Global Research & Development, CT13 9NJ Sandwich, United Kingdom.

Done at London, 3 November 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

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

Doc. Ref. EMEA/PDCO/582485/2009
EMEA-000011-PIP01-07-M03

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
Latanoprost

(Invented) name:
Xalatan and associated names

Condition(s):
Glaucoma

Pharmaceutical form(s):
Eye drops, solution

Route(s) of administration:
Ocular use

Name/corporate name of the PIP applicant:
Pfizer Global Research & Development

Information about the authorised medicinal product: see Annex II
See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Global Research & Development submitted to the EMEA on 6 August 2009 an application for modification of the agreed paediatric investigation plan as set out in the EMEA decision P/162/2009 of 12 August 2009. The application for modification proposed changes.

The procedure started on 20 August 2009.

Scope of the modification

The modification concerned the design of measures to address long term follow-up of potential safety issues in relation to paediatric use.

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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 the changes proposed by the applicant regarding the measures of the paediatric investigation plan,

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 are set out in the Annex I.

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

London, 18 September 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN

A. CONDITION(S)

Glaucoma

B. WAIVER

Not applicable.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Glaucoma

- **Proposed PIP indication**

Reduction of elevated intraocular pressure in the treatment of paediatric glaucoma

- **Subset(s) of the paediatric population concerned by the paediatric development**

From birth to less than 18 years.

- **Formulation(s)**

Eye drops, solution; ocular use (no development in addition to the authorised formulation)

- **Studies**

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	Open-label, multiple dose trial to evaluate safety and pharmacokinetics of latanoprost in children from birth to less than 18 years of age. Randomised, double-blind, active-controlled (timolol), parallel-group, multi-centre trial to evaluate safety and efficacy of latanoprost in children from birth to less than 18 years of age.

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By December 2009**
Deferral for some or all studies contained in the paediatric investigation plan:	**No**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

Invented name Name	**Strength**	**Pharmaceutical Form**	**Route of administration**
Xalatan	0.5 mg or 0.005%	Eye drops, Solution	Ocular use