



European Medicines Agency

Doc. Ref. EMEA/313699/2008
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EUROPEAN MEDICINES AGENCY DECISION

of 24 June 2008

**on the application for product specific waiver for dutasteride, tamsulosin hydrochloride
(EMEA-000216-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)

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Parliament and of the Council as amended**

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 726/2004¹;

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 Agency²;

Having regard to the application submitted by Glaxo Group Ltd. on 4 March 2008 under Article 13 of Regulation (EC) No 1901/2006 as amended;

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 May 2008 in accordance with Article 13 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 has given a positive opinion,
- (2) 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 waiver for dutasteride, tamsulosin hydrochloride, capsule, oral use, 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 2

This decision is addressed to Glaxo Group Ltd, GlaxoWellcome House, Berkley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom.

Done at London, 24 June 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



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

EMA/313699/2008
EMA-000216-PIP01-08

**POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON
A PRODUCT-SPECIFIC WAIVER FOR**

Scope of the application

Active substance:

Dutasteride, tamsulosin hydrochloride

Condition:

Benign prostatic hyperplasia

Pharmaceutical form:

Capsules

Route of administration:

Oral use

Name/corporate name of the waiver applicant:

Glaxo Group Ltd.

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Glaxo Group Ltd. submitted for agreement to the EMA on 4 March 2008 an application for a waiver on the grounds set out in Article 11 of Regulation (EC) No 1901/2006 as amended for the above mentioned medicinal product.

The procedure started on 10 April 2008.

Opinion

The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends, as set out in the appended summary report, to grant a waiver for all subsets of the paediatric population and in the above mentioned condition in accordance with Article 11(1)(b) of Regulation (EC) No 1901/2006 as amended, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

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, 8 May 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)