European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 7 January 2008

on the application for product-specific waiver for Lasofoxifene tartrate EMEA-000039-PIP01-2007 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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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 for a waiver submitted by Pfizer Limited on 24 August 2007 under Article 13 of Regulation (EC) No 1901/2006 as amended,

Having regard to the opinion of the Paediatric Committee of the European Medicines [s1]Agency, formulated on 23 November 2007 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. [s2]

HAS ADOPTED THIS DECISION:

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

Article 1

A waiver for Lasofoxifene tartrate, film-coated tablets, oral use, for the treatment of osteoporosis in postmenopausal women at increased risk of fracture, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines **[s3]**Agency annexed hereto, together with its appendices, is hereby granted.

Article 2

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, CT13 9NJ.

Done at London, 7 January 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/602212/2007
EMEA-000039-PIP001-07

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

Scope of the application

Active substance:
Lasofoxifene tartrate

Condition(s):
Treatment of osteoporosis in postmenopausal women at increased risk of fracture

Pharmaceutical form(s):
Film-coated tablets

Route(s) of administration:
Oral use

Name/corporate name of the waiver applicant:
Pfizer Limited

Basis for opinion

Pursuant to Article 13(1) of Regulation (EC) No 1901/2006 of 12 December 2006, as amended, Pfizer Limited submitted for agreement to the EMEA on 24/08/2007 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 27/09/2007.

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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 all above mentioned conditions 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.

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

London, 23 November 2007

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

Signature: (On file)