European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 11 August 2009

on the granting of a product specific waiver for Mifepristone / Misoprostol (EMEA-000411-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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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 Sun Pharmaceutical Industries Europe B.V on 2 October 2009 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 26 June 2009 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 an opinion on the granting of a product specific waiver,

(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 Mifepristone / Misoprostol, tablets, oral use, vaginal 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 2

This decision is addressed to Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87, 2132 JH Hoofddorp, The Netherlands.

Done at London, 11 August 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/360332/2009
EMEA-000411-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE GRANTING OF A PRODUCT-SPECIFIC WAIVER

Scope of the application

Active substance(s):
Mifepristone / Misoprostol

Condition(s):
Medical Abortion

Pharmaceutical form(s):
Tablets

Route(s) of administration:
Oral use
Vaginal use

Name/corporate name of the waiver applicant:
Sun Pharmaceutical Industries Europe B.V.

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Sun Pharmaceutical Industries Europe B.V. submitted to the EMEA on 02 October 2008 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 13 November 2008.

Supplementary information was provided by the applicant on 06 April 2009.

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Opinion

1. 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 product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) in accordance with Article 11(1)(c) of said Regulation, on the grounds on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in some paediatric subsets, and 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 grounds for the granting of the waiver are set out in Annex I.

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

London, 26 June 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

GROUNDS FOR THE GRANTING OF THE WAIVER

GROUNDS FOR THE GRANTING OF THE WAIVER

- **Condition**

Medical abortion

The waiver applies to:

– Boys from birth to less than 18 years of age, and premenarcheal girls,
for tablets, oral use, vaginal use,
on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

– Adolescent girls from menarche to less than 18 years of age,
for tablets, oral use, vaginal use,
on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.