EMA/343648/2010

# European Medicines Agency decision

P/117/2010

of 7 July 2010

on the granting of a product specific waiver for diclofenac sodium / omeprazole (EMEA-000820-PIP01-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Only the English text is authentic.**

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# European Medicines Agency decision

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on the granting of a product specific waiver for diclofenac sodium / omeprazole

(EMEA-000820-PIP01-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

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 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 Temmler Werke GMBH on 12 February 2010 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 May 2010 in accordance with Article 13 of Regulation (EC) No 1901/2006,

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

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 diclofenac sodium / omeprazole, modified release capsule, oral 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 Temmler Werke GmbH, Weihenstephaner Strasse 28, D-81673 – Munich, Germany.

Done at London, 7 July 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/305095/2010

# Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-000820-PIP01-09

## Scope of the application

**Active substance(s):**

Diclofenac sodium / omeprazole

**Condition(s):**

Osteoarthritis

Ankylosing spondylitis

Rheumatoid arthritis

**Pharmaceutical form(s):**

Modified release capsule

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

Temmler Werke GMBH

## Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Temmler Werke GMBH submitted to the European Medicines Agency on 12 February 2010 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 23 March 2010.

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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 all the above mentioned condition(s) 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 Norwegian Paediatric Committee member(s) agree(s) 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 European Medicines Agency, together with its appendix.

London, 21 May 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

# Annex I

# Grounds for the granting of the waiver

# 1. GROUNDS FOR THE GRANTING OF THE WAIVER

## *1.1. Condition*

Osteoarthritis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age.
- For modified release capsule, oral use.
- On the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments, as both products are available separately, and paediatric patients with arthritic conditions benefit from a flexible therapy.

## *1.2. Condition*

Ankylosing spondylitis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age.
- For modified release capsule, oral use.
- On the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments, as both products are available separately, and paediatric patients with arthritic conditions benefit from a flexible therapy.

## *1.3. Condition*

Rheumatoid arthritis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age.
- For modified release capsule, oral use.
- On the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments, as both products are available separately, and paediatric patients with arthritic conditions benefit from a flexible therapy.