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EUROPEAN MEDICINES AGENCY DECISION

of 20 July 2008

on the application for product specific waiver for Epoetin theta (EMEA-000219-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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on the application for product specific waiver for Epoetin theta (EMEA-000219-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European 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 726/2004[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 Ratiopharm GmbH on 6 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 4 June 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 Epoetin theta, Solution for injection, Intravenous and Subcutaneous 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 Ratiopharm GmbH, Graf-Arco-Strasse 3, 89079 – Ulm, Germany.

Done at London, 20 July 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMEA/PDCO/295427/2008
EMEA-000219-PIP01-08

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

Scope of the application

Active substance:
Epoetin theta

Condition(s):
Anaemia

Pharmaceutical form(s):
Solution for injection

Route(s) of administration:
Intravenous use, Subcutaneous use

Name/corporate name of the waiver applicant:
Ratiopharm GmbH

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Ratiopharm GmbH submitted for agreement to the EMEA on 6 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.

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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, by a majority of votes, to grant a waiver for all subsets of the paediatric population and all above mentioned conditions in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, 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 agrees 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, 4 June 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)