EMA/663284/2010

European Medicines Agency decision

P/232/2010

of 23 November 2010

on the refusal of a product specific waiver for 4-hydroxy-n-(2-hydroxyethyl)-butyramide (EMEA-000764-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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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 Dr. Franz Köhler Chemie GmbH on 16 November 2009 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 8 October 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 refusal of a product specific waiver.

(2) It is therefore appropriate to adopt a decision refusing 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 4-hydroxy-n-(2-hydroxyethyl)-butyramide, solution for injection, solution for infusion, intravenous 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 refused.

Article 2

This decision is addressed to Dr. Franz Köhler Chemie GmbH, Werner-von-Siemens-Strasse 24 – 28, 64625 Bensheim, Germany.

Done at London, 23 November 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/615392/2010

Opinion of the Paediatric Committee on the refusal of a product-specific waiver

EMEA-000764-PIP01-09

Active substance(s):

4-hydroxy-n-(2-hydroxyethyl)-butyramide

Condition(s):

Sedation

Pharmaceutical form(s):

Solution for injection

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Dr. Franz Köhler Chemie GmbH

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Dr. Franz Köhler Chemie GmbH submitted to the European Medicines Agency on 16 November 2009 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.

Supplementary information was provided by the applicant(s) on 27 August 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 refuse the granting of a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) as it does not meet the grounds detailed in Article 11(1) of said Regulation.

   The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

3. The grounds for refusal are summarised in Annex I.

This opinion is forwarded to the applicant(s) and the Executive Director of the European Medicines Agency, together with its annex and appendix.

London, 8 October 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

Grounds for the refusal of the waiver

1. Waiver

The waiver is refused for the following:

1.1. Condition: Sedation

The request for the waiver applied to:

- all subsets of the paediatric population from birth to less than 18 years of age,
- for solution for injection and solution for infusion for intravenous use.

The waiver request does not provide evidence to support the following grounds set out in Article 11(1) of Regulation (EC) No 1901/2006 that:

(a) the specific medicinal product is likely to be ineffective or unsafe in the paediatric population;

(b) the disease or condition for which the specific medicinal product is intended occurs only in adult populations;

(c) the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients;

because:

the PDCO disagreed with the applicant(s)' argumentation that the specific MP is likely to be unsafe. Measures would be justified by the expected therapeutic benefit and clinical trials may be feasible. The specific medicinal product may represent a significant therapeutic benefit as the needs are not met.