European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 30 October 2009

on the refusal of a product specific waiver for chloroprocaine hydrochloride (EMEA-000639-PIP01-09) 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 Sintetica Italia S.r.l on 9 June 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 18 September 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 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 chloroprocaine hydrochloride, solution for injection, intrathecal 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 Sintetica Italia S.r.l, Piazza della Repubblica, 25, 20124 – Milan, Italy.

Done at London, 30 October 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/569166/2009
EMEA-000639-PIP01-09

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

Scope of the application

Active substance(s):
Chloroprocaine hydrochloride

Condition(s):
Intrathecal anaesthesia

Pharmaceutical form(s):
Solution for injection

Route(s) of administration:
Intrathecal use

Name/corporate name of the waiver applicant:
Sintetica Italia S.r.l

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Sintetica Italia S.r.l submitted to the EMEA on 9 June 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 July 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 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 and the Executive Director of the Agency, together with its annex and appendix.

London, 18 September 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I
GROUNDS FOR THE REFUSAL OF THE WAIVER

GROUNDS FOR THE REFUSAL OF THE WAIVER

The waiver is refused for the following:

- **Condition**

Intrathecal anaesthesia

The request for the waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age
- for solution for injection for intrathecal use

as 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 part or all of 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 ineffective or unsafe; the disease or condition for which the specific medicinal product is intended does occur in the paediatric population(s); and measures would be justified by the expected therapeutic benefit and clinical trials may be feasible.