



European Medicines Agency

Doc. Ref. EMEA/471376/2008  
P/79/2008

**EUROPEAN MEDICINES AGENCY DECISION**

**of 15 September 2007**

**on the application for product specific waiver for prilocaine, lidocaine  
(EMEA-000248-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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(EMEA-000248-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<sup>1</sup>,

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<sup>2</sup>,

Having regard to the application submitted by Plethora Solutions Limited on 28 May 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 29 August 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.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1

<sup>2</sup> OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

*Article 1*

A waiver for prilocaine, lidocaine, cutaneous spray, solution, cutaneous 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 Plethora Solutions Limited, 4th Floor, 233 High Holborn, London, WC1V 7DN, United Kingdom.

Done at London, 15 September 2008

For the European Medicines Agency  
Thomas Lönngren  
Executive Director

(Signature on file)



European Medicines Agency

EMA/PDCO/457529/2008  
EMA-000248-PIP01-08

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

**Scope of the application**

Active substance:

Prilocaine, Lidocaine

Condition(s):

Premature ejaculation

Pharmaceutical form(s):

Cutaneous spray, solution

Route(s) of administration:

Cutaneous use

Name/corporate name of the waiver applicant:

Plethora Solutions Limited

**Basis for opinion**

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Plethora Solutions Limited submitted for agreement to the EMA on 28 May 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 1 July 2008.

**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, 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 Icelandic and the Norwegian Paediatric Committee members agree 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(es).

London, 29 August 2008

On behalf of the Paediatric Committee  
Dr Daniel Basseur, Chairman

(Signature on file)