



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Doc. Ref. EMA/173479/2010
P/41/2010

EUROPEAN MEDICINES AGENCY DECISION

of 31 March 2010

**on the granting of a product specific waiver for tartaric acid
(EMA-000772-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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(EMA-000772-PIP01-09) 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 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 as amended and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004¹,

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 Agency²,

Having regard to the application submitted by Pneumoflex E.U. Limited on 16 November 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 19 February 2010 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 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 tartaric acid, nebuliser solution, inhalation 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 Pneumoflex E.U. Limited, 21 St. Thomas Street, BS1 6JS – Bristol, United Kingdom.

Done at London, 31 March 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 February 2010
EMA/173479/2010

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

EMA-000772-PIP01-09

Scope of the application

Active substance(s):

Tartaric acid

Condition(s):

Stress incontinence, female

Pharmaceutical form(s):

Nebuliser solution

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Pneumoflex E.U. Limited

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Pneumoflex E.U. Limited 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 December 2009.



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 the above mentioned condition(s) in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

The Icelandic and the Norwegian Paediatric Committee members agree 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 annex and appendix.

London, 19 February 2010

On behalf of the Paediatric Committee

Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

Grounds for the granting of the waiver

GROUNDINGS FOR THE GRANTING OF THE WAIVER

Condition

Stress incontinence, female

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age
- for Nebuliser solution, inhalation use
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).