European Medicines Agency

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P/256/09

EUROPEAN MEDICINES AGENCY DECISION

of 22 December 2009

on the granting of a product specific waiver for Nitric oxide (INOmax) (EMEA-000612-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 INO Therapeutics AB on 22 May 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 13 November 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 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 Nitric oxide (INOmax), inhalation gas, endotracheopulmonary 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 INO Therapeutics AB, Agavägen 1, SE-181 81 Lidingö, Sweden.

Done at London, 22 December 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/696166/2009
EMEA-000612-PIP01-09

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

Scope of the application

Active substance(s):
Nitric oxide

(Invented) name:
INOmax

Condition(s):
Persistent Pulmonary Hypertension
Other pulmonary heart disease

Pharmaceutical form(s):
Inhalation gas

Route(s) of administration:
Endotracheopulmonary use

Name/corporate name of the waiver applicant:
INO Therapeutics AB

Information about the authorised medicinal product:
See Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, INO Therapeutics AB submitted to the EMEA on 22 May 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 25 June 2009.

Supplementary information was provided by the applicant on 30 September 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, by a majority to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) in accordance with Articles 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population, Article 11(1)(c) of said Regulation, 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 do 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 Agency, together with its annex and appendix.

London, 13 November 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

GROUNDS FOR THE GRANTING OF THE WAIVER

GROUNDS FOR THE GRANTING OF THE WAIVER

- **Condition**

  Persistent Pulmonary Hypertension

  The waiver applies to:

  – infants and toddlers (from 28 days to less than 24 months), Children (from 2 to less than 12 years), Adolescents (from 12 to less than 18 years);

  – for inhaled Nitric Oxide;

  – 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).

  and to:

  – term newborn infants (from birth to less than 28 days);

  – for inhaled Nitric Oxide;

  – on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

- **Condition**

  Other Pulmonary Heart Disease

  The waiver applies to:

  – all paediatric subsets;

  – for inhaled Nitric Oxide;

  – on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of Administration**	**Packaging**	**Content (concentration)**	**Package size**
EU/1/01/194/001	INOmax	400 ppm	Inhalation gas	Endotracheopulmonary use	gas cylinder (aluminium)	10 l	
EU/1/01/194/002	INOmax	400 ppm	Inhalation gas	Endotracheopulmonary use	gas cylinder (aluminium)	2 l	