EMA/236423/2010

European Medicines Agency decision

P/78/2010

of 7 May 2010

on the granting of a product specific waiver for mometasone furoate (Nasonex and associated names) (EMEA-000351-PIP01-08) 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 Schering-Plough Research Institute on 26 June 2008 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 19 March 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 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 mometasone furoate (Nasonex and associated names), nasal spray, suspension, nasal 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 Schering-Plough Research Institute, 2015 Galloping Hill Road, Kenilworth, NJ 07033, United States.

Done at London, 7 May 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/122419/2010

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

EMEA-000351-PIP01-08

Scope of the application

Active substance(s):

Mometasone furoate

Invented name:

Nasonex and associated names

Condition(s):

Seasonal and perennial allergic rhinitis

Pharmaceutical form(s):

Nasal spray, suspension

Route(s) of administration:

Nasal use

Name/corporate name of the PIP applicant:

Schering-Plough Research Institute

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Schering-Plough Research Institute submitted to the European Medicines Agency on 26 June 2008 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.

Supplementary information was provided by the applicant on 21 December 2009.

A meeting with the Paediatric Committee took place on 18 March 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 grant a product-specific waiver for all subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded 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; and 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 Norwegian Paediatric Committee member agrees 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 annexes and appendix.

London, 19 March 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

Grounds for the granting of the waiver

1. GROUNDS FOR THE GRANTING OF THE WAIVER

1.1. Condition

Seasonal and perennial allergic rhinitis

The waiver applies to:

- Children from birth to less than 2 years
- for nasal spray, suspension for nasal 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).

The waiver applies to:

- Children and adolescents from 2 to less than 18 years
- for nasal spray, suspension for nasal use
- 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

Invented name **Name**	**Strength**	**Pharmaceutical form**	**Route of administration**
Nasonex	50 microgram/mL	Nasal spray, suspension	Nasal use