EMA/221225/2011

European Medicines Agency decision

P/82/2011

of 6 April 2011

on the agreement of a paediatric investigation plan and on the granting of a waiver for azelastine (hydrochloride) / fluticasone (propionate) (EMEA-000990-PIP02-10) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

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 MEDA Pharma GmbH & Co. KG on 9 November 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 February 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 13 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) 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 paediatric investigation plan for azelastine (hydrochloride) / fluticasone (propionate), 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 agreed.

Article 2

A waiver for azelastine (hydrochloride) / fluticasone (propionate), 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 3

This decision is addressed to MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg, Germany.

Done at London, 6 April 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/42946/2011

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMEA-000990-PIP02-10

Scope of the application

Active substances:

Azelastine (hydrochloride) / fluticasone (propionate)

Condition:

Treatment of allergic rhinitis / rhino-conjunctivitis

Pharmaceutical form:

Nasal spray, suspension

Route of administration:

Nasal use

Name/corporate name of the PIP applicant:

MEDA Pharma GmbH & Co. KG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, MEDA Pharma GmbH & Co. KG submitted for agreement to the European Medicines Agency on 9 November 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 22 December 2010.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a waiver for one or more 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 does not occur in the specified subsets of the paediatric population 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 Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex (es) and appendix.

London, 18 February 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

1.1. Condition: Treatment of allergic rhinitis / rhino-conjunctivitis

The waiver applies to:

- children from birth to less than 24 months for nasal spray, suspension, nasal use, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in these age groups.
- children from 2 to less than 12 years for nasal spray, suspension, nasal use, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit for these age groups over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of allergic rhinitis / rhino-conjunctivitis

2.1.1. Indication(s) targeted by the PIP

Symptomatic treatment of moderate to severe allergic rhinitis / rhino-conjunctivitis

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 12 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Nasal spray, suspension

2.1.4. Studies

Area	Number of studies	Description
Quality	N.A.	Not applicable.
Non-clinical	N.A.	Not applicable.
Clinical	6	**Study 1** Randomised, double-blind 4-arm trial to compare Azelastine / Fluticasone Nasal Spray to Placebo, Azelastine Hydrochloride Nasal Spray, and Fluticasone Propionate Nasal Spray in the treatment of patients with local spring pollen-induced allergic rhinitis **Study 2** Randomised, double-blind 4-arm trial to compare Azelastine / Fluticasone Nasal Spray to Placebo, Azelastine Hydrochloride Nasal Spray, and Fluticasone Propionate Nasal Spray in the treatment of patients with local fall pollen-induced allergic rhinitis **Study 3** Randomised, double-blind 4-arm trial to compare Azelastine / Fluticasone

		Nasal Spray to Placebo, Azelastine Hydrochloride Nasal Spray, and Fluticasone Propionate Nasal Spray in the treatment of patients with prevailing seasonal pollen-induced allergic rhinitis **Study 4** Randomised, double-blind 4-arm trial to compare Azelastine / Fluticasone Nasal Spray to Placebo, Azelastine Nasal Spray, and Fluticasone Propionate Nasal Spray in the treatment of patients with Texas Mountain Cedar-induced allergic rhinitis **Study 5** Multi-centre, randomised, open-label, active-controlled, parallel-group study to evaluate safety and tolerability of Azelastine / Fluticasone Nasal Spray against Fluticasone Nasal Spray in subjects with chronic rhinitis **Study 6** Meta-analysis or systematic review to evaluate efficacy and safety of Azelastine / Fluticasone Nasal Spray in adolescents in completed studies MP-4001, MP-4002, MP-4004 and MP-4006

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	By October, 2011
Deferral for one or more studies contained in the paediatric investigation plan:	No