EMA/683356/2010

European Medicines Agency decision

P/271/2010

of 3 December 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for allergens of birch pollen (betula alba/pendula/verrucosa) (EMEA-000888-PIP01-10) 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 Allergopharma Joachim Ganzer KG on 6 April 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 November 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation 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 deferral 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 deferral.

(4) 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 allergens of birch pollen (betula alba/pendula/verrucosa), oromucosal solution, sublingual 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 deferral for allergens of birch pollen (betula alba/pendula/verrucosa), oromucosal solution, sublingual 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

A waiver for allergens of birch pollen (betula alba/pendula/verrucosa), oromucosal solution, sublingual 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 4

This decision is addressed to Allergopharma Joachim Ganzer KG, Hermann-Körner-Strasse 52, 21465, Reinbek, Germany.

Done at London, 3 December 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/608506/2010

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

EMEA-000888-PIP01-10

Scope of the application

Active substance(s):

Allergens of birch pollen (betula alba/pendula/verrucosa)

Condition(s):

Treatment of allergic rhinitis/rhino-conjunctivitis

Pharmaceutical form(s):

Oromucosal solution

Route(s) of administration:

Sublingual use

Name/corporate name of the PIP applicant:

Allergopharma Joachim Ganzer KG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Allergopharma Joachim Ganzer KG submitted for agreement to the European Medicines Agency on 6 April 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 20 May 2010.

Supplementary information was provided by the applicant on 27 August 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 deferral in accordance with Article 21 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)(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, 12 November 2010

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 5 years of age,
- for oromucosal solution, sublingual use,
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit 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

Treatment of allergic rhinitis/rhino-conjunctivitis

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

From 5 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Oromucosal solution, sublingual use

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	1	Repeat-dose toxicity study in mice
Clinical	2	Randomised, double-blind, placebo-controlled study to assess the long-term efficacy and safety of AllerSlit forte Birch in children 4 to less than 12 years of age Randomised, double-blind, placebo-controlled study to assess the long-term efficacy and safety of AllerSlit forte Birch in adults and adolescents 12 years to less than 18 years of age

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By Feb 2026
Deferral for one or more studies contained in the paediatric investigation plan:	Yes