European Medicines Agency

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P/147/2009

EUROPEAN MEDICINES AGENCY DECISION

of 20 July 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for aqueous extract of grass pollen from Dactylis glomerata, Festuca pratensis, Holcus lanatus, Lolium perenne, Phleum pratense and Poa pratensis (EMEA-000337-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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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 Allergopharma J. Ganzer KG on 23 July 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 03 April 2009, and its Corrigendum issued on 10 July 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended.

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 granting 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 aqueous extract of grass pollen from Dactylis glomerata, Festuca pratensis, Holcus lanatus, Lolium perenne, Phleum pratense and Poa pratensis, solution for sublingual use, 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 aqueous extract of grass pollen from Dactylis glomerata, Festuca pratensis, Holcus lanatus, Lolium perenne, Phleum pratense and Poa pratensis, solution for sublingual use, 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 aqueous extract of grass pollen from Dactylis glomerata, Festuca pratensis, Holcus lanatus, Lolium perenne, Phleum pratense and Poa pratensis, solution for sublingual use, 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, which supersedes the previous decision of the European Medicines Agency P/86/2009 of 18 May 2009 on identical matter, is addressed to Allergopharma J. Ganzer KG, Hermann-Körner-Strasse 52, 21456 Reinbek, Germany.

Done at London, 20 July 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/163143/2009
EMEA-000337-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance(s):
Aqueous extract of grass pollen from Dactylis glomerata, Festuca pratensis, Holcus lanatus, Lolium perenne, Phleum pratense and Poa pratensis

Condition(s):
Grass pollen induced rhinitis or rhinoconjunctivitis

Pharmaceutical form(s):
Solution for sublingual use

Route(s) of administration:
Sublingual use

Name/corporate name of the PIP applicant:
Allergopharma J. Ganzer KG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Allergopharma J. Ganzer KG submitted for agreement to the EMEA on 23 July 2008 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 27 August 2008.

Supplementary information was provided by the applicant on 16 January 2009.

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Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 40
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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 Agency, together with its annex and appendix.

London, 03 April 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

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

A. CONDITION(S)

Grass pollen induced rhinitis or rhinoconjunctivitis.

B. WAIVER

- **Condition**

  Grass pollen induced rhinitis or rhinoconjunctivitis.

  The waiver applies to:

  Preterm newborn infants, Term newborn infants (from birth to less than 28 days), Infants and toddlers (from 28 days to less than 24 months), Children (from 2 to less than 4years), 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.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

  Grass pollen induced rhinitis or rhinoconjunctivitis.

- **Proposed PIP indication**

  Grass pollen induced rhinitis or rhinoconjunctivitis.

- **Subset(s) of the paediatric population concerned by the paediatric development**

  From 4 years to less than 18 years

- **Formulation(s)**

  Solution for sublingual use

- **Studies**

Area	Number of studies	Description
Clinical	1	A multicenter, randomised, controlled, double-blind study to evaluate efficacy and safety of a perennial sublingual specific immunotherapy with a solution of grass pollen allergen extract in children with clinically relevant grass pollen sensitivity in comparison to a symptomatic standard treatment with add on placebo

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By August 2013**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**