European Medicines Agency

Doc. Ref. EMA/816085/2009
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EUROPEAN MEDICINES AGENCY DECISION

of 22 December 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for house dust mites allergen extract (EMEA-000319-PIP01-08-M01) 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.

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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 decision P/72/2009 of the European Medicines Agency on 20 April 2009,

Having regard to the application submitted by Stallergenes on 11 August 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 November 2009, in accordance with Article 22 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 of the European Medicines Agency has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an agreed Paediatric Investigation Plan.

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

Changes to the agreed Paediatric Investigation Plan for house dust mites allergen extract, tablet, 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, are hereby accepted.

Article 2

This decision, that supersedes previous decision of the European Medicines Agency P/72/2009, as far as the agreed changes to the PIP for house dust mites extract are concerned, is addressed to Stallergenes, 6 rue Alexis de Tocqueville, 92183 Antony Cedex, France.

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/714075/2009
EMEA-000319-PIP01-08-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
House dust mites allergen extract

Condition(s):
Allergic rhinitis
Asthma

Pharmaceutical form(s):
Tablet

Route(s) of administration:
Sublingual use

Name/corporate name of the PIP applicant:
Stallergenes

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Stallergenes submitted to the EMEA on 11 August 2009 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the EMEA decision P/72/2009 of 20 April 2009. The application for modification proposed changes.

The procedure started on 17 September 2009.

Scope of the modification

The changes agreed to by the PDCO include the duration of the assessment of symptoms for the primary endpoint, a modification of the stratified randomization method, and the use of a different and more specific scale for the assessment of symptoms in adolescents.

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Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report,

- to agree to the changes proposed by the applicant regarding the measures of the paediatric investigation plan.

The Icelandic and the Norwegian Paediatric Committee member(s) agree with the above-mentioned recommendation of the Paediatrics Committee

2. The measures and timelines of the 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(es) and appendix.

London, 13 November 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)

Allergic rhinitis
Asthma

B. WAIVER

- **Condition**

  Allergic rhinitis due to house mites

  The waiver applies to:

  – Newborns, infants and children from birth to less than 5 years,

  – for house dust mites allergen extract, tablets, sublingual 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.

- **Condition**

  Asthma due to house mites

  The waiver applies to:

  – All subsets of the paediatric population,

  – for house dust mites allergen extract, tablets, sublingual use,

  – on the grounds that the specific medicinal product is likely to be ineffective.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

  Allergic rhinitis due to house mites

- **Proposed PIP indication**

  Treatment of allergic rhinitis due to house mites

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

  From 5 to less than 18 years.

- **Formulation(s)**

  Tablets, sublingual use

- **Studies**

Area	Number of studies	Description
Quality		Not applicable
Non-clinical	3	1. Teratogenicity study in the rat 2. Teratogenicity study in the rabbit 3. Juvenile toxicity study
Clinical	1	1. Randomised, double-blind, placebo-controlled safety and efficacy study of sublingual immunotherapy administered as allergen-based tablet once daily to children from 5 to less than 18 years, suffering from house dust mites allergic rhinitis

Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By January 2012**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**