EMA/398971/2011

European Medicines Agency decision

P/160/2011

of 4 July 2011

on the acceptance of a modification of an agreed paediatric investigation plan for house dust mites allergen extracts (EMEA-000319-PIP01-08-M02) 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 European Medicines Agency's decision P/72/2009 issued on 20 April 2009, and the decision P/252/2009 issued on 22 December 2009,

Having regard to the application submitted by Stallergenes S.A on 3 March 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 20 May 2011, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the 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 extracts, sublingual tablet, sublingual use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Stallergenes S.A., 6 Rue Alexis de Tocqueville, 92183 - ANTONY, France.

Done at London, 4 July 2011

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

EMA/PDCO/330161/2011

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000319-PIP01-08-M02

Scope of the application

Active substance(s):

House dust mites allergen extracts

Condition(s):

Allergic rhinitis

Asthma

Pharmaceutical form(s):

Sublingual tablet

Route(s) of administration:

Sublingual use

Name/corporate name of the PIP applicant:

Stallergenes S.A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, STALLERGENES S.A. submitted to the European Medicines Agency on 3 March 2011 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/72/2009 issued on 20 April 2009 and the decision P/252/2009 issued on 22 December 2009.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 23 March 2011.

Supplementary information was provided by the applicant on 29 April 2011.

Scope of the modification

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The changes agreed to by the PDCO include the extension of the study duration, the study objectives and the timelines of the study.

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 changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion,

   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 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, 20 May 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: 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 extracts, sublingual 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.

1.2. Condition: Asthma due to house mites

The waiver applies to:

- All subsets of the paediatric population,
- for house dust mites allergen extracts, sublingual tablets, sublingual use,
- on the grounds that the specific medicinal product is likely to be ineffective.

1.3. Paediatric Investigation Plan

1.4. Condition: Allergic rhinitis due to house mites

1.4.1. Indication(s) targeted by the PIP

Treatment of allergic rhinitis due to house mites.

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

From 5 to less than 18 years of age.

1.4.3. Pharmaceutical form(s)

Sublingual tablets

1.4.4. 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

		mite allergic rhinitis.

2. 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 January 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes