



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/332274/2012

European Medicines Agency decision P/0107/2012

of 8 June 2012

on the acceptance of a modification of an agreed paediatric investigation plan for modified grass pollen extract (EMA-000284-PIP01-08-M03) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/18/2009 issued on 4 February 2009, the decision P/126/2010 issued on 28 July 2010, and the decision P/202/2011 issued on 26 August 2011,

Having regard to the application submitted by Allergy Therapeutics (UK) Ltd. on 24 February 2012 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 16 May 2012, 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 modified grass pollen extract, suspension for injection, subcutaneous 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 Allergy Therapeutics (UK) Ltd., Dominion Way, BN14 8SA - Worthing, West Sussex, United Kingdom.

Done at London, 8 June 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/145232/2012

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000284-PIP01-08-M03

Scope of the application

Active substance(s):

Modified grass pollen extract

Condition(s):

Treatment of allergic rhinitis due to pollen

Treatment of acute atopic conjunctivitis

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Allergy Therapeutics (UK) Ltd.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Allergy Therapeutics (UK) Ltd. submitted to the European Medicines Agency on 24 February 2012 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/18/2009 issued on 4 February 2009, the decision P/126/2010 issued on 28 July 2010, and the decision P/202/2011 issued on 26 August 2011.

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

The procedure started on 19 March 2012.



Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

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 Norwegian Paediatric Committee member agrees 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 and appendix.

London, 16 May 2012

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 due to pollen

Treatment of acute atopic conjunctivitis

The waiver applies to:

- 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 5 years);
- for suspension for injection, subcutaneous 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 due to pollen

Treatment of acute atopic conjunctivitis

2.1.1. Indication(s) targeted by the PIP

Treatment of rhinitis and/or conjunctivitis in adults and children caused by grass pollen, diagnosed with a positive skin prick test and/or specific IgE test to grass pollen.

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

From 5 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Suspension for injection.

2.1.4. Studies

Area	Number of studies	Description
Non-clinical	1	7 week toxicity study in juvenile rats.
Clinical	1	Randomized, placebo-controlled, double-blind efficacy and safety/tolerability study in children and adolescents aged 5 to less than 18 years.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2016
Deferral for one or more studies contained in the paediatric investigation plan:	Yes