

EMA/476174/2013

European Medicines Agency decision

P/0204/2013

of 3 September 2013

on the acceptance of a modification of an agreed paediatric investigation plan for modified grass pollen extract (EMEA-000284-PIP01-08-M04) 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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on the acceptance of a modification of an agreed paediatric investigation plan for modified grass pollen extract (EMA-000284-PIP01-08-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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, the decision P/202/2011 issued on 26 August 2011, and the decision P/0107/2012 issued on 8 June 2012,

Having regard to the application submitted by Allergy Therapeutics (UK) Limited on 24 April 2013 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 19 July 2013, 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) Limited, Dominion Way, BN14 8SA - Worthing, United Kingdom.

Done at London, 3 September 2013

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

EMA/PDCO/272137/2013 **Corr**

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

EMA-000284-PIP01-08-M04

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) Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Allergy Therapeutics (UK) Limited submitted to the European Medicines Agency on 24 April 2013 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, the decision P/202/2011 issued on 26 August 2011, and the decision P/0107/2012 issued on 8 June 2012.

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

The procedure started on 22 May 2013.

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, 19 July 2013

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:

- the paediatric population from birth to less than 5 years of age;
- 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. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	1	Measure 1 7 week toxicity study in juvenile rats.
Clinical	1	Measure 2 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 2017
Deferral for one or more measures contained in the paediatric investigation plan:	Yes