



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/357144/2019

European Medicines Agency decision P/0224/2019

of 5 July 2019

on the acceptance of a modification of an agreed paediatric investigation plan for birch, hazel and alder pollen extracts (EMEA-000808-PIP01-09-M01) 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/204/2010 issued on 27 October 2010,

Having regard to the application submitted by Allergy Therapeutics (UK) Ltd on 21 January 2019 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 26 April 2019, 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 birch, hazel and alder pollen extracts, oromucosal solution, 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 Allergy Therapeutics (UK) Ltd, Dominion Way, BN14 8SA - Worthing, United Kingdom.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/111965/2019
Amsterdam, 26 April 2019

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000808-PIP01-09-M01

Scope of the application

Active substance(s):

Birch, hazel and alder pollen extracts

Condition(s):

Treatment of allergic rhinitis / rhino-conjunctivitis

Pharmaceutical form(s):

Oromucosal solution

Route(s) of administration:

Sublingual 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 21 January 2019 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/204/2010 issued on 27 October 2010.

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

The procedure started on 26 February 2019.

Scope of the modification

Some measures 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.

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 (PIP)

1. Waiver

1.1. Condition:

Treatment of allergic rhinitis / rhino-conjunctivitis

The waiver applies to:

- the paediatric population from birth to less than 5 years of age;
- oromucosal solution, sublingual 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 / rhino-conjunctivitis

2.1.1. Indication(s) targeted by the PIP

For the sublingual hyposensitisation treatment of allergic rhinitis / rhino-conjunctivitis which are caused by an IgE-mediated allergy to alder/hazel/birch 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)

Oromucosal solution

2.1.4. Studies

| Area | Number of studies | Description |
|--------------|-------------------|--|
| Quality | | Not applicable |
| Non-clinical | | Not applicable |
| Clinical | 1 | A double blind, randomized, multicentre, placebo-controlled trial to evaluate long-term efficacy and safety/tolerability of Birch, Hazel and Alder Pollen Extract in children and adolescents aged 5 to 17 years with allergic rhinitis /rhino-conjunctivitis due to pollen during 3 years, with a 2-year blinded treatment-free follow-up period. |

3. Follow-up, completion and deferral of PIP

| | |
|--|------------------|
| Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use: | No |
| Date of completion of the paediatric investigation plan: | By December 2023 |
| Deferral for one or more studies contained in the paediatric investigation plan: | Yes |