EMA/105457/2024

European Medicines Agency decision

P/0177/2024

of 6 May 2024

on the acceptance of a modification of an agreed paediatric investigation plan for 13 Grass Aqueous Extract (EMEA-000813-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 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/221/2010 issued on 29 October 2010,

Having regard to the application submitted by Allergy Therapeutics (UK) Ltd. on 20 November 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 February 2024, 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, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) of Regulation (EC) No 1901/2006, an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for 13 Grass Aqueous Extract, suspension for injection, subcutaneous use, including changes to the deferral, 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.

EMA/PDCO/140336/2024
Amsterdam, 26 April 2024

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

EMEA-000813-PIP01-09-M01

Scope of the application

Active substance(s):

13 Grass Aqueous Extract

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of allergic rhinitis / rhino-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 20 November 2023 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/221/2010 issued on 29 October 2010.

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

An Opinion was adopted by the Paediatric Committee on 23 February 2024 for the above mentioned product. Allergy Therapeutics (UK) Ltd. received the Paediatric Committee Opinion on 4 March 2024.

On 27 March 2024 Allergy Therapeutics (UK) Ltd. submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 28 March 2024.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

1.1. to maintain its opinion and

- to agree to the changes regarding the measures and the timelines of the paediatric investigation plan and the timelines of the deferral in the scope set out in the Annex I of this opinion.

The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. 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 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 annexes 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;
- 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 / rhino-conjunctivitis

2.1.1. Indication(s) targeted by the PIP

Subcutaneous hyposensitisation treatment of allergic rhinitis / rhino-conjunctivitis caused by an IgE-mediated allergy to 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	**Description**
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	**Study 1** *Deleted during procedure EMEA-000813-PIP01-09-M01* **Study 2 (PQGrass308)** *Added during procedure EMEA-000813-PIP01-09-M01* Double-blind, randomised, placebo-controlled trial to evaluate long-term efficacy and safety / tolerability of 13 Grass Aqueous Extract (PQ Grass) in children and adolescents from 5 years to less than 18 years of age with

	seasonal allergic rhinitis/ rhinoconjunctivitis (SAR) with or without asthma due to grass pollen
Modelling and simulation studies	Not applicable
Other studies	Not applicable
Extrapolation plan	Not applicable

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 September 2032
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.