EMA/319199/2024

European Medicines Agency decision

P/0245/2024

of 18 July 2024

on the acceptance of a modification of an agreed paediatric investigation plan for dermatophagoides farinae extracts 100 %, (EMEA-000834-PIP01-10-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/285/2010 issued on 3 December 2010,

Having regard to the application submitted by Allergopharma GmbH & Co. KG on 22 February 2024 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 31 May 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 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 dermatophagoides farinae extracts 100 %, 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 Allergopharma GmbH & Co. KG, Hermann-Körner-Strasse 52-54, 21465 – Reinbek, Germany.

EMA/PDCO/89984/2024 Corr[1] Corr[2]
Amsterdam, 31 May 2024

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

EMEA-000834-PIP01-10-M01

Scope of the application

Active substance(s):

Dermatophagoides farinae extracts 100 %

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:

Allergopharma GmbH & Co. KG

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Allergopharma GmbH & Co. KG submitted to the European Medicines Agency on 22 February 2024 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 the decision P/285/2010 issued on 3 December 2010.

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

The procedure started on 2 April 2024.

[1] 12 July 2024
[2] 18 July 2024

Scope of the modification

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

Amendment of the scope of the Paediatric Investigation Plan to exclude another condition.

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 and to the deferral in the scope set out in the Annex I of this opinion.
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 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/rhinoconjunctivitis

The waiver applies to:

- The paediatric population from birth to less than 5 years of age,
- 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/rhinoconjunctivitis

2.1.1. Indication(s) targeted by the PIP

Treatment of allergic rhinitis/ rhino-conjunctivitis due to sensitisation against house dust mites

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

From 5 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Suspension for injection

2.1.4. Studies

Area	Description
Quality	Not applicable
Non-clinical	Not applicable
Clinical	**Study 1 (AL0907ac)** Double-blind, placebo-controlled, randomised trial to evaluate the efficacy and safety of the allergen Dermatophagoides pteronyssinus extracts 100% in adolescents from 12 to less than 18 years of age (and in adults) adults with allergic rhinitis/rhino-conjunctivitis due to house dust mites for 3 years followed by a 2-year blinded treatment-free period **Study 2 (AL1001ac)** Double-blind, placebo-controlled, randomised trial to evaluate the efficacy and safety of the allergen Dermatophagoides pteronyssinus extracts 100% in children from 5 to less than 12 years of age with

	allergic rhinitis/rhino-conjunctivitis due to house dust mites for 3 years followed by a 2-year blinded treatment-free period

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By February 2032
Deferral for one or more measures 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.