EMA/236232/2023

European Medicines Agency decision

P/0211/2023

of 14 June 2023

on the acceptance of a modification of an agreed paediatric investigation plan for adsorbed modified allergen extract of a mixture of 50% dermatophagoides pteronyssinus and 50% dermatophagoides farinae (EMEA-000902-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/274/2010 issued on 3 December 2010,

Having regard to the application submitted by HAL Allergy BV on 20 January 2023 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 2023, 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, 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 adsorbed modified allergen extract of a mixture of 50% dermatophagoides pteronyssinus and 50% dermatophagoides farinae, 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 HAL Allergy BV, J.H. Oortweg 15, 2333 CH – Leiden, The Netherlands.

EMA/PDCO/41470/2023
Amsterdam, 26 April 2023

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

EMEA-000902-PIP01-10-M01

Scope of the application

Active substance(s):

Adsorbed modified allergen extract of a mixture of 50% dermatophagoides pteronyssinus and 50% dermatophagoides farinae

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:

HAL Allergy BV

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, HAL Allergy BV submitted to the European Medicines Agency on 20 January 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/274/2010 issued on 3 December 2010.

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

The procedure started on 27 February 2023.

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 Paediatric Committee member of Norway 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 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:

- Infants and children 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

Treatment of allergic rhinitis/rhino-conjunctivitis

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, subcutaneous use

2.1.4. Studies

Area	**Description**
Quality	Not applicable.
Non-clinical	Bacterial Reverse Mutation (Ames) test In vitro mammalian cell gene mutation test
Clinical	Randomized, double-blind, placebo-controlled, parallel-group, efficacy, tolerability and safety study of house dust mite allergen immunotherapy in children 5 years to less than 18 years of age suffering from house dust mite allergic rhinitis/rhinoconjunctivitis.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and/or efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By March 2023
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.