EMA/688234/2015

European Medicines Agency decision

P/0284/2015

of 27 November 2015

on the acceptance of a modification of an agreed paediatric investigation plan for dermatophagoides pteronyssinus / dermatophagoides farinae (EMEA-001258-PIP01-11-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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0243/2012 issued on 22 October 2012,

Having regard to the application submitted by ALK-Abelló A/S on 10 July 2015 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 9 October 2015, 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 dermatophagoides pteronyssinus / dermatophagoides farinae, oral lyophilisate, 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 ALK-Abelló A/S, Bøge Alle 6-8, 2970 – Hørsholm, Denmark.

Done at London, 27 November 2015

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/522937/2015
London, 9 October 2015

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

EMEA-001258-PIP01-11-M01

Scope of the application

Active substance(s):

Dermatophagoides pteronyssinus / dermatophagoides farinae

Condition(s):

Treatment of allergic rhinitis

Prevention of asthma

Treatment of asthma

Pharmaceutical form(s):

Oral lyophilisate

Route(s) of administration:

Sublingual use

Name/corporate name of the PIP applicant:

ALK-Abelló A/S

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ALK-Abelló A/S submitted to the European Medicines Agency on 10 July 2015 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/0243/2012 issued on 22 October 2012.

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

The procedure started on 11 August 2015.

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

The waiver applies to:

- All subsets of the paediatric population from birth to less than 5 years of age;
- for oral lyophilisate, sublingual use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition: Prevention of asthma

The waiver applies to:

- All subsets of the paediatric population from birth to less than 5 years of age;
- for oral lyophilisate, sublingual use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.3. Condition: Treatment of asthma

The waiver applies to:

- All subsets of the paediatric population from birth to less than 5 years of age;
- for oral lyophilisate, 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

2.1.1. Indication(s) targeted by the PIP

Treatment of allergic rhinitis due to 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)

Oral lyophilisate

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	**Study 1** Double-blind, randomised, multicentre, placebo-controlled, parallel group trial to evaluate long-term efficacy and safety of house dust mites oral lyophilisate compared to placebo in children from 5 to less than 18 years with allergic rhinitis.

2.2. Condition:

Prevention of asthma

2.2.1. Indication(s) targeted by the PIP

Prevention of allergic asthma due to house dust mites

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

From 5 to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Oral lyophilisate

2.2.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	1	**Study 1** (the same as in Condition 1): Double-blind, randomised, multicentre, placebo-controlled, parallel group trial to evaluate long-term efficacy and safety of house dust mites oral lyophilisate compared to placebo in children from 5 to less than 18 years with allergic rhinitis

2.3. Condition:

Treatment of asthma

2.3.1. Indication(s) targeted by the PIP

Treatment of allergic asthma due to house dust mites

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

From 5 to less than 18 years of age

2.3.3. Pharmaceutical form(s)

Oral lyophilisate

2.3.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	1	**Study 2** Double-blind, randomised, multicentre, placebo-controlled, parallel group trial to evaluate long-term efficacy and safety of house dust mites oral lyophilisate compared to placebo in children from 5 to less than 18 years with allergic asthma

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2028
Deferral for one or more studies contained in the paediatric investigation plan:	Yes