EMA/732714/2015

European Medicines Agency decision

P/0277/2015

of 27 November 2015

on the acceptance of a modification of an agreed paediatric investigation plan for pollen from betula pendula (33%), corylus avellana (33%) and alnus glutinosa (33%), (EMEA-000852-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 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/9/2011 issued on 3 January 2011,

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 pollen from betula pendula (33%), corylus avellana (33%) and alnus glutinosa (33%), 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 ALK-Abelló A/S, Bøge Allé 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/516207/2015
London, 9 October 2015

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

EMEA-000852-PIP01-10-M01

Scope of the application

Active substance(s):

Pollen from betula pendula (33%), corylus avellana (33%) and alnus glutinosa (33%)

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:

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/9/2011 issued on 3 January 2011.

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 and timelines of the Paediatric Investigation Plan have been modified.

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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;
- for 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

Treatment of allergic rhinitis/rhino-conjunctivitis in patients with tree pollen allergy with or without mild to moderate allergic asthma

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)

Oromucosal solution

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Double-blind, randomised, multicentre, placebo-controlled, parallel-group trial to evaluate the long-term efficacy and safety/tolerability of Pollen from betula pendula in children from 5 to less than 18 years of age with allergic rhinitis/rhino-conjunctivitis.

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 September 2030
Deferral for one or more studies contained in the paediatric investigation plan:	Yes