EMA/130559/2019

European Medicines Agency decision

P/0084/2019

of 22 March 2019

on the refusal of a modification of an agreed paediatric investigation plan for chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis (EMEA-001016-PIP01-10-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/147/2011 issued on 9 June 2011,

Having regard to the application submitted by Granzer Regulatory Consulting & Services on 25 October 2018 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 1 February 2019, 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 refusal of changes to the agreed paediatric investigation plan and to the deferral.

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

[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 chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis, sublingual tablets, sublingual use, including changes to the deferral, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, are hereby refused.

Article 2

This decision is addressed to Granzer Regulatory Consulting & Services, Kistlerhofstr. 172C, 81379 - Munich, Germany.

EMA/PDCO/782149/2018
London, 1 February 2019

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

EMEA-001016-PIP01-10-M01

Scope of the application

Active substance(s):

Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis

Condition(s):

Treatment of allergic rhinitis / rhino-conjunctivitis

Pharmaceutical form(s):

Sublingual tablets

Route(s) of administration:

Sublingual use

Name/corporate name of the PIP applicant:

Granzer Regulatory Consulting & Services

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Granzer Regulatory Consulting & Services submitted to the European Medicines Agency on 25 October 2018 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/147/2011 issued on 9 June 2011.

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

The procedure started on 4 December 2018.

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 refuse the changes proposed by the applicant regarding the paediatric investigation plan and the deferral.

   The Norwegian Paediatric Committee member 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 remain unchanged and are set out in the Annex I.

3. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

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;
- sublingual tablet, 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 due to grass pollen

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)

Sublingual tablet

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	1	**Study 1** (SMART 15) Double blind, randomised, multicentre, placebo controlled trial to evaluate the long-term efficacy and safety/tolerability of grass pollen extract tablets in children and adolescents aged 5 to less than 18 years with allergic rhinitis / rhino-conjunctivitis due to grass pollen during 3 years, with a 2-year blinded treatment-free follow-up period.

Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By August 2019
Deferral for one or more studies contained in the paediatric investigation plan:	Yes