EMA/790671/2022

European Medicines Agency decision

P/0463/2022

of 28 October 2022

on the agreement of a paediatric investigation plan and on the granting of a waiver for freeze-dried allergen extract of Betula pendula pollen (EMEA-003117-PIP02-21) 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 application submitted by ROXALL Medizin GmbH on 14 December 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 September 2022, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a waiver.

[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

A paediatric investigation plan for freeze-dried allergen extract of Betula pendula pollen, solution for skin-prick test, epicutaneous use, 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, is hereby agreed.

Article 2

A waiver for freeze-dried allergen extract of Betula pendula pollen, solution for skin-prick test, epicutaneous use, 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, is hereby granted.

Article 3

This decision is addressed to ROXALL Medizin GmbH, 4 Carl-Petersen-Straße, 20535 - Hamburg Germany.

EMA/PDCO/582121/2022
Amsterdam, 9 September 2022

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMEA-003117-PIP02-21

Scope of the application

Active substance(s):

Freeze-dried allergen extract of Betula pendula pollen

Condition(s):

Diagnosis of IgE-mediated allergy to tree pollen of the birch group

Pharmaceutical form(s):

Solution for skin-prick test

Route(s) of administration:

Epicutaneous use

Name/corporate name of the PIP applicant:

ROXALL Medizin GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, ROXALL Medizin GmbH submitted for agreement to the European Medicines Agency on 14 December 2021 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 31 January 2022.

Supplementary information was provided by the applicant on 24 May 2022. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Paediatric Committee member of Norway 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 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:

Diagnosis of IgE-mediated allergy to tree pollen of the birch group

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- solution for skin-prick test, epicutaneous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Diagnosis of IgE-mediated allergy to tree pollen of the birch group

2.1.1. Indication(s) targeted by the PIP

Diagnosis of IgE-mediated allergy to tree pollen of the birch group in adult and paediatric patients between 2 years and 18 years

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for skin-prick test

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1** Open-label dose/response, active-controlled trial to assess the sensitivity and specificity of 4 different concentrations (10, 25, 50 and 100 HEP/mL) of birch prick test in children from 2 years to less than 18 years of age with and without allergy to birch pollen (INM-STBV-01-1999) **Study 2** Open-label dose/response, active-controlled trial to assess the sensitivity and specificity of 4 different concentrations (10, 25, 50 and

	100 HEP/mL) of birch prick test in children from 2 to less than 18 years of age with and without allergy to birch pollen (T502-SSP-007)
Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	Not applicable

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 April 2016
Deferral for one or more measures contained in the paediatric investigation plan:	No