EMA/934709/2022

European Medicines Agency decision

P/0548/2022

of 30 December 2022

on the refusal of a modification of an agreed paediatric investigation plan for aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch, alder and hazel pollen (EMEA-000662-PIP02-09-M05) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

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/240/2010 issued on 26 November 2010, decision P/0002/2012 issued on 23 January 2012, decision P/0147/2012 issued on 24 July 2012 and decision P/0014/2014 issued on 22 January 2014,

Having regard to the application submitted by LETI Pharma GmbH on 25 July 2022 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 11 November 2022, 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, 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 aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch, alder and hazel pollen, suspension for injection, subcutaneous 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 LETI Pharma GmbH, Gutenbergstrasse 10, 85737 – Ismaning, Germany.

EMA/PDCO/877015/2022 Corr
Amsterdam, 11 November 2022

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

EMEA-000662-PIP02-09-M05

Scope of the application

Active substance(s):

Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch, alder and hazel pollen

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:

LETI Pharma GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, LETI Pharma GmbH submitted to the European Medicines Agency on 25 July 2022 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/240/2010 issued on 26 November 2010, the decision P/0002/2012 issued on 23 January 2012, the decision P/0147/2012 issued on 24 July 2012 and the decision P/0014/2014 issued on 22 January 2014.

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

The procedure started on 12 September 2022.

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 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 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 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:

- the paediatric population 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

For the subcutaneous treatment of patients with allergic rhinitis / rhino-conjunctivitis with or without intermittent allergic asthma due to sensitisation against tree pollen (Betula alba group)

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

2.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable
Non-clinical		Not applicable
Clinical	2	1) Double-blind randomized, multicentre, placebo-controlled trial to evaluate long-term efficacy and safety/tolerability of the aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of Betula alba pollen in adolescents aged 12 to less than 18 years (and adults) with allergic rhinitis/rhinoconjunctivitis due to birch pollen during 3 years, with a 2-year blinded treatment-free follow-up period. 2) Double blind, randomized, multicentre, placebo-controlled trial to evaluate long-term efficacy and safety/tolerability of the aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch pollen in children aged 5 to less than 12 years with allergic rhinitis /rhino-conjunctivitis due to pollen during 3 years, with a

Area	Number of studies	Description
		2-year blinded treatment-free follow-up period.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By November 2021
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.