EMA/471477/2012

European Medicines Agency decision

P/0147/2012

of 24 July 2012

on the acceptance of a modification of an agreed paediatric investigation plan for aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract from the pollen of Betula alba (EMEA-000630-PIP02-09-M02) 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/240/2010 issued on 26 November 2010 and the decision P/0002/2012 issued on 23 January 2012,

Having regard to the application submitted by LETI Pharma GmbH on 23 March 2012 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 8 June 2012, 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 aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract from the pollen of Betula alba, suspension for injection, subcutaneous 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 LETI Pharma GmbH, Stockumerstr. 28, 58453 – Witten, Germany.

Done at London, 24 July 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/211607/2012

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

EMEA-000630-PIP02-09-M02

Scope of the application

Active substance(s):

Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract from the pollen of Betula alba

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 23 March 2012 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 and the decision P/0002/2012 issued on 23 January 2012.

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

The procedure started on 16 April 2012.

Scope of the modification

Some measures 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 Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 8 June 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

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 longterm 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 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 2020
Deferral for one or more studies contained in the paediatric investigation plan:	Yes