EMA/71305/2014

European Medicines Agency decision

P/0327/2014

of 11 December 2014

on the acceptance of a modification of an agreed paediatric investigation plan for bilastine (Bilaxten and associated names) (EMEA-000347-PIP01-08-M04) 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/88/2009 issued on 18 May 2009, the decision P/196/2011 issued on 26 August 2011, the decision P/0137/2012 issued on 20 July 2012, and the decision P/0288/2013 issued on 29 November 2013,

Having regard to the application submitted by Faes Farma S.A. on 18 September 2014 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 14 November 2014, 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 bilastine (Bilaxten and associated names), tablet, dispersible tablet, oral liquid, oral 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 Faes Farma S.A., Avenida Autonomía, 10, 48940 – Leioa, Spain.

Done at London, 11 December 2014

For the European Medicines Agency
Zaide Frias
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/599533/2014

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

EMEA-000347-PIP01-08-M04

Scope of the application

Active substance(s):

Bilastine

Invented name:

Bilaxten and associated names

Condition(s):

Treatment of allergic rhinoconjunctivitis

Treatment of urticaria

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Dispersible tablet

Oral liquid

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Faes Farma S.A.

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Faes Farma S.A. submitted to the European Medicines Agency on 18 September 2014 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/88/2009 issued on 18 May 2009, the decision P/196/2011 issued on 26 August 2011, the decision P/0137/2012 issued on 20 July 2012, and the decision P/0288/2013 issued on 29 November 2013.

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

The procedure started on 14 October 2014.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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 annexes and appendix.

London, 14 November 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 rhinoconjunctivitis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 2 years of age;
- for tablet, dispersible tablet and oral liquid for oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

1.2. Condition:

Treatment of urticaria

The waiver applies to:

- All subsets of the paediatric population from birth to less than 2 years of age;
- for tablet, dispersible tablet and oral liquid for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

The waiver applies to:

- Adolescents from 12 to less than 18 years of age;
- for tablet, dispersible tablet and oral liquid for oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of allergic rhinoconjunctivitis

2.1.1. Indication(s) targeted by the PIP

Treatment of the symptoms of allergic rhinoconjunctivitis including perennial allergic rhinitis and seasonal allergic rhinitis.

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

From 2 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Tablet

Dispersible tablet

Oral liquid

2.1.4. Measures

Area	Number of studies	Description
Quality	2	**Study 1:** Development of dispersible tablet **Study 2:** Development of oral liquid
Non-clinical	0	Not applicable.
Clinical	4	**Study 3:** A comparative study for the efficacy and safety of bilastine 20mg versus cetirizine 10mg and placebo in the treatment of perennial allergic rhinitis during 4 weeks, followed by a long term safety extension with bilastine 20mg **Study 4:** Population Pharmacokinetic modelling of bilastine in children with allergic rhinoconjunctivitis (SAR/PAR) or chronic urticaria **Study 5:** A multicentre, double-blind, randomised, placebo-controlled, parallel groups study to evaluate the safety and tolerability of bilastine 10 mg once daily in children with either allergic rhinoconjunctivitis or chronic urticaria

2.2. Condition:

Treatment of urticaria

2.2.1. Indication(s) targeted by the PIP

Treatment of the symptoms of urticaria.

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

From 2 to less than 12 years of age.

2.2.3. Pharmaceutical form(s)

Tablet

Dispersible tablet

Oral liquid

2.2.4. Measures

Same studies as for the condition: Treatment of allergic rhinoconjunctivitis:

Area	Number of studies	Description
Quality	2	**Study 1:** Development of dispersible tablet **Study 2:** Development of oral liquid
Non-clinical	0	Not applicable.
Clinical	4	**Study 3:** A comparative study for the efficacy and safety of bilastine 20mg versus cetirizine 10mg and placebo in the treatment of perennial allergic rhinitis during 4 weeks, followed by a long term safety extension with bilastine 20mg **Study 4:** Population Pharmacokinetic modelling of bilastine in children with allergic rhinoconjunctivitis (SAR/PAR) or chronic urticaria **Study 5:** A multicentre, double-blind, randomised, placebo-controlled, parallel groups study to evaluate the safety and tolerability of bilastine 10 mg once daily in children with either allergic rhinoconjunctivitis or chronic urticaria

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 July 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of allergic rhinoconjunctivitis

Authorised indications:

- Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria in adults and adolescents (12 years of age and over)

2. Treatment of urticaria

Authorised indications:

- Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria in adults and adolescents (12 years of age and over)

Authorised pharmaceutical form(s):

Tablet

Authorised route(s) of administration:

Oral use