European Medicines Agency

Doc. Ref. EMEA/272633/2009
P/88/2009

EUROPEAN MEDICINES AGENCY DECISION

of 18 May 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for bilastine (EMEA-000347-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 application submitted by FAES FARMA, S.A. on 24 July 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 3 April 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

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 deferral and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision granting a Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a deferral.

(4) It is therefore appropriate to adopt a Decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

A Paediatric Investigation Plan for bilastine, tablets, dispersible tablets, oral liquid, oral 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 deferral for bilastine, tablets, dispersible tablets, oral liquid, oral 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

A waiver for bilastine, tablets, dispersible tablets, oral liquid, oral 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 4

This decision is addressed to FAES FARMA, S.A., Máximo Aguirre, 14, 48940 Leioa, Spain.

Done at London, 18 May 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency

Doc. Ref. EMEA/272633/2009
EMEA-000347-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance(s):
Bilastine

Condition(s):
Allergic rhinoconjunctivitis
Urticaria

Pharmaceutical form(s):
Tablets
Dispersible tablets
Oral liquid

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
FAES FARMA, S.A.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, FAES FARMA, S.A. submitted for agreement to the EMEA on 24 July 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 27 August 2008.

Supplementary information was provided by the applicant on 2 February 2009.

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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 18 of said Regulation,

- to grant a deferral in accordance with Article 21 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 Articles 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population, 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 Icelandic and the Norwegian Paediatric Committee member(s) agree 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 Agency, together with its annex(es) and appendix.

London, 3 April 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

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

A. CONDITION(S)

C.1 Allergic rhinoconjunctivitis
C.2 Urticaria

B. WAIVER

- **Condition**

Allergic rhinoconjunctivitis

The waiver applies to:

- Paediatric population from birth to less than 2 years of age 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)

- **Condition**

Urticaria

The waiver applies to:

- Paediatric population from birth to less than 2 years of age for oral use

on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

and

- adolescents from 12 to less than 18 years of age, 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, as extrapolation of efficacy results from adults is possible.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

C.1 Allergic rhinoconjunctivitis
C.2 Urticaria

- **Proposed PIP indication**

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

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 2 years to less than 18 years.
From 12 to less than 18 years, extrapolation of efficacy results from adults with urticaria is possible.

- **Formulation(s)**

Tablets, oral use
Dispersible tablets, oral use
Oral liquid

- **Studies**

Area	Number of studies	Description
Quality	2	Development of dispersible tablets Development of oral liquid
Clinical	4	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 A Multi-Center Randomised, Double-Blind, Placebo-Controlled, Parallel Study to Evaluate the Efficacy, Safety and Pharmacokinetics of Once or Twice Daily Bilastine (10 or 20 mg) Compared with Placebo Given Orally in The Treatment of the Symptoms of Seasonal Allergic Rhino-Conjunctivitis with Allergy to Mountain Cedar Pollen Population Pharmacokinetic modelling of bilastine in children with allergic rhinoconjunctivitis (SAR/PAR) or chronic urticaria A multicentre, double-blind, double-dummy, randomised 3-arm parallel study to evaluate the safety and tolerability of bilastine 10 mg once daily and cetirizine 5 or 10 mg once daily compared to placebo in children with either allergic rhinoconjunctivitis or chronic urticaria

Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By December 2012**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**