European Medicines Agency

Doc. Ref. EMEA/24357/2009
P/4/2009

EUROPEAN MEDICINES AGENCY DECISION

of 27 January 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for mometasone furoate, formoterol fumarate dihydrate (EMEA-000025-PIP01-07-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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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 decision P/85/2008 of the European Medicines Agency on 14 October 2008,

Having regard to the application submitted by Novartis Europharm Limited on 3 November 2008 under Article 22 of Regulation (EC) No 1901/2006 as amended for changes to an agreed Paediatric Investigation Plan,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 December 2008, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

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 acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an 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 mometasone furoate, formoterol fumarate dihydrate, pressurised metered dose inhaler (MDI) with HFA-227 as propellant, suspension, inhalation 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, are hereby accepted.

Article 2

This decision, that supersedes previous decision of the European Medicines Agency P/85/2008 on identical matter, is addressed to Novartis Europharm Limited, Wimblehurst Road, Horsham, RH12 5AB, United Kingdom.

Done at London, 27 January 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency

Doc. Ref. EMEA/PDCO/639088/2008
EMEA-000025-PIP01-07-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance:
Mometasone furoate
Formoterol fumarate dihydrate

Condition(s):
Persistent asthma

Pharmaceutical form(s):
Pressurised metered dose inhaler (MDI) with HFA-227 as propellant, suspension

Route(s) of administration:
Inhalation use

Name/corporate name of the PIP applicant:
Novartis Europharm Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the EMEA on 3 November 2008 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the EMEA decision Doc. Ref. EMEA/524768/2008 (P/85/2008) of 14 October 2008 proposing changes.

The procedure started on 13 November 2008.

Scope of the modification

The applicant proposed modifications to the agreed PIP to improve the clarity of the agreed measures.

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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 the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan.

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 subsets of the paediatric population and condition 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 and appendix.

London, 12 December 2008

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 SUBSETS OF THE PAEDIATRIC POPULATION AND CONDITION COVERED BY THE WAIVER

A. CONDITION(S) / DISEASE(S)
Persistent Asthma

B. WAIVER

- **Condition**

Persistent asthma

  - **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to:
Newborn infants (0-27 d), Infants & toddlers (28 d-23 months), and children 2 to less than 5 years for the pressurised metered dose inhaler, suspension.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Persistent asthma

  - **Proposed PIP indication**

Treatment of persistent asthma

  - **Subset(s) covered**

Children and adolescents from 5 years to less than 18 years

  - **Formulation(s)**

Pressurised metered dose inhaler, suspension

Studies / Measures

Area	Subarea	Number	Description
Clinical	Efficacy and safety	3	1) Double-blind, randomised, multi-centre, placebo-controlled efficacy and safety studies in adolescents 12 years and older (and adults) with persistent asthma previously treated with low-dose inhaled corticosteroids 2) Double-blind, randomised, multi-centre, placebo-controlled efficacy and safety studies in adolescents 12 years and older (and adults) with persistent asthma previously treated with medium-dose inhaled corticosteroids 3) Double-blind, randomised, multi-centre, parallel-group efficacy and safety studies in adolescents 12 years and older (and adults) with persistent asthma previously treated with high-dose inhaled corticosteroids
Clinical	Safety Study	1	1-year randomised, multi-centre, evaluator blinded safety study in adolescents 12 years and older (and adults) with persistent asthma
Clinical	Efficacy and safety	1	12 week randomised, multi-centre, evaluator blinded efficacy and safety study in adolescents 12 years and older (and adults) with persistent asthma

Clinical	Handling study	1	An open-label, multi-centre patient handling study in adolescents 12 years and older (and adults) with asthma or COPD
Clinical	Efficacy and safety	1	An evaluator-blinded, active-controlled, efficacy and safety study in the treatment of children (5 to less than 12 years) previously treated with inhaled corticosteroids
Clinical	Safety study	1	6-month, randomised, open-label, evaluator-blinded safety study of two doses in children (5 to less than 12 years) previously treated with medium- to high-dose inhaled corticosteroids
Clinical	Pharmacokinetic	1	A randomised, double-blind, multi-centre, cross-over study to compare the single dose bronchodilatory effect of formoterol fumarate in combination with mometasone furoate delivered via pressurised metered dose inhaler in children aged 5 to less than 12 years old with persistent asthma.
Clinical	HPA axis study	1	A randomised, open-label, active-controlled evaluation of the effects of MF/F on HPA axis function in children aged 5 to less than 12 years old with persistent asthma.
Clinical	PK/PD study with spacer	1	A phase II study to evaluate the impact of a spacer device on the systemic exposure in paediatric subjects 5 to less than12 years of age

Need for long-term follow-up on any potential safety issues in relation to paediatric use: Yes
Date of completion of the paediatric investigation plan: June 2012
A deferral has been granted: Yes