European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 20 March 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for fluticasone propionate / formoterol fumarate (EMEA-000127-PIP01-07) 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 Mundipharma Research Ltd on 14 January 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 6 February 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 fluticasone propionate / formoterol fumarate, pressurised inhalation, 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, is hereby agreed.

Article 2

A deferral for fluticasone propionate / formoterol fumarate, pressurised inhalation, 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, is hereby granted.

Article 3

A waiver for fluticasone propionate / formoterol fumarate, pressurised inhalation, 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, is hereby granted.

Article 4

This decision is addressed to Mundipharma Research Ltd, Cambridge Science Park, Milton Road, Cambridge, CB4 0GW, United Kingdom.

Done at London, 20 March 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/57037/2009
EMEA-000127-PIP01-07

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

Scope of the application

Active substances:
Fluticasone propionate / formoterol fumarate

Condition(s):
Asthma

Pharmaceutical form(s):
Pressurised inhalation, suspension

Route(s) of administration:
Inhalation use

Name/corporate name of the PIP applicant:
Mundipharma Research Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Mundipharma Research Ltd submitted for agreement to the EMEA on 14 January 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 14 February 2008.

Supplementary information was provided by the applicant on 28 November 2008.

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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 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 Norwegian Paediatric Committee member 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 conditions 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, 06 February 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 COVERED BY THE WAIVER

A. CONDITION(S)

Asthma

B. WAIVER

- **Condition**

Asthma

The waiver applies to:

Preterm newborn infants, term newborn infants (from birth to less than 28 days), infants and toddlers (from 28 days to less than 24 months), children from 2 to less than 5 years, for HFA pressurised metered dose inhaler (pMDI), inhalation use on the grounds that the specific medicinal product does not represent a significant therapeutic benefit.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Asthma

- **Proposed PIP indication**

For the treatment of asthma where the combination use of an inhaled corticosteroid (ICS) and long acting beta-2-agonist (LABA) is appropriate, for:
- asthma patients not adequately controlled with ICS and "as needed" inhaled short-acting beta-2-agonist,
- asthma patients already adequately controlled on both ICS and LABA.

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

From 5 years to less than 18 years

- **Formulation(s)**

HFA pressurised metered dose inhaler (pMDI), Inhalation use
fluticasone propionate 50 mcg plus formoterol fumarate 5 mcg per actuation

- **Studies**

Area	Number of studies	Description
Clinical	1	An open-label, single dose, parallel group study to determine the systemic exposure of fluticasone propionate plus formoterol fumarate pMDI in adolescent and adult subjects with mild to moderate asthma
	1	An open, randomised, parallel group, multicentre efficacy and safety study in adolescent and adult subjects with mild to moderate-severe persistent asthma.
	1	An open, randomised, active controlled, multicentre efficacy and safety study in children aged 4 to less than 12 years with mild to moderate

		persistent asthma
	1	A randomized, double blind, active controlled, multicentre efficacy and safety study in paediatric subjects aged 4 to less than 12 years with moderate to severe persistent asthma.

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By December 2013**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**