EMA/441528/2011

European Medicines Agency decision

P/157/2011

of 4 July 2011

on the acceptance of a modification of an agreed paediatric investigation plan for fluticasone propionate / formoterol fumarate dihydrate (EMEA-000127-PIP01-07-M01) 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/39/2009 issued on 20 March 2009,

Having regard to the application submitted by Mundipharma Research Ltd on 7 March 2011 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 20 May 2011, 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 fluticasone propionate / formoterol fumarate dihydrate, pressurised inhalation, suspension, inhalation 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 Mundipharma Research Ltd, Cambridge Science Park, Milton Road, CB4 0GW – Cambridge, United Kingdom.

Done at London, 4 July 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/257462/2011

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

EMEA-000127-PIP01-07-M01

Scope of the application

Active substance(s):

Fluticasone propionate / formoterol fumarate dihydrate

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 22 of Regulation (EC) No 1901/2006 as amended, Mundipharma Research Ltd submitted to the European Medicines Agency on 7 March 2011 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/39/2009 issued on 20 March 2009.
The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 23 March 2011.

A meeting with the Paediatric Committee took place on 18 May 2011.

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, 20 May 2011

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:

Asthma

The waiver applies to:

- all subsets of the paediatric population from birth to less than 5 years of age,
- for HFA pressurised metered dose inhaler (pMDI), inhalation use,
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit.

2. Paediatric Investigation Plan

2.1. Condition:

Asthma

2.1.1. Indication(s) targeted by the PIP

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.

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)

HFA pressurised metered dose inhaler (pMDI),

fluticasone propionate 50 mcg plus formoterol fumarate 5 mcg per actuation.

2.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.

Clinical	4	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. 2. An open, randomised, parallel group, multicentre efficacy and safety study in adolescent and adult subjects with mild to moderate-severe persistent asthma. 3. 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. 4. A randomized, double blind, active controlled, multicentre efficacy and safety study in paediatric subjects aged 5 to less than 12 years with moderate to severe persistent asthma.

3. Follow-up, completion and deferral of PIP

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