EMA/624740/2014

European Medicines Agency decision

P/0297/2014

of 24 November 2014

on the acceptance of a modification of an agreed paediatric investigation plan for fluticasone propionate / formoterol fumarate (Flutiform and associated names) (EMEA-000127-PIP01-07-M03) 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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An agency of the European Union

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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, the decision P/157/2011 issued on 4 July 2011, and the decision P/252/2011 issued on 26 October 2011,

Having regard to the application submitted by Mundipharma Research Limited on 7 August 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 10 October 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[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 (Flutiform and associated names), pressurised inhalation, suspension, inhalation use, including changes to the deferral, 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 Limited, Cambridge Science Park, Milton Road, CB4 0GW – Cambridge, United Kingdom.

Done at London, 24 November 2014

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

EMA/PDCO/503664/2014

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

EMEA-000127-PIP01-07-M03

Scope of the application

Active substance(s):

Fluticasone propionate / formoterol fumarate

Invented name:

Flutiform and associated names

Condition(s):

Treatment of asthma

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Pressurised inhalation, suspension

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Mundipharma Research Limited

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, Mundipharma Research Limited submitted to the European Medicines Agency on 7 August 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/39/2009 issued on 20 March 2009, the decision P/157/2011 issued on 4 July 2011, and the decision P/252/2011 issued on 26 October 2011.

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

The procedure started on 16 September 2014.

Scope of the modification

Some measures and timelines 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 and to the deferral 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, 10 October 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 (PIP)

1. Waiver

1.1. Condition:

Treatment of asthma

The waiver applies to:

- all subsets of the paediatric population from birth to less than 5 years of age;
- for pressurised inhalation, suspension, inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit.

2. Paediatric investigation plan

2.1. Condition:

Treatment of asthma

2.1.1. Indication(s) targeted by the PIP

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)

Pressurised inhalation, suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1:** Development of lower strength HFA pressurised metered dose inhaler (pMDI), appropriate to the paediatric population.
Non-clinical studies	0	Not applicable.

Clinical studies	4	**Study 2:** 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. **Study 3:** An open, randomised, parallel group, multicentre efficacy and safety study in adolescent and adult subjects with mild to moderate-severe persistent asthma. **Study 4:** 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. **Study 5:** 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.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2014
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of asthma

Authorised indication(s):

The fixed-dose combination of fluticasone propionate and formoterol fumarate (invented name) is indicated in the regular treatment of asthma where the use of a combination product (an inhaled corticosteroid (ICS) and a long-acting-beta2-agonist (LABA) is appropriate:

- for patients not adequately controlled with inhaled corticosteroid and "as required" inhaled sort-acting-beta2-agonist

or

- for patients already adequately controlled on both an inhaled corticosteroid and a long-acting-beta2-agonist.

Flutiform 50mcg/5mcg & Flutiform 125mcg/5mcg per actuation is indicated in adults and adolescents

Flutiform 250mcg/10mcg per actuation is indicated in adults only

Authorised pharmaceutical form(s):

Pressurised inhalation, suspension

Authorised route(s) of administration:

Inhalation use