EMA/324470/2018

European Medicines Agency decision

P/0159/2018

of 15 June 2018

on the acceptance of a modification of an agreed paediatric investigation plan for beclometasone (dipropionate) / formoterol (fumarate dihydrate) (Foster and associated names, Kantos and associated names, Inuvair and associated names, Kantos Master and associated names), (EMEA-000548-PIP01-09-M08) 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/88/2010 issued on 1 June 2010, the decision P/192/2011 issued on 3 August 2011, the decision P/0046/2012 issued on 29 February 2012, the decision P/0177/2012 issued on 17 August 2012, the decision P/0041/2013 issued on 25 February 2013, the decision P/0291/2013 issued on 29 November 2013, the decision P/0001/2017 issued on 5 January 2017 and the decision P/0320/2017 issued on 31 October 2017,

Having regard to the application submitted by Chiesi Farmaceutici S.p.A. on 2 February 2018 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 27 April 2018, 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 beclometasone (dipropionate) / formoterol (fumarate dihydrate) (Foster and associated names, Kantos and associated names, Inuvair and associated names, Kantos Master and associated names), pressurised inhalation, solution, inhalation powder, 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 Chiesi Farmaceutici S.p.A., via Palermo 26/A, 43122 – Parma, Italy.

EMA/PDCO/87641/2018
London, 27 April 2018

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

EMEA-000548-PIP01-09-M08

Scope of the application

Active substance(s):

Beclometasone (dipropionate) / formoterol (fumarate dihydrate)

Invented name:

Foster and associated names

Kantos and associated names

Inuvair and associated names

Kantos Master and associated names

Condition(s):

Treatment of asthma

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Pressurised inhalation, solution

Inhalation powder

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Chiesi Farmaceutici S.p.A.

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, Chiesi Farmaceutici S.p.A. submitted to the European Medicines Agency on 2 February 2018 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/88/2010 issued on 1 June 2010, the decision P/192/2011 issued on 3 August 2011, the decision P/0046/2012 issued on 29 February 2012, the decision P/0177/2012 issued on 17 August 2012, the decision P/0041/2013 issued on 25 February 2013, the decision P/0291/2013 issued on 29 November 2013, the decision P/0001/2017 issued on 5 January 2017 and the decision P/0320/2017 issued on 31 October 2017.

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

The procedure started on 27 February 2018.

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 Norwegian Paediatric Committee member agrees 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.

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:

- the paediatric population from birth to less than 6 years of age;
- pressurised inhalation, solution, inhalation powder, inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: treatment of asthma

2.1.1. Indication(s) targeted by the PIP

Maintenance therapy of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting beta2-agonist;
- patients already adequately controlled on both inhaled corticosteroids and long-acting beta2-agonists.

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Pressurised inhalation, solution (pMDI)

Inhalation powder (DPI)

Beclometasone dipropionate plus formoterol fumarate dihydrate 100 µg + 6 µg per actuation, pMDI

Beclometasone dipropionate plus formoterol fumarate dihydrate 100 µg + 6 µg per actuation, DPI

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	0	*Study 1 deleted in procedure EMEA-000548-PIP01-09-M06* *Study 2 deleted in procedure EMEA-000548-PIP01-09-M08*
Non-clinical studies	0	Not applicable

Clinical studies	7	**Study 3:** Open, randomized, 2-way crossover, single dose PK study in asthmatic children aged 5 years to less than 12 years (Paed 1 – pMDI) **Study 4:** Multicentre, randomised, double blind, 12 week, active-controlled, 3-arm parallel group efficacy and safety study in asthmatic children aged 5 years to less than 12 years (Paed 2 – pMDI) **Study 5:** Multicentre, randomised, double blind, single dose, placebo and active controlled, 5-period cross-over study to evaluate the dose-related bronchodilator effect in asthmatic children aged 5 years to less than 12 years (Paed 3– pMDI) **Study 6:** Open, randomized, 2-way crossover, single dose PK study in asthmatic children aged 5 years to less than 12 years (Paed 4 – DPI/R) Study 7 *deleted in procedure EMEA-000548-PIP01-09-M08* Study 8 *deleted in procedure EMEA-000548-PIP01-09-M08* **Study 9:** Single-center, knemometry study in asthmatic children aged 5 years to less than 12 years (pMDI-50/6-KNE) ***Study 10:*** *deleted in procedure EMEA-000548-PIP01-09-M06* **Study 11:** Open, randomized, 3-way crossover, single dose PK/PD study in asthmatic adolescents 12 to less than 18 years (and adults) (pMDI-100/6-ADO) **Study 12:** Open, randomized, 2-way crossover, single dose PK/PD study in Asthmatic adolescents 12 to less than 18 years (and adults) (DPI-100/6-ADO)

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 April 2018
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 indications: Regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate:

   - Patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting beta2-agonist or;
   - Patients already adequately controlled on both inhaled corticosteroids and long-acting beta2-agonists.

   (Adults only)

Authorised pharmaceutical form(s):

Pressurised inhalation, solution

Inhalation powder

Authorised route(s) of administration:

Inhalation use