EMA/335695/2010

# European Medicines Agency decision

P/88/2010

of 1 June 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver 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) 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 application submitted by Chiesi Farmaceutici S.p.A. on 27 March 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 April 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 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 agreeing 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 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, 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 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, 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 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, 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 Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma, 43100, Italy.

Done at London, 1 June 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/213490/2010

# Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-000548-PIP01-09

## Scope of the application

**Active substance(s):**

Beclometasone dipropionate / formoterol fumarate dihydrate

**Invented name(s):**

Foster and associated names

Kantos and associated names

Inuvair and associated names

Kantos Master and associated names

**Condition(s):**

Asthma

**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 16(1) of Regulation (EC) No 1901/2006 as amended, Chiesi Farmaceutici S.p.A. submitted for agreement to the European Medicines Agency on 27 March 2009 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 30 April 2009.

Supplementary information was provided by the applicant on 5 February 2010.

A meeting with the Paediatric Committee took place on 18 March 2010.

## 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 Icelandic and the Norwegian Paediatric Committee members agree 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 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, 16 April 2010

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(s) covered by the waiver

# 1. Condition(s)

Asthma

# 2. Waiver

## *2.1. Condition*

Asthma

The waiver applies to:

- The paediatric population from birth to less than 5 years of age
- for
  - pressurised inhalation, solution
  - inhalation powder
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

# 3. Paediatric Investigation Plan

## *3.1. Condition to be investigated*

Asthma

### 3.1.1. Indication 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 or
- patients already adequately controlled on both inhaled corticosteroids and long-acting beta2-agonists.

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

From 5 years to less than 18 years of age.

### 3.1.3. Pharmaceutical forms

Pressurised inhalation, solution (pMDI)

Inhalation powder (DPI)

Beclometasone dipropionate plus formoterol fumarate dihydrate 50 µg + 6 µg per actuation, pMDI

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

Beclometasone dipropionate plus formoterol fumarate dihydrate 50 µg + 6 µg per actuation, DPI

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

## 3.1.4. Studies

| Area | Number of studies | Description |
|---|---|---|
| Quality | Total number of quality studies | Development of an age-appropriate strength:<br>- Beclometasone dipropionate (BDP) plus formoterol fumarate dihydrate (FF) 50 + 6 µg per actuation, pMDI<br>- Beclometasone dipropionate plus formoterol fumarate dihydrate 50 µg + 6 µg per actuation, DPI |
| Non-clinical | Total number of studies | Not applicable |
| Clinical | Total number of studies | 1) Open, randomized, 2-way crossover, single dose PK study in asthmatic children aged 5 years to less than 12 years (Paed 1 – pMDI)<br>2) 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)<br>3) 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)<br>4) Open, randomized, 2-way crossover, single dose PK study in asthmatic children aged 5 years to less than 12 years (Paed 4 – DPI)<br>5) 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 5 – DPI)<br>6) 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 6 – DPI)<br>7) Single-center, knemometry study in asthmatic children aged 5 years to less than 12 years (pMDI-50/6-KNE)<br>8) Single-center, knemometry study in asthmatic children aged 5 years to less than 12 years (DPI-50/6-KNE)<br>9) 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)<br>10) Open, randomized, 2-way crossover, single dose PK/PD study in |

| Area | Number of studies | Description |
|---|---|---|
| | | Asthmatic adolescents 12 to less than 18 years (and adults) (DPI-100/6-ADO) |

# 4. 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 October 2014 |
| Deferral for one or more studies contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

| EU Number | Invented name<br><br>Name | Strength | Pharmaceutical form | Route of administration | Packaging | Content (concentration) | Package size |
|---|---|---|---|---|---|---|---|
| N/A | Foster and associated names<br><br>Kantos and associated names<br><br>Inuvair and associated names<br><br>Kantos Master and associated names | 100 µg + 6 µg per actuation | Pressurised inhalation, solution | Inhalation use | | | |