EMA/285017/2012

European Medicines Agency decision

P/0105/2012

Of 4 June 2012

on the acceptance of a modification of an agreed paediatric investigation plan for tiotropium bromide (monohydrate) (Spiriva Respimat and associated names, Spiriva), (EMEA-000035-PIP01-07-M05) 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/61/2008 issued on 15 August 2008, the decision P/25/2010 issued on 3 March 2010, the decision P/194/2010 issued on 26 October 2010, and the decision P/295/2011 issued on 20 December 2011,

Having regard to the application submitted by Boehringer Ingelheim International GmbH on 27 February 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 May 2012, 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 tiotropium bromide (monohydrate) (Spiriva Respimat and associated names, Spiriva), solution for inhalation, inhalation powder, hard capsule, 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 Boehringer Ingelheim International GmbH, Binger Str. 173, 55216 - Ingelheim am Rhein, Germany.

Done at London, 4 June 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/158824/2012

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

EMEA-000035-PIP01-07-M05

Scope of the application

Active substance(s):

Tiotropium bromide (monohydrate)

Invented name:

Spiriva Respimat and associated names

Spiriva

Condition(s):

Treatment of Cystic fibrosis

Authorised indication(s):

See Annex II

Pharmaceutical forms:

Solution for inhalation

Inhalation powder, hard capsule

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Boehringer Ingelheim International GmbH

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, Boehringer Ingelheim International GmbH submitted to the European Medicines Agency on 27 February 2012 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/61/2008 issued on 15 August 2008, the decision P/25/2010 issued on 3 March 2010, the decision P/194/2010 issued on 26 October 2010, and the decision P/295/2011 issued on 20 December 2011.

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

The procedure started on 19 March 2012.

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 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.

London, 16 May 2012

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: treatment of Cystic fibrosis

The waiver applies to:

- infants less than one year of age;
- for solution for inhalation via the Respimat inhaler, inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for inhalation powder, hard capsules, 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 Cystic fibrosis

2.1.1. Indication(s) targeted by the PIP

Long-term, once-daily, maintenance treatment of bronchospasm associated with cystic fibrosis.

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

From 1 year to less than 18 years of age.

2.1.2. Pharmaceutical form(s)

Solution for inhalation via the Respimat inhaler.

2.1.3. Studies

Area	Subarea	Number	Description
Clinical	Handling study	1	Handling study to assess the use of the device in children below 5 years of age.
Clinical	PK, safety and tolerability	1	Multi-centre, randomized study investigating the safety, tolerability and pharmacokinetics of single and multiple doses in children and adolescents 5 years and older (and adults).
Clinical	Dose ranging study	1	Multi-centre, randomized, double-blind, placebo-controlled study to assess efficacy, safety and tolerability in children and adolescents 5 years and older (and adults).

Area	Subarea	Number	Description
Clinical	Efficacy and safety	1	Multi-centre, randomized, double-blind, placebo-controlled study to assess efficacy and safety in children and adolescents 5 years and older (and adults). Toddlers and children 1-5 years will be included for safety assessment only.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2012
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

Treatment of chronic obstructive pulmonary disease (COPD)

Authorised indications:

Tiotropium is indicated as a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD).

Invented name	Strength	Pharmaceutical form	Route of administration
Spiriva Respimat	2.5 micro-gram per puff	Solution for inhalation	Inhalation use
Spiriva	18 micro-gram	Inhalation powder, hard capsule	Inhalation use