EMA/472512/2012

European Medicines Agency decision

P/0184/2012

of 21 August 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for indacaterol (acetate) / mometasone (furoate) (EMEA-001217-PIP01-11) 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 Novartis Europharm Limited on 5 December 2011 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 6 July 2012, 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 indacaterol (acetate) / mometasone (furoate), inhalation powder, hard capsule, 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 indacaterol (acetate) / mometasone (furoate), inhalation powder, hard capsule, 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 indacaterol (acetate) / mometasone (furoate), inhalation powder, hard capsule, 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 Novartis Europharm Limited, Wimblehurst Road, Horsham, RH12 5AB – Horsham, United Kingdom.

Done at London, 21 August 2012

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

EMA/PDCO/309943/2012

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

EMEA-001217-PIP01-11

Scope of the application

Active substance(s):

Indacaterol (acetate) / mometasone (furoate)

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Inhalation powder, hard capsule

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted for agreement to the European Medicines Agency on 5 December 2011 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 12 January 2012.

Supplementary information was provided by the applicant on 23 April 2012. The applicant proposed modifications to the paediatric investigation plan.

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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 Norwegian Paediatric Committee member agrees 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 annex(es) and appendix.

Langen, Germany, 6 July 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 asthma

The waiver applies to:

- All subsets of the paediatric population from birth to less than 6 years of age;
- for inhalation powder, hard capsule, 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

Treatment of persistent asthma.

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)

Inhalation powder, hard capsule.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1** Open label, uncontrolled trial to investigate the inhalation flow profiles generated through Concept1, Diskus, Turbuhaler and Handihaler in children from 6 to less than 18 years of age (and in adults) with asthma.
Non-clinical	0	Not applicable.

Area	Number of studies	Description
Clinical	6	**Study 2** Double-blind, double-dummy, randomised, multiple dose, parallel-group active controlled trial to evaluate the efficacy and safety of two doses of mometasone furoate, delivered via Concept1 or Twisthaler, in children from 12 to less than 18 years of age with persistent asthma. **Study 3** Double-blind, randomised, multiple dose, parallel-group active controlled trial to evaluate PK and PD, safety and tolerability of indacaterol acetate in children from 6 to less than 12 years of age with asthma. **Study 4** Double blind, double-dummy, randomised, multiple dose, parallel group active controlled trial to demonstrate superiority of indacaterol acetate 150 µg with low dose mometasone furoate over mometasone furoate 200 µg in children from 12 to less than 18 years of age (and in adults) with asthma. **Study 5** Double-blind, double dummy, randomised, multiple dose, parallel group active controlled trial to demonstrate superiority of indacaterol acetate 150 µg with high dose mometasone furoate once daily over mometasone furoate 400 µg twice daily in children from 12 to less than 18 years of age (and in adults) with asthma. **Study 6** Double-blind, double dummy, randomised, multiple dose, parallel group active controlled trial to demonstrate superiority of indacaterol acetate 150 µg with medium dose mometasone furoate over mometasone furoate 400 µg in children from 12 to less than 18 years of age (and in adults) with asthma. **Study 7** Double-blind, triple-dummy, randomised, multiple dose, parallel-group active controlled, multicentre trial to evaluate the efficacy and safety of indacaterol acetate/mometasone furoate in children from 6 to less than 12 years of age with asthma.

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 October 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes