EMA/75528/2018

European Medicines Agency decision

P/0057/2018

of 16 March 2018

on the acceptance of a modification of an agreed paediatric investigation plan for indacaterol (acetate) / mometasone (furoate) (EMEA-001217-PIP01-11-M04) 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/0184/2012 issued on 21 August 2012, the decision P/0193/2015 issued on 4 September 2015, the decision P/0104/2016 issued on 15 April 2016 and the decision P/0141/2017 issued on 7 June 2017,

Having regard to the application submitted by Novartis Europharm Limited on 6 November 2017 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 26 January 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.

(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 indacaterol (acetate) / mometasone (furoate), 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 Novartis Europharm LTD., Frimley Business Park, GU16 7SR – Camberley, United Kingdom.

EMA/PDCO/736542/2017
London, 26 January 2018

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

EMEA-001217-PIP01-11-M04

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 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the European Medicines Agency on 6 November 2017 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/0184/2012 issued on 21 August 2012, the decision P/0193/2015 issued on 4 September 2015, the decision P/0104/2016 issued on 15 April 2016 and the decision P/0141/2017 issued on 7 June 2017.

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

The procedure started on 28 November 2017.

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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 annex 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:

- all subsets of the paediatric population from birth to less than 6 years of age;
- 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. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Open label, uncontrolled trial to investigate the inhalation flow profiles generated through Concept1 inhaler in children from 6 to less than 18 years of age with asthma.
Non-clinical studies	0	Not applicable.
Clinical studies	5	**Study 2** Double-blind, double-dummy, randomised, multiple dose, parallel-group active-controlled trial to evaluate efficacy and safety and pharmacokinetics of two doses of mometasone (furoate), delivered via Concept1 or Twisthaler in terms of non-inferiority in children from 12 to less than 18 years of age (and in adults) with persistent asthma.

		Study 3 Double-blind, randomised, multiple dose, parallel-group, active-controlled trial to evaluate PK and PD, safety and tolerability of different doses 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 evaluate efficacy and safety of indacaterol (acetate) / mometasone (furoate) compared to mometasone (furoate) in terms of superiority in children from 12 to less than 18 years of age (and in adults) with asthma. Study 5 Deleted in procedure EMEA-001217-PIP01-11-M01 Study 6 Deleted in procedure EMEA-001217-PIP01-11-M01 **Study 7** Double-blind, triple-dummy, randomised, multiple dose, parallel-group, active-controlled trial to evaluate efficacy and safety of indacaterol (acetate) / mometasone (furoate) compared to mometasone (furoate) in terms of superiority and to salmeterol / fluticasone in terms of non-inferiority in children from 6 to less than 12 years of age with asthma. **Study 8** Double blind, triple-dummy, randomised, multiple dose, parallel group, active-controlled trial to evaluate efficacy and safety of indacaterol (acetate) / mometasone (furoate) compared to mometasone (furoate) in terms of superiority and to salmeterol / fluticasone in terms of non-inferiority in children from 12 to less than 18 years of age (and in adults) with 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 issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By October 2020
Deferral for one or more studies contained in the paediatric investigation plan:	Yes