MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100102-PIP01-21-M01)

MHRA-100102-PIP01-21-M02

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 Pharmaceuticals UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Novartis Pharmaceuticals UK Limited submitted to the licensing authority on 31/01/2023 13:19 GMT an application for a Modification

The procedure started on 25/05/2023 15:35 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100102-PIP01-21-M02

Of 12/06/2023 10:40 BST

On the adopted decision for INDACATEROL ACETATE; MOMETASONE FUROATE (MHRA-100102-PIP01-21-M02) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for INDACATEROL ACETATE; MOMETASONE FUROATE, Inhalation powder, hard capsule , INHALATION USE .

This decision is addressed to Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, UNITED KINGDOM, W12 7FQ

ANNEX I

1. Waiver

1.1 Condition:

Treatment of asthma The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Inhalation powder, hard capsule Route(s) of administration: INHALATION USE Reason for granting waiver: 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(s):

Treatment of asthma

2.2 Indication(s) targeted by the PIP:

Treatment of persistent asthma

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

The paediatric population from 6 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Inhalation powder, hard capsule

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Open label, uncontrolled trial to investigate the inhalation flow profiles generated through Concept1 inhaler in children from 6 years 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 the efficacy and safety and pharmacokinetics of two doses of mometasone (furoate), delivered via Concept1 or Twisthaler, in children from 12 years to less than 18 years of age (and in adults) with persistent asthma. Study 3 (CQMF149G2202) 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 years to less than 12 years of age with asthma. Study 4 (CQVM149B2303) Double blind, double dummy, randomised, 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 years 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 (CQVM149B2301) Double-blind, randomised, active controlled, two way crossover , two period, two treatment (indacaterol acetate/mometasone furoate versus budesonide) study, with 12 weeks treatment duration each, to evaluate the efficacy and safety of indacaterol acetate/mometasone furoate compared to budesonide in terms of superiority in children from 6 years to less than 12 years of age with asthma. Study 8 (CQVM149B2301) Double-blind, triple-dummy, randomised, multiple dose, parallel-group active controlled, to evaluate the 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 years to less than 18 years of age (and in adults) with asthma.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	31/08/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes