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 and to the deferral.

MHRA-101516-PIP01-24-M01

Scope of the Application

Active Substance(s)

FLUTICASONE FUROATE; VILANTEROL TRIFENATATE

Condition(s)

Treatment of asthma

Pharmaceutical Form(s)

Inhalation powder, pre-dispensed

Route(s) of Administration

INHALATION USE

Name / Corporate name of the PIP applicant

GlaxoSmithKline UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GlaxoSmithKline UK Limited submitted to the licensing authority on 09/07/2024 16:27 BST an application for a Modification

The procedure started on 27/09/2024 09:53 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 and to the deferral.

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-101516-PIP01-24-M01

Of 25/10/2024 07:09 BST

On the adopted decision for FLUTICASONE FUROATE; VILANTEROL TRIFENATATE (MHRA-101516-PIP01-24-M01) 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 FLUTICASONE FUROATE; VILANTEROL TRIFENATATE, Inhalation powder, pre-dispensed , INHALATION USE .

This decision is addressed to GlaxoSmithKline UK Limited, GSK House, 980 Great West Road, Brentford, Middlesex, UNITED KINGDOM, TW8 9GS

ANNEX I

1. Waiver

1.1 Condition:

Treatment of asthma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years of age. Pharmaceutical form(s): Inhalation powder, pre-dispensed Route(s) of administration: INHALATION USE Reason for granting waiver: On the grounds 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 asthma where use of a combination product (long acting beta agonist and inhaled corticosteroid) is appropriate.

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

The paediatric population from 5 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Inhalation powder, pre-dispensed

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	1	Study 16 Repeat dose toxicity and toxicokinetic study in the juvenile dog.
Clinical Studies	14	Studies in adolescents (12 years to less than 18 years of age) and adults: Study 1 12 week efficacy and safety study of low-dose fluticasone (furoate) / vilanterol combination in adolescent (and adult) subjects with persistent asthma. Study 2 12 week efficacy and safety study of high-dose fluticasone (furoate) / vilanterol combination in adolescent (and adult) subjects with persistent asthma. Study 3 12 week efficacy study for vilanterol (as an add-on to inhaled steroid) in adolescent (and adult) subjects with persistent asthma. Study 4 Long-term safety study of fluticasone (furoate) / vilanterol combination in adolescent (and adult) subjects with persistent asthma. Study 5 Exacerbation study of fluticasone (furoate) /vilanterol combination in adolescent (and adult) subjects with persistent asthma. Study 6 Efficacy study of low-dose fluticasone (furoate) in adolescent

		(and adult) subjects with persistent asthma.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Clinical studies continued: Studies in children (5 years to less than 12 years of age): Study 7 Repeat dose Pharmacokinetic (PK)/ Pharmacodynamic (PD), safety and tolerability study of fluticasone (furoate) in children 5 to less than 12 years of age with persistent asthma. Study 8 Dose ranging study of fluticasone (furoate) in children 5 to less than 12 years of age with persistent asthma. Study 9 PK/ PD, safety and tolerability study of vilanterol in children 5 to less than 12 years of age with persistent asthma. Study 10 Dose ranging study of vilanterol in children 5 to less than 12 years of age with persistent asthma. Study 11 PK/PD, safety and tolerability study of fluticasone (furoate)/vilanterol combination in children 5 to less than 12 years of age with persistent asthma. Study 12 Efficacy and safety study of fluticasone (furoate) /vilanterol combination in children 5 to less than 12 years of age with asthma. Study 13 Fluticasone (furoate) knemometry study in children 5 to less than 12 years of age with persistent asthma. Study 14 This study was deleted during procedure EMEA-000431-PIP01-08-M06. Study 15 Phase IV study to assess the effect of fluticasone (furoate) on growth velocity in pre-pubertal children with asthma.
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:	31/10/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes