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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-102479-PIP01-26

Scope of the Application

Active Substance(s)

FLUTICASONE FUROATE; UMECLIDINIUM BROMIDE; 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 11/05/2026 18:12 BST an application for a Paediatric Investigation Plan

The procedure started on 12/05/2026 17:04 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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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-102479-PIP01-26

Of 09/07/2026 16:43 BST

On the adopted decision for FLUTICASONE FUROATE; UMECLIDINIUM BROMIDE; VILANTEROL TRIFENATATE (MHRA-102479-PIP01-26) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for FLUTICASONE FUROATE; UMECLIDINIUM BROMIDE; VILANTEROL TRIFENATATE, Inhalation powder, pre-dispensed , INHALATION USE .

This decision is addressed to GlaxoSmithKline UK Limited, 79 New Oxford Street, London, UNITED KINGDOM, WC1A 1DG

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 12 years of age Pharmaceutical form(s): Inhalation powder, pre-dispensed 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 as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of asthma

2.2 Indication(s) targeted by the PIP:

Maintenance treatment of asthma in patients aged 12 years or older who have inadequately controlled asthma despite therapy with inhaled corticosteroids and long acting beta agonists.

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

The paediatric population from 12 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	0	Not applicable.
Clinical Studies	1	Study 1 (ARIA-206867) Double-blind, randomised study to evaluate the safety and efficacy and pharmacokinetics (PK) of fluticasone furoate (FF) / umeclidinium bromide (UMEC)/ vilanterol (VI) compared to FF/VI in adolescents form 12 years to less than 18 years of age with inadequately controlled asthma on stable maintenance therapy with inhaled corticosteroids (ICS) and long-acting # adrenoreceptor agonist (LABA).
Extrapolation, Modeling & Simulation Studies	1	Study 2 Extrapolation study to support the assessment of benefit: risk of FF/UMEC/VI for the treatment of asthma in adolescent subjects.
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:	30/06/2027

Deferral of one or more studies contained in the paediatric investigation plan:	Yes