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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-101687-PIP01-24-M01

Scope of the Application

Active Substance(s)

MEPOLIZUMAB

Condition(s)

Treatment of Hypereosinophilic Syndrome

Pharmaceutical Form(s)

Powder for solution for injection Solution for injection in pre-filled syringe

Route(s) of Administration

SUBCUTANEOUS 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 06/11/2024 14:27 GMT an application for a Modification

The procedure started on 18/12/2024 19:12 GMT

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-101687-PIP01-24-M01

Of 07/01/2025 11:00 GMT

On the adopted decision for MEPOLIZUMAB (MHRA-101687-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 MEPOLIZUMAB, Powder for solution for injection Solution for injection in pre-filled syringe , SUBCUTANEOUS USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Hypereosinophilic Syndrome. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age. Pharmaceutical form(s): Powder for solution for injection Solution for injection in pre-filled syringe Route(s) of administration: SUBCUTANEOUS 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 Hypereosinophilic Syndrome.

2.2 Indication(s) targeted by the PIP:

Treatment of Hypereosinophilic Syndrome.

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

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

2.4 Pharmaceutical Form(s):

Powder for solution for injection Solution for injection in pre-filled syringe

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	2	Study 1, RSD 100P8V Fertility, early embryonic and embryo-foetal development in mice. Study 2, CD2003/01020/00 Pre- and postnatal development in Cynomolgus monkeys.
Clinical Studies	1	Study 3 A 52-week, open-label multi-centre study of the efficacy and safety of mepolizumab administered in children 6 years of age to less than 18 years of age with hypereosinophilic syndrome.
Extrapolation, Modeling & Simulation Studies	3	Study 4 Modelling and simulation study, to support the use of mepolizumab in children 6 years of age to less than 18 years of age with hypereosinophilic syndrome. Study 5 Modelling prediction study to support the use of mepolizumab in children 6 years of age to less than 18 years of age with hypereosinophilic syndrome. Study 6 Extrapolation study, to support the use of mepolizumab in children 6 years of age to less than 18 years of age with hypereosinophilic syndrome.
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:	31/10/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes