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-102020-PIP01-25-M01

Scope of the Application

Active Substance(s)

TEZEPELUMAB

Condition(s)

Treatment of Asthma

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

AstraZeneca UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Limited submitted to the licensing authority on 15/07/2025 16:13 BST an application for a Modification

The procedure started on 30/07/2025 12:50 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-102020-PIP01-25-M01

Of 05/08/2025 09:55 BST

On the adopted decision for TEZEPELUMAB (MHRA-102020-PIP01-25-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 TEZEPELUMAB, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to AstraZeneca UK Limited, Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, UNITED KINGDOM, CB2 0AA

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): Solution for injection 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 over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of asthma.

2.2 Indication(s) targeted by the PIP:

Reduction of the frequency of asthma exacerbations in children and adolescent patients (5 to 17 years) with uncontrolled asthma despite the daily use of controller medications described in Step 4 or Step 5 of the Global Initiative for Asthma (GINA) Guidelines.

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):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	4	Study 1 Open-label, single-dose study to evaluate the pharmacokinetic (PK) profile of tezepelumab in adolescent subjects 12 to less than 18 years with asthma requiring daily controller medications. Study 2 Double-blind study to evaluate the efficacy and safety of tezepelumab in adolescents 12 to less than 18 years (and adults) with uncontrolled asthma requiring daily controller medications (Step 4 or Step 5 of the GINA guidelines). Study 3 deleted during procedure EMEA001613-PIP01-14-M02. Study 4 Open-label study to evaluate the pharmacokinetic (PK) profile of single dose of tezepelumab 70 mg SC in children aged 5 to 11 years with mild, moderate or severe asthma requiring daily controller medications. Study 5 Double-blind study to evaluate the efficacy and safety of tezepelumab in children 5 to less than 12 years with uncontrolled asthma requiring daily controller medications.

Extrapolation, Modeling & Simulation Studies	1	Study 6 Modelling and simulation study for selection of dose and dose regimen in children 5 to less than 12 years.
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:	30/09/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes