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-102138-PIP01-25

Scope of the Application

Active Substance(s)

3-(1-(2-((S)-2-(3-Cyclopropyl-4-fluorophenyl)-3-(3-(4-fluoro-1-methyl-1H-indazol-5-yl)-2-oxo-2,3-dihydro-1H-imidazol-1-yl)-4-methyl-4,5,6,7-tetrahydro-2H-pyrazolo[4,3-c]pyridine-5-carbonyl)-7-((S)-2,2-dimethyltetrahydro-2Hpyran-4-yl)indolizin-3-yl)cyclopropyl)-1,2,4-oxadiazol-5(4H)-one

Condition(s)

Treatment of type 2 diabetes mellitus

Pharmaceutical Form(s)

Tablet Age-appropriate formulation for oral use

Route(s) of Administration

ORAL 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 19/09/2025 21:01 BST an application for a Paediatric Investigation Plan

The procedure started on 04/11/2025 14:00 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 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-102138-PIP01-25

Of 10/02/2026 17:00 GMT

On the adopted decision for 3-(1-(2-((S)-2-(3-Cyclopropyl-4-fluorophenyl)-3-(3-(4-fluoro-1-methyl-1H-indazol-5-yl)-2-oxo-2,3-dihydro-1H-imidazol-1-yl)-4-methyl-4,5,6,7-tetrahydro-2H-pyrazolo[4,3-c]pyridine-5-carbonyl)-7-((S)-2,2-dimethyltetrahydro-2Hpyran-4-yl)indolizin-3-yl)cyclopropyl)-1,2,4-oxadiazol-5(4H)-one; (AZD5004) (MHRA-102138-PIP01-25) 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 3-(1-(2-((S)-2-(3-Cyclopropyl-4-fluorophenyl)-3-(3-(4-fluoro-1-methyl-1H-indazol-5-yl)-2-oxo-2,3-dihydro-1H-imidazol-1-yl)-4-methyl-4,5,6,7-tetrahydro-2H-pyrazolo[4,3-c]pyridine-5-carbonyl)-7-((S)-2,2-dimethyltetrahydro-2Hpyran-4-yl)indolizin-3-yl)cyclopropyl)-1,2,4-oxadiazol-5(4H)-one; (AZD5004), Tablet Age-appropriate formulation for oral use , ORAL USE .

This decision is addressed to AstraZeneca UK Limited, 2 Pancras Square, London, UNITED KINGDOM, N1C 4AG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of type 2 diabetes mellitus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 10 years of age Pharmaceutical form(s): Tablet Age-appropriate formulation for oral use Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of type 2 diabetes mellitus

2.2 Indication(s) targeted by the PIP:

Indicated in children aged 10 years and above for the treatment of insufficiently controlled T2DM as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance, and in addition to other medicinal products for the treatment of T2DM

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

The paediatric population from 10 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Tablet Age-appropriate formulation for oral use

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate formulation for oral use.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 Double-blind, randomised, placebo-controlled study to evaluate the efficacy, safety, and tolerability of AZD5004 in male and female children and adolescents aged from 10 years to less than 18 years of age with type 2 diabetes mellitus (T2DM).
Extrapolation, Modeling & Simulation Studies	1	Study 3 PopPK model for dose selection.
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:	No
Date of completion of the paediatric investigation plan:	31/12/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes