

**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-102132-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 obesity

#### 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 21:13 BST an application for a Paediatric Investigation Plan

The procedure started on 04/11/2025 13:54 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-102132-PIP01-25

Of 16/01/2026 08:48 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-102132-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 obesity The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 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 specific medicinal product does not represent a significant therapeutic benefit over existing treatments
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### 2. Paediatric Investigation Plan:

#### 2.1 Condition(s):

Treatment of obesity

## 2.2 Indication(s) targeted by the PIP:

As an adjunct to diet and exercise for weight management in adolescents from 12 years to less than 18 years of age with obesity (BMI  $\geq$  95th percentile for age and sex on age- and sex- specific growth charts) and in adolescents from 12 years to less than 18 years of age who are overweight (BMI  $\geq$  85th percentile for age and sex on age- and sex-specific growth charts) in the presence of at least one weight-related comorbidity. As an adjunct to diet and exercise for weight management in children from 6 years to less than 12 years of age with obesity (BMI  $\geq$  95th percentile for age and sex on age- and sex- specific growth charts)

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

The paediatric population from 6 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	2	Study 2 Double-blind, randomised, parallel-arm, placebo-controlled trial to evaluate the PK, efficacy, safety, and tolerability of AZD5004 compared to placebo as an adjunct to lifestyle intervention in adolescent from 12 years to less than 18 years of age with obesity or overweight and at least one weight-related comorbidity. Study 3 Double-blind, randomised, multiple-dose, placebo controlled trial to evaluate the PK, efficacy, safety, and tolerability of AZD5004 compared to placebo as an adjunct to lifestyle intervention in children from 6 years to less than 12 years of age with obesity.
Extrapolation, Modeling & Simulation Studies	1	Study 4 PopPK model for dose selection.

<b>Other Studies</b>	0	Not applicable.
<b>Other Measures</b>	0	Not applicable.

### 3. Follow-up, completion and deferral of a PIP:

<b>Concerns on potential long term safety and efficacy issues in relation to paediatric use:</b>	No
<b>Date of completion of the paediatric investigation plan:</b>	31/12/2036
<b>Deferral of one or more studies contained in the paediatric investigation plan:</b>	Yes