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-102136-PIP01-25

Scope of the Application

Active Substance(s)

Human amylin analogue, amylin receptor selective, long-acting, N-terminally lipidated (AZD6234)

Condition(s)

Treatment of obesity

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 19/09/2025 02:29 BST an application for a Paediatric Investigation Plan

The procedure started on 04/11/2025 13:28 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-102136-PIP01-25

Of 14/01/2026 18:59 GMT

On the adopted decision for Human amylin analogue, amylin receptor selective, long-acting, N-terminally lipidated (AZD6234) (MHRA-102136-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 Human amylin analogue, amylin receptor selective, long-acting, N-terminally lipidated (AZD6234), Solution for injection , SUBCUTANEOUS 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): 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 obesity

2.2 Indication(s) targeted by the PIP:

Adjunct to diet and exercise for chronic weight management in adolescents 12 to 18 years of age living with obesity (BMI $\geq$ 95th percentile for age and sex on age and sex-specific growth chart) or overweight (BMI $\geq$ 85th percentile for age and sex on age and sex-specific growth chart) in the presence of at least one weight-related comorbidity Adjunct to diet and exercise in children 6 to 12 years of age living with obesity (BMI $\geq$ 95th percentile for age and sex on age and sex-specific growth chart).

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):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate formulation of AZD6234.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	3	Study 2 Randomised, double-blind, parallel-arm, multicentre, placebo-controlled study to assess the pharmacokinetics (PK), efficacy, and safety of AZD6234 as an adjunct to lifestyle intervention in adolescents from 12 years to less than 18 years of age with obesity or overweight with at least one weight-related comorbidity. Study 3 Open-label study to assess the safety, tolerability, and PK of AZD6234 in children from 6 years to less than 12 years of age with obesity. Study 4 Randomised, double-blind, parallel-arm, multicentre, placebo-controlled study to assess the PK, efficacy, and safety of AZD6234 as an adjunct to lifestyle intervention in children from 6 years to less than 12 years of age with obesity.

Extrapolation, Modeling & Simulation Studies	2	Study 5 Population PK model and population PK/PD model to predict exposures and reduction of body weight to support dose selection for clinical Study 2. Study 6 Paediatric Population PK model and paediatric population PK/PD model exposure-response. to characterise the paediatric PK and to explore the exposure-response in paediatric participants to support paediatric dosing of AZD6234.
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:	31/12/2037
Deferral of one or more studies contained in the paediatric investigation plan:	Yes