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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-102112-PIP01-25

Scope of the Application

Active Substance(s)

Retatrutide

Condition(s)

Obesity

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Eli Lilly and Company Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Eli Lilly and Company Ltd submitted to the licensing authority on 22/09/2025 18:55 BST an application for a Paediatric Investigation Plan

The procedure started on 17/11/2025 17:58 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-102112-PIP01-25

Of 03/06/2026 17:01 BST

On the adopted decision for Retatrutide (MHRA-102112-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 Retatrutide, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Eli Lilly and Company Ltd, Lilly House, Basing View, Basingstoke, Basingstoke, UNITED KINGDOM, RG21 4FA

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:

Chronic Weight Management

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	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 1 (347412) Double-blind, randomised, placebo controlled, superiority trial to evaluate the safety, efficacy, and PK of retatrutide in adolescents from 12 years to less than 18 years of age with obesity or who are overweight and have related co-morbidities. Study 2 (332712) Double-blind, randomised, placebo controlled, superiority trial to evaluate the safety, efficacy, and PK of retatrutide in children from 6 years to less than 12 years of age with obesity.
Extrapolation, Modeling & Simulation Studies	2	Study 3 (465312) Population PK model to confirm the dose of retatrutide for paediatric participants from 12 years to less than 18 years of age with obesity or who are overweight and have related co-morbidities, that should achieve an exposure matched to that observed in adults with overweight or obesity. Study 4 (432112) Population PK model to confirm the dose of retatrutide in paediatric participants from 6 years to less than 12 years of age with obesity that should achieve an exposure matched to that observed in adolescents and adults with obesity.

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:	01/11/2035
Deferral of one or more studies contained in the paediatric investigation plan:	Yes