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-100820-PIP01-22-M03

Scope of the Application

Active Substance(s)

TIRZEPATIDE

Condition(s)

Treatment of obesity

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Eli Lilly Nederland

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Eli Lilly Nederland submitted to the licensing authority on 16/09/2025 16:37 BST an application for a Modification

The procedure started on 07/10/2025 13:15 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-100820-PIP01-22-M03

Of 04/12/2025 18:49 GMT

On the adopted decision for TIRZEPATIDE (MHRA-100820-PIP01-22-M03) 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 TIRZEPATIDE, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Eli Lilly Nederland, Papendorpseweg 83, Utrecht, NETHERLANDS, 3528 BJ

ANNEX I

1. Waiver

1.1 Condition:

Treatment of obesity The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to 6 years. Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: On the grounds 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	3	Study 1 (I8F-MC-GPHV) Randomised, double-blind, placebo-controlled study to assess the safety, tolerability and pharmacokinetics after 8 weeks of treatment with tirzepatide administered via the subcutaneous route in children from 6 years to less than 12 years of age with obesity. Study 2 (I8F-MC-GPHP) Randomised, double-blind, parallel-arm, multicentre, placebo-controlled trial to assess the efficacy, safety, and PK of tirzepatide as an adjunct to lifestyle intervention in adolescents aged 12 years to less than 18 years of age with obesity and overweight. Study 3 (J4M-MC-PW02) Randomised, double-blind, parallel arm, multicentre, placebo-controlled trial to assess the efficacy, safety and PK of tirzepatide 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 Population pharmacokinetic (PK) model to assist with dose finding in children from 6 years to less than 12 years 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:	31/08/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes