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-101826-PIP01-25

Scope of the Application

Active Substance(s)

Orforglipron

Condition(s)

Treatment of obesity

Pharmaceutical Form(s)

Capsules, hard Age-appropriate oral solid dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Eli Lilly and Company

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Eli Lilly and Company submitted to the licensing authority on 18/02/2025 14:03 GMT an application for a Paediatric Investigation Plan

The procedure started on 26/06/2025 15:10 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 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-101826-PIP01-25

Of 25/09/2025 21:05 BST

On the adopted decision for Orforglipron (MHRA-101826-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 Orforglipron, Capsules, hard Age-appropriate oral solid dosage form , ORAL USE .

This decision is addressed to Eli Lilly and Company, Lily House, Basing View, 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): Capsules, hard Age-appropriate oral solid dosage form 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.

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):

Capsules, hard Age-appropriate oral solid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral solid dosage form
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 Double-blind, randomised, multiple dose, placebo-controlled trial to evaluate pharmacokinetics, safety and efficacy of orforglipron compared to placebo in children from 12 years to less than 18 years of age with obesity or overweight. Study 3 Double-blind, randomised, multiple dose, placebo-controlled trial to evaluate pharmacokinetics, safety and efficacy of orforglipron compared to placebo in children from 6 years to less than 12 years of age with obesity.
Extrapolation, Modeling & Simulation Studies	1	Study 4 Population pharmacokinetic modelling exposure-response analysis to select the doses for the paediatric population from 6 years to less than 12 years of age and to confirm selected doses for the entire paediatric population.
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:	30/09/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes