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-101964-PIP01-25

Scope of the Application

Active Substance(s)

3-((1S,2S)-1-(5-((S)-2,2-dimethyltetrahydro-2H-pyran-4-yl)-2-((S)-3-(3-(4-fluoro-1-methyl-1H-indazol-5-yl)-2-oxo-2,3-dihydro-1H-imidazol-1-yl)-2-(4-fluoro-3,5-dimethylphenyl)-4-methyl-4,5,6,7-tetrahydro-2H-pyrazolo[4,3-c]pyridine-5-carbonyl)-1H-indol-1-yl)-2-methylcyclopropyl)-5-oxo-1,2,4-oxadiazol-4-ide hemicalcium; Orforglipron

Condition(s)

Treatment of type 2 diabetes mellitus

Pharmaceutical Form(s)

Capsule, hard

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 29/05/2025 19:18 BST an application for a Paediatric Investigation Plan

The procedure started on 20/08/2025 14:08 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-101964-PIP01-25

Of 07/10/2025 20:08 BST

On the adopted decision for Orforglipron (MHRA-101964-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, Capsule, hard , ORAL USE .

This decision is addressed to Eli Lilly and Company, Lilly House, Basing View, Basingstoke, UNITED KINGDOM, RG214FA

ANNEX I

1. Waiver

1.1 Condition:

Treatment of type 2 diabetes mellitus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 10 years of age Pharmaceutical form(s): Capsule, hard Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of type 2 diabetes mellitus

2.2 Indication(s) targeted by the PIP:

Treatment of type 2 diabetes mellitus

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

The paediatric population from 10 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Capsule, hard

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 Open-label, randomised, active controlled trial to evaluate pharmacokinetics, safety and efficacy of orforglipron compared to dulaglutide in children from 10 years to less than 18 years of age with type 2 diabetes mellitus.
Extrapolation, Modeling & Simulation Studies	1	Study 2 Modelling and simulation analyses, to evaluate the use of the product in the treatment of type 2 diabetes mellitus in children from 10 years to less than 18 years of age.
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:	30/09/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes