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 (MHRA-100578-PIP01-22-M01)

MHRA-100578-PIP01-22-M02

Scope of the Application

Active Substance(s)

SEMAGLUTIDE; Cagrilintide

Condition(s)

Treatment of obesity

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Novo Nordisk Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Novo Nordisk Limited submitted to the licensing authority on 18/12/2025 15:49 GMT an application for a Modification

The procedure started on 09/01/2026 12:30 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 accept change(s) to the agreed paediatric investigation plan

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-100578-PIP01-22-M02

Of 02/04/2026 10:58 BST

On the adopted decision for SEMAGLUTIDE; Cagrilintide (MHRA-100578-PIP01-22-M02) 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 SEMAGLUTIDE; Cagrilintide, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Novo Nordisk Limited, CMR, 3 City Place, Beehive Ring Road, Gatwick, UNITED KINGDOM, RH6 0PA

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 8 years of age. 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:

Weight management in children and adolescents from 8 years to less than 18 years of age.

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

The paediatric population from 8 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	2	Study 1 Dose range-finding juvenile toxicity study in C57BI/6J mice. Study 2 Definitive juvenile toxicity study in C57BI/6J mice.
Clinical Studies	1	Study 3 (NN9838-4968) A 68-week double-blinded, placebo and active-controlled, randomised, parallel-group, multi-national clinical study evaluating the PK, efficacy and safety of CagriSema (cagrilintide in fixed-dose combination with semaglutide) subcutaneous use (s.c.) versus semaglutide s.c. and placebo s.c., and cagrilintide s.c. versus placebo s.c., as an adjunct to a reduced-calorie diet and increased physical activity in children and adolescents from 8 years to less than 18 years of age with overweight and obesity.
Extrapolation, Modeling & Simulation Studies	1	Study 4 Population pharmacokinetic (pop-PK) dose finding modelling and simulation study.
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:	Yes

Date of completion of the paediatric investigation plan:	31/07/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes