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-101698-PIP01-24

Scope of the Application

Active Substance(s)

NNC0487-0111

Condition(s)

Treatment of obesity

Pharmaceutical Form(s)

Solution for injection, Tablet

Route(s) of Administration

SUBCUTANEOUS USE, ORAL 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 12/08/2025 21:10 BST an application for a Paediatric Investigation Plan

The procedure started on 02/09/2025 19:49 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-101698-PIP01-24

Of 03/02/2026 09:34 GMT

On the adopted decision for NNC0487-0111 (MHRA-101698-PIP01-24) 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 NNC0487-0111, Solution for injection, Tablet , SUBCUTANEOUS USE, ORAL 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 6 years of age Pharmaceutical form(s): Solution for injection Tablet Route(s) of administration: SUBCUTANEOUS USE 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:

Weight management

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

The paediatric population 6 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection Tablet

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 (NN9490-8216) Double-blinded, randomised, placebo-controlled, parallel-group, multi-centre study to evaluate the efficacy, safety and pharmacokinetics of NNC0487-0111 administered subcutaneously or orally, as an adjunct therapy in children and adolescents from 6 years to less than 18 years of age with obesity or overweight with at least one weight related comorbidity.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Population PK modelling analysis of NNC0487-0111 to support dose selection in children and adolescent population from 6 years to less than 18 years of age with obesity or overweight. Study 3 Population PK and exposure-response analyses of NNC0487-0111 in adults and the paediatric population from 6 years to less than 18 years of age to provide evidence that PK and efficacy of the lower oral dose levels investigated in adults are applicable also to children and adolescents with obesity or overweight.
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:	31/12/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes