MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100467-PIP01-22-M01

Scope of the Application

Active Substance(s)

SEMAGLUTIDE

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 Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Novo Nordisk Ltd submitted to the licensing authority on 21/03/2022 15:41 GMT an application for a Modification

The procedure started on 04/11/2022 17:33 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 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-100467-PIP01-22-M01

Of 25/11/2022 16:35 GMT

On the adopted decision for SEMAGLUTIDE (MHRA-100467-PIP01-22-M01) 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, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Novo Nordisk Ltd, 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 Route(s) of administration: Subcutaneous 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:

Treatment of obesity

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	2	Study 1 (NN9536-4451) Randomised, double-blind, placebo-controlled trial to evaluate the tolerability, safety and efficacy on weight management of semaglutide once-weekly versus placebo as an adjunct to a reduced-calorie diet and increased physical activity, in adolescents with overweight or obesity aged 12 years to less than 18 years. Study 2 (NN9536-4512) Long-term, randomised, double-blind, placebo-controlled trial to evaluate the tolerability, safety and efficacy on weight management of semaglutide once-weekly versus placebo as an adjunct to a reduced-calorie diet and increased physical activity in children with obesity aged 6 years to less than 12 years.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and Simulation Study. PK simulation in adolescent (12 years to less than 18 years) population based on population PK model of semaglutide in adults and previous liraglutide trials in paediatric population, to support dose selection of semaglutide in the paediatric target population.

		Study 4 Modelling and Simulation Study. PK simulation in children (6 years to less than 12 years) based on population PK model of semaglutide in adults and adolescents and previous liraglutide trials in the paediatric population, to support dose selection of semaglutide in the paediatric target 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:	Yes
Date of completion of the paediatric investigation plan:	30/06/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes