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-100287-PIP01-21

Scope of the Application

Active Substance(s)

SEMAGLUTIDE

Condition(s)

Treatment of obesity

Pharmaceutical Form(s)

Tablet

Route(s) of Administration

Oral 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 21/12/2021 15:30 GMT an application for a Paediatric Investigation Plan

The procedure started on 31/08/2022 07:34 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100287-PIP01-21

Of 09/12/2022 10:02 GMT

On the adopted decision for SEMAGLUTIDE (MHRA-100287-PIP01-21) 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 SEMAGLUTIDE, Tablet , Oral 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): Tablet 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:

Weight management in children and adolescents with obesity and/or overweight

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):

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 (NN9932-7562) Double-blind, randomised, parallel group, placebo-controlled, clinical study evaluating the safety, efficacy and acceptability of oral semaglutide once daily versus placebo in children and adolescents from 6 years to less than 18 years of age with obesity or overweight.
Extrapolation, Modeling & Simulation Studies	2	Study 2 (NN9932-7562) Population pharmacokinetic (PK) based simulation study to support dose selection in the expected paediatric study population of PIP clinical study 1. Study 3 Population PK model and exposure-response based on PIP clinical study 1 (NN9932-7562) and historical data from OASIS 1 (adult study), to support the dose in the target population of children and adolescents with obesity or overweight aged 6 years to less than 18 years.
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:	31/01/2031

Deferral of one or more studies contained in the paediatric investigation plan:	Yes