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-100405-PIP01-21-M01

Scope of the Application

Active Substance(s)

LIRAGLUTIDE

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 02/03/2022 12:37 GMT an application for a Modification

The procedure started on 14/11/2022 21:13 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-100405-PIP01-21-M01

Of 30/11/2022 20:26 GMT

On the adopted decision for LIRAGLUTIDE (MHRA-100405-PIP01-21-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 LIRAGLUTIDE, 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 2 years of age Pharmaceutical form(s): Solution for injection (prefilled pen) Route(s) of administration: SUBCUTANEOUS 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). Paediatric Subset(s): The paediatric population from 2 years to less than 6 years. Pharmaceutical form(s): Solution for injection (prefilled pen) 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	1	Study 1 A pre-filled pen or other device which can deliver a starting dose of 0.3 mg must be made available for paediatric use.
Non-Clinical Studies	1	Study 2 6-week juvenile repeat dose toxicity study in rats, preceded by dose range finding, to investigate potential harmful effects on the developing nervous system and on sexual maturation.
Clinical Studies	5	Study 3 Randomised, double-blind, placebo-controlled trial to evaluate tolerability, safety, pharmacokinetics and pharmacodynamics in obese children aged 12 years to less than 18 years and Tanner stages 2–5 pubertal development. Study 4 Randomised, double-blind, placebo-controlled, multicentre trial with a follow-up period off drug evaluating the efficacy and safety of liraglutide in conjunction with lifestyle modifications for weight loss (structured diet and exercise programme, counselling) in obese adolescents aged 12 years to less than 18 years and Tanner stages 2–5 pubertal development. Study 5 Randomised, double-blind,

		placebo-controlled trial to evaluate tolerability, safety, pharmacokinetics and pharmacodynamics in obese children aged 7 years to less than 12 years. Study 6 Randomised, double-blind, placebo-controlled, multicentre trial with an open-label and follow-up period evaluating the efficacy and safety of liraglutide in conjunction with lifestyle modifications for weight loss (structured diet and exercise programme, counselling) in obese children with Prader Willi Syndrome (PWS). Study 7 Randomised, double-blind, placebo-controlled, multicentre trial with an open-label and follow-up period evaluating the efficacy and safety of liraglutide in obese children, aged 6 years to less than 12 years and Tanner stage below 2 or with premature adrenarche.
Extrapolation, Modeling & Simulation Studies	0	Not applicable
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:	30/06/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes