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-100275-PIP01-21

Scope of the Application

Active Substance(s)

SEMAGLUTIDE

Condition(s)

Treatment of non-alcoholic steatohepatitis (NASH)

Pharmaceutical Form(s)

Solution for injection in pre-filled pen

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 17/11/2021 15:22 GMT an application for a Paediatric Investigation Plan

The procedure started on 07/03/2022 12:23 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 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-100275-PIP01-21

Of 21/03/2022 16:58 GMT

On the adopted decision for SEMAGLUTIDE (MHRA-100275-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, Solution for injection in pre-filled pen , 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 non-alcoholic steatohepatitis (NASH) 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 in pre-filled 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 non-alcoholic steatohepatitis (NASH)

2.2 Indication(s) targeted by the PIP:

Treatment of non-alcoholic steatohepatitis (NASH) in children and adolescents aged 8 years to less than 18 years old

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 in pre-filled pen

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 Double-blind, randomised, parallel group, placebo-controlled multi-national, safety and efficacy clinical study of semaglutide in children and adolescents aged 8 years to less than 18 years with NASH and liver fibrosis. (NN9931-XXXX)
Extrapolation, Modeling & Simulation Studies	1	Study 2 Modelling and simulation study to evaluate the use of semaglutide in children and adolescents aged 8 years to less than 18 years with NASH and liver fibrosis.
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:	31/01/2035
Deferral of one or more studies contained in the paediatric investigation plan:	Yes