EMA/351981/2023

European Medicines Agency decision

P/0347/2023

of 8 September 2023

on the acceptance of a modification of an agreed paediatric investigation plan for semaglutide (Wegovy), (EMEA-001441-PIP07-21-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0481/2022 issued on 2 December 2022,

Having regard to the application submitted by Novo Nordisk A/S on 23 May 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 July 2023, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for semaglutide (Wegovy), tablet, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0095/2015 issued on 8 May 2015, the decision P/0217/2016 issued on 12 August 2016 and the decision P/0007/2019 issued on 3 January 2019, including subsequent modifications thereof.

Article 3

This decision is addressed to Novo Nordisk A/S, Novo Allé 1, 2880 – Bagsværd, Denmark.

EMA/PDCO/267262/2023
Amsterdam, 21 July 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001441-PIP07-21-M01

Scope of the application

Active substance(s):

Semaglutide

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of obesity

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novo Nordisk A/S

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novo Nordisk A/S submitted to the European Medicines Agency on 23 May 2023 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0481/2022 issued on 2 December 2022.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 10 July 2023.

Scope of the modification

Administrative modification to link this PIP to other agreed PIPs for this active substance.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion;

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of obesity

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- tablet, oral use;
- 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:

Treatment of obesity

2.1.1. Indication(s) targeted by the PIP

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

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1** 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. (N9932-7562)
Modelling and simulation studies	**Study 2** Population pharmacokinetic (PK)-based simulation study to support dose selection in the expected paediatric study population of PIP clinical study 1 (NN9932-7562).

	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 than18 years of age.
Other studies	Not applicable
Extrapolation plan	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By January 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of type 2 diabetes mellitus (3 mg, 7 mg and 14 mg)
2. Treatment of obesity

Authorised indication(s):

1. Treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise;

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- in combination with other medicinal products for the treatment of diabetes.

2. Treatment of adults as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of

- · ≥30 kg/m2 (obesity), or
- · ≥27 kg/m2 to <30 kg/m2 (overweight) in the presence of at least one weight-related comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease

Treatment of adolescents (≥12 years) as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adolescents ages 12 years and above with

• obesity* and

• body weight above 60 kg.

Invented name(s):

1. Rybelsus
2. Wegovy

Authorised pharmaceutical form(s):

1. Tablet
2. Solution for injection (injection)

Authorised route(s) of administration:

1. Oral use
2. Subcutaneous use
   - Authorised via centralised procedure