EMA/521852/2021

European Medicines Agency decision

P/0461/2021

of 29 October 2021

on the acceptance of a modification of an agreed paediatric investigation plan for semaglutide (Ozempic), (EMEA-001441-PIP03-17-M02) 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.

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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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0007/2019 issued on 3 January 2019, and decision P/0326/2019 issued on 10 September 2019,

Having regard to the application submitted by Novo Nordisk A/S on 4 June 2021 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 10 September 2021, 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 and to the deferral.

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

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for semaglutide (Ozempic), solution for injection in pre-filled pen, subcutaneous use, including changes to the deferral, 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 is addressed to Novo Nordisk A/S, Novo Allé 1, 2880 – Bagsværd, Denmark.

EMA/PDCO/346611/2021
Amsterdam, 10 September 2021

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

EMEA-001441-PIP03-17-M02

Scope of the application

Active substance(s):

Semaglutide

Invented name:

Ozempic

Condition(s):

Treatment of obesity

Authorised indication(s):

See Annex II

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 A/S

Information about the authorised medicinal product:

See Annex II

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 4 June 2021 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/0007/2019 issued on 3 January 2019, and decision P/0326/2019 issued on 10 September 2019.

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

The procedure started on 12 July 2021.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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 paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member 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;
- solution for injection, subcutaneous 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

Treatment of obesity

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 1** Randomised, double-blind, placebo-controlled trial to evaluate the tolerability, safety and efficacy of semaglutide once-weekly versus placebo as an adjunct to a reduced-calorie diet and increased physical activity, in adolescents with overweight or obesity, 12 to less than 18 years of age (NN9536-4451).

		Study 2 Long-term, randomised, double-blind, placebo-controlled trial to evaluate the tolerability, safety and efficacy of semaglutide once-weekly versus placebo as an adjunct to a reduced-calorie diet and increased physical activity, in children with obesity aged 6 to less than 12 years (NN9536-4512).
Extrapolation, modelling and simulation studies	2	**Study 3** Modelling and Simulation Study. PK simulation in adolescent (12 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 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 PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

Treatment of type 2 diabetes mellitus

Authorised indication(s):

- Ozempic is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise;
- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications;
- in addition to other medicinal products for the treatment of diabetes.

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Subcutaneous use