EMA/512494/2023 Corr.[1]

European Medicines Agency decision

P/0468/2023

of 1 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for liraglutide (Saxenda), (EMEA-000128-PIP02-09-M05) 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.

[1] 21 May 2024.

European Medicines Agency decision

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on the acceptance of a modification of an agreed paediatric investigation plan for liraglutide (Saxenda), (EMEA-000128-PIP02-09-M05) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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[2],

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[3],

Having regard to the European Medicines Agency's decision P/0084/2012 issued on 21 May 2012, the decision P/0086/2015 issued on 8 May 2015, the decision P/0154/2016 issued on 15 June 2016, the decision P/0383/2019 issued on 4 December 2019, and the decision P/0309/2021 issued on 13 August 2021,

Having regard to the application submitted by Novo Nordisk A/S on 29 June 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 13 October 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.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for liraglutide (Saxenda), solution for injection, subcutaneous 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/105/2008 issued on 28/11/2008, including subsequent modifications thereof.

Article 3

This decision is addressed to Novo Nordisk A/S, Novo Alle, DK-2880 – Bagsværd, Denmark.

EMA/PDCO/322744/2023 Corr.[1]
Amsterdam, 13 October 2023

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

EMEA-000128-PIP02-09-M05

Scope of the application

Active substance(s):

Liraglutide

Invented name and authorisation status:

See Annex II

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 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 29 June 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/0084/2012 issued on 21 May 2012, the decision P/0086/2015 issued on 8 May 2015, the decision P/0154/2016 issued on 15 June 2016, the decision P/0383/2019 issued on 4 December 2019, and the decision P/0309/2021 issued on 13 August 2021.

[1] 21 May 2024.

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

The procedure started on 14 August 2023.

Scope of the modification

Some measures 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 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 2 years of age;
- for solution for injection, subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

and to:

- the paediatric population from 2 years to less than 6 years of age;
- for 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 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** *This study was deleted as a result of procedure EMEA-000128-PIP02-09-M05.*
Non-clinical studies	**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	**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, modelling and simulation studies	Not applicable.
Other studies	Not applicable.
Other measures	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 2024
Deferral for one or more studies 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 obesity

Authorised indication(s):

Adults

- Saxenda is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients 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 such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

  Treatment with Saxenda should be discontinued after 12 weeks on the 3.0 mg/day dose if patients have not lost at least 5% of their initial body weight.

Adolescents (≥12 years)

- Saxenda can be used as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescent patients from the age of 12 years and above with obesity (BMI corresponding to ≥30 kg/m2 for adults by international cut-off points)* and body weight above 60 kg.

  Treatment with Saxenda should be discontinued and re-evaluated if patients have not lost at least 4% of their BMI or BMI z score after 12 weeks on the 3.0 mg/day or maximum tolerated dose.

  - Invented name(s): Saxenda
  - Authorised pharmaceutical form(s): Solution for injection
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via centralised procedure