EMA/380505/2016

European Medicines Agency decision

P/0154/2016

of 15 June 2016

on the acceptance of a modification of an agreed paediatric investigation plan for liraglutide (Saxenda) (EMEA-000128-PIP02-09-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/0084/2012 issued on 21 May 2012 and the decision P/0086/2015 issued on 8 May 2015,

Having regard to the application submitted by Novo Nordisk A/S on 5 February 2016 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 29 April 2016, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for liraglutide (Saxenda), solution for injection (pre-filled pen), 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 agreed paediatric investigation plan 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 November 2008, including subsequent modifications thereof.

Article 3

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

Done at London, 15 June 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/136717/2016
London, 29 April 2016

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

EMEA-000128-PIP02-09-M02

Scope of the application

Active substance(s):

Liraglutide

Invented name:

Saxenda

Condition(s):

Treatment of obesity

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection (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

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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 5 February 2016 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 and the decision P/0086/2015 issued on 8 May 2015.

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

The procedure started on 1 March 2016.

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 to the paediatric investigation plan 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 2 years of age;
- for solution for injection (prefilled pen), for 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 to less than 6 years of age;
- for solution for injection (prefilled pen), for 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 (prefilled pen)

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	1	**Study 1** A prefilled pen or other device which can deliver discrete dosages 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 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 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 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 to less than 12 years and Tanner stage below 2 or with premature adrenarche.
Extrapolation, modelling and simulation studies	0	Not applicable.
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 August 2023
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

Condition(s) and authorised indication(s):

1. Treatment of obesity

Authorised indications:

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 (obese), or
- ≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Subcutaneous use