EMA/459439/2017

European Medicines Agency decision

P/0218/2017

of 9 August 2017

on the acceptance of a modification of an agreed paediatric investigation plan for liraglutide (Victoza), (EMEA-000128-PIP01-07-M08) 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/105/2008 of 28 November, the decision P/108/2010 of 21 June 2010, the decision P/288/2010 issued on 22 December 2010, the decision P/102/2011 issued on 3 May 2011, the decision P/0122/2012 issued on 4 July 2012, the decision P/0003/2013 on 21 January 2013, the decision P/0318/2014 issued on 19 December 2014 and the decision P/0176/2016 issued on 1 July 2016,

Having regard to the application submitted by Novo Nordisk A/S on 31 March 2017 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 23 June 2017, 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 (Victoza), solution for injection in prefilled 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 decision is addressed to Novo Nordisk A/S, Novo Nordisk A/S, Novo Alle, DK-2880 - Bagsvaerd, Denmark.

EMA/PDCO/230855/2017
London, 23 June 2017

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

EMEA-000128-PIP01-07-M08

Scope of the application

Active substance(s):

Liraglutide

Invented name:

Victoza

Condition(s):

Treatment of type 2 diabetes mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection in prefilled 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 31 March 2017 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/105/2008 of 28 November, the decision P/108/2010 of 21 June 2010, the decision P/288/2010 issued on 22 December 2010, the decision P/102/2011 issued on 3 May 2011, the decision P/0122/2012 issued on 4 July 2012, the decision P/0003/2013 on 21 January 2013, the decision P/0318/2014 issued on 19 December 2014 and the decision P/0176/2016 issued on 1 July 2016.

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

The procedure started on 25 April 2017.

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 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 type 2 diabetes mellitus

The waiver applies to:

- children less than 10 years;
- for liraglutide 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.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of type 2 diabetes mellitus

2.1.1. Indication(s) targeted by the PIP

Treatment of type 2 diabetes mellitus

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

From 10 to less than 18 years

2.1.3. Pharmaceutical form(s)

Solution for injection (in prefilled pen), for subcutaneous use

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical	2	Study 1: A pharmacokinetic / pharmacodynamic trial in paediatric patients with type 2 diabetes (NN2211-1800). Study 2: Efficacy and safety trial in paediatric patients with type 2 diabetes (NN2211-3659).

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 issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By January 2019
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):

1. Treatment of type 2 diabetes mellitus

Authorised indications:

Victoza is indicated for treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with:

- Metformin or a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin or sulphonylurea.
- Metformin and a sulphonylurea or metformin and a thiazolidinedione in patients with insufficient glycaemic control despite dual therapy.

2. 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
  - $\geq$ 30 kg/m^2 (obese), or
  - $\geq$ 27 kg/m^2 to < 30 kg/m^2 (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.

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.

Authorised pharmaceutical formulation(s):

Solution for injection in pre-filled pen

Authorised route(s) of administration:

Subcutaneous use