EMA/19766/2013

European Medicines Agency decision

P/0003/2013

of 21 January 2013

on the acceptance of a modification of an agreed paediatric investigation plan for liraglutide (Victoza), (EMEA-000128-PIP01-07-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.

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on the acceptance of a modification of an agreed paediatric investigation plan for liraglutide (Victoza), (EMEA-000128-PIP01-07-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[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 issued on 28 November 2008, the decision P/108/2010 issued on 21 June 2010, the decision P/288/2010 issued on 22 December 2010, the decision P/102/2011 issued on 3 May 2011, and the decision P/0122/2012 issued on 4 July 2012,

Having regard to the application submitted by Novo Nordisk A/S on 17 September 2012 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 7 December 2012, 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 Alle, 2880 – Bagsværd, Denmark.

Done at London, 21 January 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/609554/2012

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

EMEA-000128-PIP01-07-M05

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 17 September 2012 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 issued on 28 November 2008, the decision P/108/2010 issued on 21 June 2010, the decision P/288/2010 issued on 22 December 2010, the decision P/102/2011 issued on 3 May 2011, and the decision P/0122/2012 issued on 4 July 2012.

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

The procedure started on 10 October 2012.

Scope of the modification

Some measures and timelines of the original Opinion 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 Icelandic and the Norwegian Paediatric Committee members agree 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 annex(es) and appendix.

London, 7 December 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

1. Waiver

1.1. Condition: Treatment of type 2 diabetes mellitus

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. Studies

Area	Number of studies	Description
Quality	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.
Clinical	2	Study 2: A pharmacokinetic / pharmacodynamic trial in paediatric patients with type 2 diabetes (NN2211-1800). Study 3: Efficacy and safety trial in paediatric patients with type 2 diabetes (NN2211-3659).

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 May 2016.
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.

Authorised pharmaceutical formulation(s):

Solution for injection in pre-filled pen

Authorised route(s) of administration:

Subcutaneous use