EMA/247793/2011

European Medicines Agency decision

P/102/2011

of 3 May 2011

on the acceptance of a modification of an agreed paediatric investigation plan for liraglutide (Victoza) (EMEA-000128-PIP01-07-M03) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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 issued on 28 November 2008, the decision P/108/2010 issued on 21 June 2010, and the decision P/288/2010 issued on 22 December 2010,

Having regard to the application submitted by Novo Nordisk A/S on 10 January 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on London, 18 March 2011, 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, 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, 3 May 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/43679/2011

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

EMEA-000128-PIP01-07-M03

Scope of the application

Active substance(s):

Liraglutide

Invented name:

Victoza

Condition(s):

Type 2 diabetes mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection, 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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 10 January 2011 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, and the decision P/288/2010 issued on 22 December 2010.

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

The procedure started on 19 January 2011.

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 member(s) do agree with the above-mentioned recommendation of the Paediatric Committee.

   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, 18 March 2011

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. Condition(s)

Type 2 diabetes mellitus

2. Waiver

2.1. Condition: Type 2 diabetes mellitus

2.1.1. Indication

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.

3. Paediatric Investigation Plan

3.1. Condition to be investigated: Type 2 diabetes mellitus

3.1.1. Indication(s) (authorised and planned)

- 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.
- Triple treatment with liraglutide + metformin + basal insulin in adults with type 2 diabetes mellitus.

3.1.2. Indication targeted by the PIP:

Treatment of type 2 diabetes mellitus

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

From 10 to less than 18 years.

3.1.4. Pharmaceutical form(s)

Liraglutide solution for injection, prefilled pen, for subcutaneous use

3.1.5. Studies

Area	# of studies	Description
Quality	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	A pharmacokinetic / pharmacodynamic trial in paediatric patients with type 2 diabetes (NN2211-1800). Multicentre, 14-week, double-blind, randomised, parallel-group, placebo-controlled clinical trial of liraglutide in children treated with metformin for type 2 diabetes, followed by an open-label extension of at least 38 weeks.

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By November 2015
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):

1. 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.

EU Number	Invented Name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/09/529/001	Victoza	6 mg/ml	Solution for injection in pre-filled pen	Subcutaneous use	cartridge (glass) in pre-filled pen	3.0 ml	1 pre-filled pen
EU/1/09/529/002	Victoza	6 mg/ml	Solution for injection in pre-filled pen	Subcutaneous use	cartridge (glass) in pre-filled pen	3.0 ml	2 pre-filled pens
EU/1/09/529/003	Victoza	6 mg/ml	Solution for injection in pre-filled pen	Subcutaneous use	cartridge (glass) in pre-filled pen	3.0 ml	3 pre-filled pens
EU/1/09/529/004	Victoza	6 mg/ml	Solution for injection in pre-filled pen	Subcutaneous use	cartridge (glass) in pre-filled pen	3.0 ml	5 pre-filled pens
EU/1/09/529/005	Victoza	6 mg/ml	Solution for injection in pre-filled pen	Subcutaneous use	cartridge (glass) in pre-filled pen	3.0 ml	10 pre-filled pens