European Medicines Agency

Doc. Ref. EMEA/625240/2008
P/105/2008

EUROPEAN MEDICINES AGENCY DECISION

of 28 November 2008

on the application for agreement of a Paediatric Investigation Plan for liraglutide EMEA-000128-PIP01-07 in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

EUROPEAN MEDICINES AGENCY DECISION

of 28 November 2008

on the application for agreement of a Paediatric Investigation Plan for liraglutide EMEA-000128-PIP01-07 in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 application submitted by Novo Nordisk A/S on 9 January 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 November 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency, following a re-examination procedure of the Paediatric Committee's opinion according to art. 25(3) of Regulation (EC) No 1901/2006 as amended, has given a positive opinion,

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan,

(3) It is therefore appropriate to adopt a Decision granting a waiver,

(4) It is therefore appropriate to adopt a Decision granting a deferral.

HAS ADOPTED THIS DECISION:

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

Article 1

A Paediatric Investigation Plan for liraglutide, solution for injection, prefilled, subcutaneous use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A waiver for liraglutide, solution for injection, prefilled, subcutaneous use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A deferral for liraglutide, solution for injection, prefilled, subcutaneous use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

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

Done at London, 28 November 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

EMEA/PDCO/517080/2008
EMEA-000128-PIP01-07

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR (AFTER RE-EXAMINATION)

Scope of the application

Active substance:
Liraglutide

Condition(s):
Type 2 diabetes mellitus

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

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Novo Nordisk A/S submitted for agreement to the EMEA on 9 January 2008 a paediatric investigation plan for the above mentioned medicinal product.

An Opinion was adopted by the Paediatric Committee on 29 August 2008 for the above mentioned product. Novo Nordisk A/S received the Paediatric Committee Opinion on 3 September 2008.

On 29 September 2008 Novo Nordisk A/S submitted to the EMEA a written request, including detailed grounds for re-examination of the Opinion.

The re-examination procedure started on 16 October 2008.

A meeting with the Paediatric Committee took place on 12 November 2008.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 40
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for the re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, revises its opinion and recommends, as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended,
- to grant a deferral in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended,
- to grant a waiver for one or more subsets of the paediatric population, in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, and concluded in accordance with Article 11(1)(b) of Regulation (EC) No 1901/2006 as amended, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets.

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 agreed paediatric investigation plan and the subset of the paediatric population and condition covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex(es) and appendix.

London, 14 November 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN AND THE SUBSET OF THE PAEDIATRIC POPULATION AND CONDITION COVERED BY THE WAIVER

A. CONDITION(S)

Type 2 diabetes mellitus

B. WAIVER

- **Condition**

  Type 2 diabetes mellitus

  - **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

    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.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

  Type 2 diabetes mellitus

- **Proposed PIP indication**

  Treatment of type 2 diabetes mellitus

- **Subset(s) of the paediatric population concerned by the paediatric development**

  From 10 to less than 18 years

- **Formulation(s)**

  Liraglutide solution for injection, prefilled pen, for subcutaneous use

- **Studies**

Area	Subarea	# of studies	Description
Quality	formulation	-	A prefilled pen or other device which can deliver discrete dosages of 0.3 mg must be made available for paediatric use.
Clinical	PK/PD	1	Two part randomised, double-blind, placebo-controlled pharmacokinetic / pharmacodynamic trial in paediatric and adult patients with type 2 diabetes.
Clinical	Safety and efficacy	1	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.

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 April 2013**
Deferral for initiation of some or all studies contained in the paediatric investigation plan:	**Yes**
Deferral for completion of some or all studies contained in the paediatric investigation plan:	**Yes**