EMA/314402/2014

European Medicines Agency decision

P/0172/2014

of 11 July 2014

on the acceptance of a modification of an agreed paediatric investigation plan for insulin detemir (Levemir), (EMEA-000412-PIP01-08-M01) 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/269/2010 issued on 26 November 2010,

Having regard to the application submitted by Novo Nordisk A/S on 5 May 2014 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 May 2014, 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 insulin detemir (Levemir), solution for injection, 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 Allé, DK-2880 – Bagsværd, Denmark.

Done at London, 11 July 2014

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

EMA/PDCO/274185/2014

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

EMEA-000412-PIP01-08-M01

Scope of the application

Active substance(s):

Insulin detemir

Invented name:

Levemir

Condition(s):

Treatment of type I diabetes mellitus

Treatment of type II diabetes mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

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 May 2014 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/269/2010 issued on 26 November 2010.

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

The procedure started on 21 May 2014.

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 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 annexes and appendix.

London, 23 May 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 (PIP)

1. Waiver

1.1. Condition: treatment of type I diabetes mellitus

The waiver applies to:

- children from birth to less than one year of age;
- solution for injection, subcutaneous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

1.2. Condition: treatment of type II diabetes mellitus

The waiver applies to:

- children from birth to less than 10 years of age;
- solution for injection, 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 I diabetes mellitus

2.1.1. Indication(s) targeted by the PIP

Treatment of type I diabetes mellitus

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

From 1 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.

Area	Number of studies	Description
Clinical studies	3	**Study 1:** 52-Week, Multinational, Multi-Centre, Open-Labelled, Randomised, Parallel, Efficacy and Safety Comparison of Insulin Detemir and NPH Insulin in Children and Adolescents 2-16 years with Type 1 Diabetes on a Basal-Bolus Regimen with Insulin Aspart as Bolus Insulin (NN304-1689) **Study 2:** 52-Week, Multinational, Multi-Centre, Open-Labelled Extension Trial of Insulin Detemir in Children and Adolescents 3-17 years with Type 1 Diabetes on a Basal-Bolus Regimen with Insulin Aspart as Bolus Insulin (NN304-1690) **Study 3:** 6 + 6-month multi-national, multi-centre, open-label, randomised, parallel-group study comparing the efficacy and safety of insulin degludec (IDeg) and insulin detemir, both in combination with mealtime insulin aspart, in children and adolescents with type 1 diabetes mellitus, aged 1 to less than 18 years of age (NN1250-3561)
Extra-polation, modelling and simulation studies	1	**Study 4:** PK modelling study in children from 1 to less than 18 years of age, compared to adults, all with type 1 diabetes mellitus.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition: treatment of type II diabetes mellitus

2.2.1. Indication(s) targeted by the PIP

Treatment of type II diabetes mellitus

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

From 10 to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Solution for injection

2.2.4. Measures

Area	Number of studies	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	3	Study 1: same as for condition “treatment of type I diabetes mellitus” Study 2: same as for condition “treatment of type I diabetes mellitus” Study 3: same as for condition “treatment of type I diabetes mellitus”
Extra-polation, modelling and simulation studies	2	Study 4: same as for condition “treatment of type I diabetes mellitus” **Study 5:** Extrapolation and modelling study, to extend efficacy results in adults with type 2 diabetes mellitus and children and adolescents with type 1 diabetes mellitus, to children and adolescents with type 2 diabetes mellitus.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety /efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By July 2013
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):

Treatment of diabetes mellitus

Authorised indication(s):

- treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Subcutaneous use