EMA/441093/2016

European Medicines Agency decision

P/0217/2016

of 12 August 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for semaglutide (EMEA-001441-PIP02-15) 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 application submitted by Novo Nordisk on 8 June 2015 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 June 2016, in accordance with Article 18 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

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

Has adopted this decision:

Article 1

A paediatric investigation plan for semaglutide, tablet, oral 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 deferral for semaglutide, tablet, oral 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 waiver for semaglutide, tablet, oral 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, Vandtaarnsvej 108-110, 2860 – Soeborg, Denmark.

EMA/PDCO/262054/2016
London, 24 June 2016

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-001441-PIP02-15

Scope of the application

Active substance(s):

Semaglutide

Condition(s):

Treatment of type 2 diabetes mellitus

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novo Nordisk

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Novo Nordisk submitted for agreement to the European Medicines Agency on 8 June 2015 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 14 July 2015.

Supplementary information was provided by the applicant on 1 April 2016. The applicant proposed modifications to the paediatric investigation plan.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 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:

- the paediatric population from birth to less than 10 years;
- tablet, oral 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(s).

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 of age

2.1.3. Pharmaceutical form(s)

Tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	5	**Study 1** *(This study is the same as study 1 (14725-070) of semaglutide EMEA-001441-PIP01-13 for the SC formulation, P/0095/2015 of 8 May 2015 and subsequent modifications thereof).* In *vitro* binding study to evaluate the potency of GLP-1 agonists semaglutide, exenatide and liraglutide on the rat GPL-1 receptor.

Area	Number of measures	Description
		Study 2 *(This study is the same as study 2 (214276) of semaglutide EMEA-001441-PIP01-13 for the SC formulation, P/0095/2015 of 8 May 2015 and subsequent modifications thereof).* Dose range-finding juvenile toxicity study to evaluate the influence of daily subcutaneous administration of semaglutide on the developing organism. **Study 3** *(This study is the same as study 3 (*214479*) of semaglutide EMEA-001441-PIP01-13 for the SC formulation, P/0095/2015 of 8 May 2015 and subsequent modifications thereof).* Definitive juvenile toxicity study in the rat to evaluate the influence of daily subcutaneous administration of semaglutide on the developing organism. **Study 4** Exploratory toxicity study with the excipient SNAC only. To assess the toxicity of SNAC and its possible subclinical effects on non-standard biochemical and morphological parameters after 13 weeks repeat dosing to Sprague-Dawley (CD) rats. **Study 5** Carcinogenicity study with the excipient SNAC only. To assess the carcinogenic potential and toxicokinetics of SNAC, an oral absorption enhancer, when administered orally to Sprague-Dawley rats for up to 104 weeks.
Clinical studies	1	**Study 6** Randomised, 52-week, double-blind, parallel-group, placebo-controlled trial to evaluate the efficacy, safety and pharmacokinetics of semaglutide in paediatric patients from 10 to less than 18 years of age with type 2 diabetes mellitus as adjunct to diet and exercise and metformin, with or without concomitant basal insulin or diet and exercise and basal insulin alone.
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/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes