EMA/399460/2016

European Medicines Agency decision

P/0227/2016

of 26 August 2016

on the acceptance of a modification of an agreed paediatric investigation plan for dulaglutide (Trulicity), (EMEA-000783-PIP01-09-M04) 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/37/2011 issued on 24 January 2011, the decision P/0039/2014 issued on 5 March 2014, the decision P/0105/2015 issued on 29 April 2015, and the decision P/0017/2016 issued on 29 January 2016,

Having regard to the application submitted by Eli Lilly & Company on 7 March 2016 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 19 August 2016, 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 following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) Regulation (EC) No 1901/2006, 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 dulaglutide (Trulicity), solution for injection (pre-filled 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 Eli Lilly & Company, Erl Wood Manor, Sunninghill Road, GU20 6PH - Windlesham, Surrey, United Kingdom.

EMA/PDCO/474806/2016
London, 19 August 2016

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

EMEA-000783-PIP01-09-M04

Scope of the application

Active substance(s):

Dulaglutide

Invented name:

Trulicity

Condition(s):

Treatment of type 2 diabetes mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection (pre-filled pen)

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Eli Lilly & Company

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, Eli Lilly & Company submitted to the European Medicines Agency on 7 March 2016 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/37/2011 issued on 24 January 2011, the decision P/0039/2014 issued on 5 March 2014, the decision P/0105/2015 issued on 29 April 2015, and the decision P/0017/2016 issued on 29 January 2016.

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

An Opinion was adopted by the Paediatric Committee on 27 May 2016. Eli Lilly & Company received the Paediatric Committee Opinion on 7 June 2016.

On 7 July 2016 Eli Lilly & Company submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 21 July 2016.

A meeting with the Paediatric Committee took place on 18 August 2016.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

Final Opinion

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

1.1. to revise its opinion and

- to agree to the changes regarding the measures of the paediatric investigation plan in the scope set out in the Annex I of this opinion;

1.2. following re-examination, to amend the scope of the modifications of the paediatric investigation plan.

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 annexes 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:

- all subsets of the paediatric population from birth to less than 10 years of age;
- for solution for injection (pre-filled pen), 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(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)

Solution for injection (pre-filled pen)

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a pre-filled pen for subcutaneous use.
Non-clinical studies	2	**Study 2** Juvenile toxicity study to evaluate potential effects on sexual maturation, reproductive function, and neurobehavioural development and function in immature rats exposed to dulaglutide. **Study 3** Comparative analysis of the tumourigenic potential of dulaglutide versus liraglutide. Comparative analysis of affinity (IC50) and potency (EC50) for

		the GLP-1 receptor binding of dulaglutide versus liraglutide.
Clinical studies	1	**Study 4** Double blind, randomised, multi-centre, placebo-controlled superiority trial to evaluate pharmacokinetics, pharmacodynamics, safety and efficacy of dulaglutide in children from 10 to less than 18 years of age with open-label extension to evaluate safety.

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 June 2022
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. Treatment of type 2 diabetes mellitus

Authorised indication(s):

Trulicity is indicated in adults with type 2 diabetes mellitus to improve glycaemic control as:

- Monotherapy

When diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications.

- Add-on therapy

In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.

Authorised pharmaceutical form(s)

Solution for injection

Authorised route(s) of administration

Subcutaneous use