EMA/375056/2013

European Medicines Agency decision

P/0173/2013

of 30 July 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for 3-[[4-[(1S)-1-[4-(4-tert-butylphenyl)-3,5-dimethyl-phenoxy]-4,4,4-trifluorobutyl]benzoyl]amino]propanoic acid (EMEA-001237-PIP01-11) 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 Eli Lilly and Company on 5 December 2011 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 14 June 2013, 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 3-[[4-[(1S)-1-[4-(4-tert-butylphenyl)-3,5-dimethyl-phenoxy]-4,4,4-trifluorobutyl]benzoyl]amino]propanoic acid, 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 3-[[4-[(1S)-1-[4-(4-tert-butylphenyl)-3,5-dimethyl-phenoxy]-4,4,4-trifluorobutyl]benzoyl]amino]propanoic acid, 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 3-[[4-[(1S)-1-[4-(4-tert-butylphenyl)-3,5-dimethyl-phenoxy]-4,4,4-trifluorobutyl]benzoyl]amino]propanoic acid, 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 Eli Lilly and Company, Erl Wood Manor, Sunninghill Rd, GU20 6PH - Windlesham, Surrey, United Kingdom.

Done at London, 30 July 2013

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

EMA/PDCO/201574/2013

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

EMEA-001237-PIP01-11

Scope of the application

Active substance(s):

3-[[4-[(1S)-1-[4-(4-tert-butylphenyl)-3,5-dimethyl-phenoxy]-4,4,4-trifluorobutyl]benzoyl]amino]propanoic acid

Invented name:

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:

Eli Lilly and Company

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company submitted for agreement to the European Medicines Agency on 5 December 2011 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 12 January 2012.

Supplementary information was provided by the applicant on 22 March 2013. 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.

London, 14 June 2013

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. 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 tablet, for 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	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	Measure 1 Double-blind, placebo-controlled, randomised, multicentre, single dose trial to evaluate pharmacokinetics (PK), pharmacodynamics (PD) in paediatric patients from 10 to less than 18 years of age with type 2 diabetes mellitus. Measure 2 A 12-week, parallel design, double-blind, placebo-controlled, randomised, multicentre study with a single-arm extension up to 52 weeks to evaluate efficacy, safety and tolerability in paediatric patients from 10 to less than or equal to 21 years of age with type 2 diabetes mellitus, not optimally controlled on maximum tolerated doses of metformin.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes