EMA/37133/2011

European Medicines Agency decision

P/37/2011

of 24 January 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for GLP-1 analogue linked to human IgG4 Fc-fragment (LY2189265) (EMEA-000783-PIP01-09) 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 & Company on 14 December 2010 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 January 2011, 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, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) of Regulation (EC) No 1901/2006, 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 GLP-1 analogue linked to human IgG4 Fc-fragment (LY2189265), solution for injection in pre-filled pen, 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 deferral for GLP-1 analogue linked to human IgG4 Fc-fragment (LY2189265), solution for injection in pre-filled pen, 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 waiver for GLP-1 analogue linked to human IgG4 Fc-fragment (LY2189265), solution for injection in pre-filled pen, 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 by Eli Lilly & Company, Erl Wood Manor, Sunninghill Rd, GU20 6PH - Windlesham, Surrey, United Kingdom.

Done at London, 24 January 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/37133/2011

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation plan and a deferral and a waiver (after re-examination)

EMEA-000783-PIP01-09

Scope of the application

Active substance(s):

GLP-1 analogue linked to human IgG4 Fc-fragment (LY2189265)

Condition(s):

Treatment of Type 2 diabetes mellitus

Pharmaceutical form(s):

Solution for injection in pre-filled pen

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Eli Lilly & Company

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Eli Lilly & Company submitted for agreement to the European Medicines Agency on 14 December 2009 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.

An Opinion was adopted by the Paediatric Committee on 12 November 2010 for the above mentioned product. Eli Lilly & Company received the Paediatric Committee Opinion on 18 November 2010.

On 15 December 2010, Eli Lilly & Company submitted to the European Medicines Agency a written request, including detailed grounds for re-examination of the Opinion.

The procedure started on 21 January 2010.

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Supplementary information was provided by the applicant on 26 August 2010.

The re-examination procedure started on 22 December 2010.

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 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 Articles 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.

   1.2. To amend the measures 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 annex(es) and appendix(ces).

London, 14 January 2011

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 solution for injection in 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 in pre-filled pen

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Development of an auto-injector for subcutaneous use.
Non-clinical	0	Not applicable.
Clinical	2	Study 2 Double-blind, randomised, multi-centre, placebo-controlled trial to evaluate safety, pharmacokinetics and pharmacodynamics of LY2189265– in children from 10 to less than 18 years of age with type 2 diabetes mellitus. Study 3 Double blind, randomised, multi-centre, placebo-controlled superiority trial to evaluate safety and efficacy of LY2189265– 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

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 March 2020
Deferral for one or more studies contained in the paediatric investigation plan:	Yes