



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/304282/2012

European Medicines Agency decision P/0101/2012

of 30 May 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for poly (oxy-1,2-ethanediyl), α -hydro- ω -methoxy-, 28B-ester with 28B-(N6-carboxy-L-Lysine)-29B-L-prolineinsulin (human) (LY 2605541) (EMEA-001097-PIP01-10) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Eli Lilly and Company on 17 January 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 13 April 2012, in accordance with Article 18 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 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 poly (oxy-1,2-ethanediyl), α -hydro- ω -methoxy-, 28B-ester with 28B-(N6-carboxy-L-Lysine)-29B-L-prolineinsulin (human) (LY 2605541), solution for injection, 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 poly (oxy-1,2-ethanediyl), α -hydro- ω -methoxy-, 28B-ester with 28B-(N6-carboxy-L-Lysine)-29B-L-prolineinsulin (human) (LY 2605541), solution for injection, 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 poly (oxy-1,2-ethanediyl), α -hydro- ω -methoxy-, 28B-ester with 28B-(N6-carboxy-L-Lysine)-29B-L-prolineinsulin (human) (LY 2605541), solution for injection, 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 Eli Lilly and Company, Research Centre, Erl Wood Manor, Sunninghill Road, GU20 6PH – Windlesham, United Kingdom.

Done at London, 30 May 2012

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/64597/2012

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

EMA-001097-PIP01-10

Scope of the application

Active substance(s):

Poly (oxy-1,2-ethanediyl), α -hydro- ω -methoxy-, 28B-ester with 28B-(N6-carboxy-L-Lysine)-29B-L-prolineinsulin (human) (LY 2605541)

Condition(s):

Treatment of type 1 diabetes mellitus

Treatment of type 2 diabetes mellitus

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous 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 17 January 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 23 February 2011.

Supplementary information was provided by the applicant on 23 January 2012.

A meeting with the Paediatric Committee took place on 11 April 2012.



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, or occurs only in the adult population, and with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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 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.

London, 13 April 2012

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 I Diabetes Mellitus

The waiver applies to:

- Children from birth to less than 6 years of age,
- for solution for injection, subcutaneous use,
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfill a therapeutic need in the paediatric population.

1.2. Condition: Treatment of Type II Diabetes Mellitus

The waiver applies to:

- Children from birth to less than 10 years of age,
- for 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.

and to:

- Children from 10 to less than 18 years of age,
- for solution for injection, subcutaneous use,
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfill a therapeutic need in the paediatric population.

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 6 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	0	N/A
Non-clinical	1	Study 1 10 week juvenile repeat dose toxicity study in rats to investigate potential effects on the developing nervous system.
Clinical	1	Study 2 Randomised, active controlled (insulin glargine), open label, parallel, multicenter, with preprandial insulin lispro, safety and efficacy study (52 weeks) with an integrated pharmacokinetic substudy (4 weeks) in paediatric patients with type 1 diabetes mellitus from 6 to less than 18 years of age.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By November 2016
Deferral for one or more studies contained in the paediatric investigation plan:	Yes