EMA/26216/2011

European Medicines Agency decision

P/21/2011

of 25 January 2011

on the acceptance of a modification of an agreed paediatric investigation plan for exenatide (Byetta), (EMEA-000689-PIP01-09-M02) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

P/21/2011

of 25 January 2011

on the acceptance of a modification of an agreed paediatric investigation plan for exenatide (Byetta), (EMEA-000689-PIP01-09-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/237/09 issued on 30 November 2009, and the decision P/12/2010 issued on 20 January 2010,

Having regard to the application submitted by Eli Lilly and Company on 4 October 2010 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 10 December 2010, 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 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 exenatide (Byetta), solution for injection in pre-filled pen, powder and solvent for suspension for injection, 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 and Company, Erl Wood Manor, Windlesham, GU20 6PH, United Kingdom.

Done at London, 25 January 2011

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

EMA/PDCO/661586/2010

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

EMEA-000689-PIP01-09-M02

Scope of the application

Active substance(s):

Exenatide

Invented name:

Byetta

Condition(s):

Type 2 diabetes mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection in pre-filled pen

Powder and solvent for suspension for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Eli Lilly and Company

Information about the authorised medicinal product:

See Annex II

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company submitted to the European Medicines Agency on 4 October 2010 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/237/2009 issued on 30 November 2009, and the decision P/12/2010 issued on 20 January 2010.
The applicant proposed modifications to the paediatric investigation plan and requested changes to the deferral and the waiver.

The procedure started on 13 October 2010.

A meeting with the Paediatric Committee took place on 9 December 2010.

Scope of the modification

Some measures and timelines of the two clinical studies of the original Opinion have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral and to the waiver in the scope set out in the Annex I of this opinion.

   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 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.

London, 10 December 2010

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(s): Treatment of Type 2 diabetes mellitus

Indication:

Treatment of type 2 diabetes mellitus in combination with metformin, and/or sulphonylureas in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.

The waiver applies to:

- children from birth to less than 10 years;
- for exenatide (Byetta), solution for injection, prefilled pen, and powder and solvent for suspension 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.

Indication:

Treatment of type 2 diabetes mellitus in combination with thiazolidinediones and with metformin with a thiazolidinedione.

The waiver applies to:

- children from birth to less than 10 years;
- for exenatide (Byetta), solution for injection, prefilled pen, and powder and solvent for suspension 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.

The waiver applies to:

- children from 10 to less than 18 years;
- for exenatide (Byetta), solution for injection, prefilled pen, and powder and solvent for suspension for injection, subcutaneous use;
- on the grounds that the combination of medicinal products is likely to be unsafe in the paediatric population.

Indication:

Treatment of type 2 diabetes mellitus in combination with insulin with or without other oral antidiabetic agents.

This waiver applies to:

- children from birth to less than 10 years;
- for exenatide (Byetta), solution for injection, prefilled pen, and powder and solvent for suspension 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.

The waiver applies to:

- children from 10 to less than 18 years;
- for exenatide (Byetta), solution for injection, prefilled pen, and powder and solvent for suspension 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.

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 in combination with metformin, and/or sulphonylureas in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 10 to less than 18 years

2.1.3. Pharmaceutical form(s)

Solution for injection in pre-filled pen

Powder and solvent for suspension for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	1. Double-blind, placebo-controlled, randomized, multi-center parallel study of the safety and efficacy of exenatide twice daily (as monotherapy and adjunctive therapy to oral antidiabetic agents) in children and adolescents with type 2 diabetes mellitus (H8O-MC-GWBQ) 2. Double-blind, placebo-controlled, randomized, multi-center parallel study of the safety and efficacy of exenatide once weekly (as monotherapy and adjunctive therapy to oral antidiabetic agents) in children and adolescents with type 2 diabetes mellitus

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 August 2016
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 indications:

- Treatment of Type 2 Diabetes Mellitus in adult patients, in combination with metformin in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.
- Treatment of Type 2 Diabetes Mellitus in adult patients, in combination with sulphonylureas in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.
- Treatment of Type 2 Diabetes Mellitus in adult patients, in combination with thiazolidinediones in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.
- Treatment of Type 2 Diabetes Mellitus in adult patients, in combination with metformin and a sulphonylurea in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.
- Treatment of Type 2 Diabetes Mellitus in adult patients, in combination with metformin and a thiazolidinedione in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.

EU Number	**Invented name Name**	**Strength**	**Pharmaceutical form**	**Route of administration**	**Packaging**	**Content (concentration)**	**Package size**
EU/1/06/362/001	BYETTA	5 micrograms	Solution for injection	subcutaneous use	Pre-filled pen (glass)	1,2 ml	1 pre-filled pen
EU/1/06/362/002	BYETTA	5 micrograms	Solution for injection	subcutaneous use	Pre-filled pen (glass)	1,2 ml	3 pre-filled pens
EU/1/06/362/003	BYETTA	10 micrograms	Solution for injection	subcutaneous use	Pre-filled pen (glass)	2,4 ml	1 pre-filled pen
EU/1/06/362/004	BYETTA	10 micrograms	Solution for injection	subcutaneous use	Pre-filled pen (glass)	2,4 ml	3 pre-filled pens