EMA/507484/2011

European Medicines Agency decision

P/189/2011

of 2 August 2011

on the granting of a product specific waiver for teriparatide (Forsteo), (EMEA-001135-PIP01-11) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.

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Only the English text is authentic.

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 Limited on 9 March 2011 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 June 2011 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.

(2) 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 waiver for teriparatide (Forsteo), solution for injection (in a pre-filled pen), transdermal system, subcutaneous use, transdermal 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 2

This decision is addressed to Eli Lilly & Company Limited, Erl Wood Manor, Sunninghill Road, GU20 6PH Windlesham, United Kingdom.

Done at London, 2 August 2011

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

EMA/PDCO/393414/2011

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-001135-PIP01-11

Scope of the application

Active substance(s):

Teriparatide

Invented name:

Forsteo

Condition(s):

Treatment of fractures

Treatment of osteoporosis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection (in a pre-filled pen)

Transdermal system

Route(s) of administration:

Subcutaneous use

Transdermal use

Name/corporate name of the PIP applicant:

Eli Lilly & Company Limited

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Eli Lilly & Company Limited submitted to the European Medicines Agency on 9 March 2011 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 20 April 2011.

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to grant a product-specific waiver for all subsets of the paediatric population and all the above mentioned condition(s) in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in 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, 17 June 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition: Treatment of fractures

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for solution for injection (in a pre-filled pen), subcutaneous use;
- for transdermal system, transdermal use;
- on the grounds that the specific medicinal product is likely to be unsafe.

1.2. Condition: Treatment of osteoporosis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for solution for injection (in a pre-filled pen), subcutaneous use;
- for transdermal system, transdermal use;
- on the grounds that the specific medicinal product is likely to be unsafe.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of osteoporosis

   Authorised indications:

   Treatment of osteoporosis in postmenopausal woman and in men at increased risk of fracture. In postmenopausal women, a significant reduction in the incidence of vertebral and nonvertebral fractures but not hip fractures has been demonstrated.

   Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/03/247/001	Forsteo	20 µg/80 µl	Solution for injection	Subcutaneous use	pre-filled pen (glass)	2.4 ml	1 pre-filled pen
EU/1/03/247/002	Forsteo	20 µg/80 µl	Solution for injection	Subcutaneous use	pre-filled pen (glass)	2.4 ml	3 pre-filled pens