European Medicines Agency

Doc. Ref. EMA/164721/2010
P/23/2010

EUROPEAN MEDICINES AGENCY DECISION

of 15 March 2010

on the granting of a product specific waiver for strontium ranelate (Protelos) (EMEA-000732-PIP01-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(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 as amended 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 Les Laboratoires Servier on 19 October 2009 under Article 13 of Regulation (EC) No 1901/2006 as amended,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 January 2010 in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended,

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

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 strontium ranelate (Protelos), granules for oral suspension, 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 2

This decision is addressed to Les Laboratoires Servier, 22, rue Garnier, 92578 - Neuilly-sur-Seine Cedex, France.

Done at London, 15 March 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency

Doc. Ref. EMA/PDCO/19923/2010
EMEA-000732-PIP01-09

OPINION OF THE PAEDIATRIC COMMITTEE ON THE GRANTING OF A PRODUCT-SPECIFIC WAIVER

Scope of the application

Active substance(s):
Strontium ranelate

Invented name:
Protelos

Condition(s):
Osteoporosis

Pharmaceutical form(s):
Granules for oral suspension

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant(s):
Les Laboratoires Servier

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Les Laboratoires Servier submitted to the European Medicines Agency on 19 October 2009 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 19 November 2009.

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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 Icelandic and the Norwegian Paediatric Committee members agree 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(s) and the Executive Director of the European Medicines Agency, together with its annex and appendix.

London, 15 January 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

GROUNDS FOR THE GRANTING OF THE WAIVER

GROUNDS FOR THE GRANTING OF THE WAIVER

- **Condition**

Osteoporosis

Indication

Treatment of postmenopausal osteoporosis to reduce the risk of vertebral and hip fractures

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age,
- for granules for oral suspension, oral use,
- on the grounds that the specific medicinal product is likely to be unsafe.

- **Condition**

Osteoporosis

Indication

Treatment of male osteoporosis to reduce the risk of vertebral and hip fractures

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age,
- for granules for oral suspension, oral use,
- on the grounds that the specific medicinal product is likely to be unsafe.

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	**Invented name Name**	**Strength**	**Pharmaceutical form**	**Route of administration**	**Packaging**	**Package size**
EU/1/04/288/001	Protelos	2g	Granules for oral suspension	Oral use	Sachet (paper/PE/alu)	7 sachets
EU/1/04/288/002	Protelos	2g	Granules for oral suspension	Oral use	Sachet (paper/PE/alu)	14 sachets
EU/1/04/288/003	Protelos	2g	Granules for oral suspension	Oral use	Sachet (paper/PE/alu)	28 sachets
EU/1/04/288/004	Protelos	2g	Granules for oral suspension	Oral use	Sachet (paper/PE/alu)	56 sachets
EU/1/04/288/005	Protelos	2g	Granules for oral suspension	Oral use	Sachet (paper/PE/alu)	84 sachets
EU/1/04/288/006	Protelos	2g	Granules for oral suspension	Oral use	Sachet (paper/PE/alu)	100 sachets