EMA/704354/2010

European Medicines Agency decision

P/268/2010

of 17 November 2010

on review of a granted waiver for duloxetine hydrochloride (Cymbalta/Xeristar/Yentreve/Ariclaim) (EMEA-000420-PIP01-10) 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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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 opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 January 2010,

Having regard to the decision of the European Medicines Agency P/21/2010, adopted on 2 March 2010,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued of its own motion on 12 November 2010 in accordance with Article 14(2) 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 of its own motion on the review of the granted waiver.

(2) It is therefore appropriate to adopt a decision reviewing the granted 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 review of the granted waiver for duloxetine hydrochloride (Cymbalta/Xeristar/Yentreve/Ariclaim) (EMEA-000420-PIP01-10) hard gastro-resistant capsules, 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 agreed.

Article 2

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

Done at London, 17 November 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/704389/2010

Opinion of the Paediatric Committee on the review of the granted product specific waiver

EMEA-000420-PIP01-10

Scope of the waiver

Active substance(s):

Duloxetine hydrochloride

Invented name:

Cymbalta/Xeristar/Yentreve/Ariclaim

Condition(s):

Treatment of chronic pain

Treatment of major depressive disorder

Treatment of generalized anxiety disorder

Treatment of diabetic neuropathic pain

Treatment of stress urinary incontinence

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Gastro-resistant capsule, hard

Route(s) of administration:

Oral use

Name/corporate name of the waiver addressee:

Eli Lilly & Company

Information about the authorised medicinal product:

See Annex II

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Scope of the review

Condition: Treatment of chronic low back pain.

Scope of the changes: The scope of the waiver in condition “Treatment of chronic low back pain” has been extended to “Treatment of chronic pain”.

Basis for opinion

On 15 January 2010, an opinion on granting of a product specific waiver was adopted by the Paediatric Committee, followed by the European Medicines Agency’s decision P/21/2010 issued on 2 March 2010. According to Article 14(2) of Regulation (EC) No 1901/2006 as amended, the Paediatric Committee may, at any time, adopt an opinion advocating the review of a granted waiver.

The procedure started on 13 October 2010.

Opinion

1. The Paediatric Committee, having assessed the granted product specific waiver, recommends as set out in the appended summary report:

   - to review the granted product-specific waiver for one or more subsets of the paediatric population in the above specified condition(s) on its own motion in accordance with Article 14(2) of said Regulation;
   - the reviewed waiver is based on 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 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 addressee of the waiver and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

London, 12 November 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

1. Waiver

1.1. Condition: Treatment of chronic pain

The waiver applies to:

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

1.2. Condition: Treatment of major depressive disorder

The waiver applies to:

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

1.3. Condition: Treatment of generalized anxiety disorder

The waiver applies to:

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

1.4. Condition: Treatment of diabetic neuropathic pain

The waiver applies to:

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

1.5. Condition: Treatment of stress urinary incontinence

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for capsules for oral 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):

Treatment of diabetic peripheral neuropathic pain in adults.
Treatment of major depressive disorder.
Treatment of generalised anxiety disorder.
Treatment of moderate to severe Stress Urinary Incontinence (SUI) in women.

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Package size
EU/1/04/296/001	CYMBALTA	30 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	28 capsules
EU/1/04/296/002	CYMBALTA	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	28 capsules
EU/1/04/296/003	CYMBALTA	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	84 capsules
EU/1/04/296/004	CYMBALTA	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	98 capsules
EU/1/04/296/005	CYMBALTA	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	56 capsules
EU/1/04/296/006	CYMBALTA	30 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	7 capsules
EU/1/04/296/007	CYMBALTA	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	500 capsules
EU/1/04/296/008	CYMBALTA	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	100 capsules
EU/1/04/296/009	CYMBALTA	30 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	98 capsules
EU/1/04/297/001	XERISTAR	30 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	28 capsules
EU/1/04/297/002	XERISTAR	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	28 capsules
EU/1/04/297/003	XERISTAR	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	84 capsules
EU/1/04/297/004	XERISTAR	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	98 capsules

EU/1/04/297/005	XERISTAR	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	56 capsules
EU/1/04/297/006	XERISTAR	30 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	7 capsules
EU/1/04/297/007	XERISTAR	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	500 capsules
EU/1/04/297/008	XERISTAR	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	100 capsules
EU/1/04/280/001	YENTREVE	20 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	56
EU/1/04/280/002	YENTREVE	40 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	28
EU/1/04/280/003	YENTREVE	40 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	56
EU/1/04/280/004	YENTREVE	40 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	98
EU/1/04/280/005	YENTREVE	40 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	140
EU/1/04/280/006	YENTREVE	40 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	2 x 98
EU/1/04/280/007	YENTREVE	20 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	28
EU/1/04/280/008	YENTREVE	20 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	98
EU/1/04/283/008	ARICLAIM	30 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	7
EU/1/04/283/009	ARICLAIM	30 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	28
EU/1/04/283/010	ARICLAIM	30 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	98
EU/1/04/283/011	ARICLAIM	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	28
EU/1/04/283/012	ARICLAIM	60 mg	Gastro-resistant capsule, hard	Oral use	blister (PVC/PE/PCTFE/alu)	98