European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 14 September 2008

on the application for product specific waiver for bortezomib (Velcade) EMEA-000233-PIP01-08 in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 Janssen-Cilag International NV on 06 May 2008 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 31 July 2008 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 a positive opinion,

(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 bortezomib (Velcade), powder of solution for injection, intravenous use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 2

This decision is addressed to Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

Done at London, 14 September 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

London, 31 July 2008
EMEA/466976/2008
EMEA-000233-PIP01-08

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A PRODUCT-SPECIFIC WAIVER FOR

Scope of the application

Active substance:
Bortezomib

Invented name :
Velcade

Condition(s):
Mantle cell lymphoma

Pharmaceutical form(s):
Powder of solution for injection

Route(s) of administration:
Intravenous use

Name/corporate name of the waiver applicant:
Janssen-Cilag International NV

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International NV submitted for agreement to the EMEA on 6 May 2008 an application for a waiver on the grounds set out in Article 11 of Regulation (EC) No 1901/2006 as amended for the above mentioned medicinal product.

The procedure started on 5 June 2008.

Opinion

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 waiver for all subsets of the paediatric population and all above mentioned conditions in accordance with Article 11(1) (b) of Regulation (EC) No 1901/2006 as amended, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

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

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its appendix.

London, 31 July 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented Name	Strength	Pharma-ceutical Form	Route Admini-stration	Packaging	Content	Package Size
EU/1/04/274/001	VELCADE	1 mg/ml when reconstituted	Powder for solution for injection	Intravenous use	vial (glass)	3.5 mg	vial (glass)
EMEA/H/C/000539/II/0026/002	VELCADE	1 mg/ml when reconstituted	Powder for solution for injection	Intravenous use	vial (glass)	1 mg	vial (glass)