European Medicines Agency

Doc. Ref. EMEA/575498/2008
P/102/2008

EUROPEAN MEDICINES AGENCY DECISION

of 6 November 2008

on the application for product specific waiver for lenalidomide (Revlimid) (EMEA-000371-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

EUROPEAN MEDICINES AGENCY DECISION

of 6 November 2008

on the application for product specific waiver for lenalidomide (Revlimid) (EMEA-000371-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

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 Celgene Europe Limited on 24 July 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 17 October 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 lenalidomide (Revlimid), hard capsule, oral 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 Celgene Europe Limited, Morgan House, Madeira Walk, SL4 1EP Windsor, Berkshire, United Kingdom.

Done at London, 6 November 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

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

EMEA/575498/2008
EMEA-000371-PIP01-08

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

Scope of the application

Active substance:
Lenalidomide

Invented name
Revlimid

Condition(s):
Myelodysplastic Syndrome

Pharmaceutical form(s):
Hard capsule

Route(s) of administration:
Oral use

Name/corporate name of the waiver applicant:
Celgene Europe Limited

Information about the authorised medicinal product:
see Annex I

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Celgene Europe Limited submitted for agreement to the EMEA on 24 July 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 27 August 2008.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 40
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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)(a) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product is likely to be 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.

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

London, 17 October 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

ANNEX I

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
EU/1/07/391/001	Revlimid	5 mg	Hard capsule	Oral use	Blister (PCTFE/PVC/alu)	21 capsules
EU/1/07/391/002	Revlimid	10 mg	Hard capsule	Oral use	Blister (PCTFE/PVC/alu)	21 capsules
EU/1/07/391/003	Revlimid	15 mg	Hard capsule	Oral use	Blister (PCTFE/PVC/alu)	21 capsules
EU/1/07/391/004	Revlimid	25 mg	Hard capsule	Oral use	Blister (PCTFE/PVC/alu)	21 capsules