EMA/157193/2011

European Medicines Agency decision

P/50/2011

of 4 March 2011

on the granting of a product specific waiver for lenalidomide (Revlimid) (EMEA-000371-PIP02-09) 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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on the granting of a product specific waiver for lenalidomide (Revlimid) (EMEA-000371-PIP02-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 Celgene Europe Ltd. on 19 June 2009 under Article 16(1) of Regulation (EC) No 1901/2006 and also requesting a waiver under Article 13 of said Regulation,

Having regard to the withdrawal by the applicant of its proposed paediatric investigation plan and the change to the scope of the requested waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 January 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 lenalidomide (Revlimid), capsule, hard, 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 Celgene Europe Limited, Riverside House, Riverside Walk, Windsor SL4 1NA, Berkshire, United Kingdom.

Done at London, 4 March 2011

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

EMA/PDCO/24675/2011

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

EMEA-000371-PIP02-09

Scope of the application

Active substance(s):

Lenalidomide

Invented name:

Revlimid

Condition(s):

Treatment of diffuse large B-cell lymphoma

Treatment of mantle cell lymphoma

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Celgene Europe Ltd.

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, Celgene Europe Ltd. submitted to the European Medicines Agency on 19 June 2009 an application for a paediatric investigation plan and a product-specific waiver on the grounds set out in Article 13 of said Regulation for the above mentioned medicinal product.

The procedure started on 17 September 2009.

Supplementary information was provided by the applicant on 04 November 2010.

The applicant withdrew its proposed paediatric investigation plan and changed the scope of the requested waiver.

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, 14 January 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 diffuse large B-cell lymphoma and treatment of mantle cell lymphoma

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age
- for capsule, hard, 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):

1. Treatment of multiple myeloma

Authorised indication(s):

Revlimid in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.

EU Number	(Invented) name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Package size
EU/1/07/391/001	Revlimid	5 mg	Capsule, hard	Oral use	blister (PCTFE/PVC/alu)	21 capsules
EU/1/07/391/002	Revlimid	10 mg	Capsule, hard	Oral use	blister (PCTFE/PVC/alu)	21 capsules
EU/1/07/391/003	Revlimid	15 mg	Capsule, hard	Oral use	blister (PCTFE/PVC/alu)	21 capsules
EU/1/07/391/004	Revlimid	25 mg	Capsule, hard	Oral use	blister (PCTFE/PVC/alu)	21 capsules