EMA/565633/2017

European Medicines Agency decision

P/0279/2017

of 4 October 2017

on the granting of a product specific waiver for lenalidomide (Revlimid), (EMEA-000371-PIP04-16) 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-PIP04-16) 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 Limited on 11 May 2017 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 August 2017 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.

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, 1 Longwalk Road, Stockley Park, UB11 1DB – Uxbridge, United Kingdom.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/367267/2017 Cor
London, 18 August 2017

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

EMEA-000371-PIP04-16

Scope of the application

Active substance(s):

Lenalidomide

Invented name:

Revlimid

Condition(s):

Treatment of mature B-cell neoplasms

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 Limited

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 Limited submitted to the European Medicines Agency on 11 May 2017 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 20 June 2017.

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 the above mentioned condition(s) in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 annexes and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of mature B-cell neoplasms

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for capsule, hard, oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of mature B-cell neoplasms

Authorised indication(s):

- Revlimid as monotherapy is indicated for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.
- Revlimid as combination therapy is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.
- Revlimid in combination with dexamethasone is indicated for the treatment of multiple myeloma in adult patients who have received at least one prior therapy.
- Revlimid as monotherapy is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma.

2. Myelodysplastic Syndrome

Authorised indication(s):

- Revlimid as monotherapy is indicated for the treatment of adult patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.

Authorised pharmaceutical form(s):

Capsule, hard

Authorised route(s) of administration:

Oral use