EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 February 2015
EMA/CHMP/91664/2015 Rev 1[1]
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[2] (post authorisation)

Revlimid

lenalidomide

On 18 December 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Revlimid. The marketing authorisation holder for this medicinal product is Celgene Europe Limited. They may request a re- examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:

Revlimid is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant (see section 4.2).

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Revlimid will be as follows[3]:

Revlimid is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant (see section 4.2).

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 is indicated for the treatment of patients with transfusion-dependent anaemia 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.

[1] Correction of a discrepancy between the indication and the posology section in the SmPC. Reference to age which was initially included in section 4.2 “Posology and method of administration” was deleted to reflect the recommended indication. For clarity regarding the use of lenalidomide in combination, a reference to section 4.2, where the combination therapy is described, was also added to the indication.
[2] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[3] The text in bold represents the new or the amended indication.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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