4th October 2011

Circular No. P 13/2011

Dear Healthcare Professional,

Re: European Medicines Agency concludes that benefit-risk balance with Revlimid remains positive

Revlimid (lenalidomide) is an anti-cancer agent for the treatment of multiple myeloma in combination with dexamethasone, in those patients who have received at least one previous therapy in the past.

Revlimid which is marketed in Malta, was reviewed following the results of three new studies showing a higher rate of new cancers in patients with newly diagnosed multiple myeloma who were being treated with Revlimid and received other treatments concomitantly. The studies showed a four-fold increase in the number of new cancers in patients being treated with Revlimid, including solid tumours and cancers of the blood and the immune system. Although the studies were carried out in patients for whom Revlimid is not currently indicated, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) was concerned that the results could also be relevant for the approved patient population.

The Committee weighed the benefits of Revlimid against the risks in the approved patient population and concluded that the benefits of Revlimid, particularly improved survival continue to outweigh the risks but recommended that the prescribing information for Revlimid be updated with a warning and advice to doctors on the risk of new cancers. Doctors are also reminded that the current review of the benefits and risks of Revlimid only covers the approved patient population. The Committee's conclusion does not cover its use outside of the current authorised indication.

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt

Prescribers are encouraged to maintain vigilance on Revlimid. Suspected adverse drug reactions may be reported using the Medicines Authority yellow card scheme or online at http://www.medicinesauthority.gov.mt/pub/adr.doc or to the marketing authorisation holder or their local representative.

The Committee's opinion has now been forwarded to the European Commission for the adoption of an E.U. wide decision. The Medicines Authority has participated in the discussions held at the EMA and is in agreement with the full **press release** issued by the EMA, attached here for your perusal. A **question-and-answer** document with more information about the outcome of this assessment is also available.

Healthcare professionals are encouraged to check the Medicines Authority website regularly for product safety updates as these are issued on an ongoing basis.

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