



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency concludes that benefit-risk balance of Revlimid remains positive

The European Medicines Agency has confirmed that the benefit-risk balance for Revlimid (lenalidomide) remains positive within its approved patient population but advises doctors of the risk of new cancers as a result of treatment with the medicine.

Revlimid is used in combination with dexamethasone (an anti-inflammatory medicine) to treat adult patients with multiple myeloma whose disease has been treated at least once in the past.

Revlimid 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 Agency's 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. The Committee reviewed all available data on new cancers in the approved population, including data from studies and post-marketing data. It concluded that the risk of new cancers, such as skin cancers and some invasive solid tumours, was observed in studies in the approved population. The Committee also reviewed available data from the three studies in newly diagnosed multiple myeloma patients.

The Committee 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.

The Committee's opinion has now been forwarded to the European Commission for the adoption of a decision.



Notes

1. This press release, along with all related documents, is available on the Agency's website.
2. Multiple myeloma is a cancer of the plasma cells in the bone marrow.
3. The Committee observed in studies in the approved population that there were 3.98 cases of new cancer for every 100 patient-years in patients receiving Revlimid compared with 1.38 cases in those not receiving Revlimid (patient-years is the sum of the lengths of time all patients have been under treatment).
4. Revlimid has been authorised in the EU since 14 June 2007. See the [Revlimid European public assessment report](#).
5. The review of Revlimid was carried out under Article 20 of Regulation (EC) No 726/2004/EC and was requested by the European Commission in March 2011. This type of procedure is triggered for medicines that have been authorised via the centralised procedure, which is managed by the European Medicines Agency.
6. The prescribing information will be updated with data on newly diagnosed multiple myeloma patients showing the four-fold increase in the number of new cancers in patients being treated with Revlimid.
7. All other opinions and documents adopted by the CHMP at their September 2011 plenary meeting will be published on Friday, 23 September 2011 at 12.00 noon UK time on a dedicated web page.
8. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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