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Questions and answers on the review of Revlimid (lenalidomide)

Outcome of a procedure under Article 20 of Regulation (EC) No 726/2004

The European Medicines Agency has completed a review of Revlimid, following data showing a higher number of new cancers in patients treated with the medicine compared with patients not taking the medicine. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Revlimid in its approved population continue to outweigh its risks but recommended that a warning be added to the prescribing information.

What is Revlimid?

Revlimid is an anticancer medicine. It 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. Multiple myeloma is a cancer of the plasma cells in the bone marrow.

The active substance in Revlimid, lenalidomide, is an immunomodulating agent. This means that it affects the activity of the immune system (the body's natural defences). Lenalidomide works in a number of different ways in multiple myeloma: it blocks the development of tumour cells, prevents the growth of blood vessels within tumours and also stimulates some of the specialised cells of the immune system to attack the cancerous cells.

Revlimid has been authorised in the EU since 14 June 2007 and is marketed in 21 Member States[1].

Why was Revlimid reviewed?

Revlimid was reviewed because of data from three studies showing a higher rate of new cancers in patients being treated with Revlimid compared with patients not taking the medicine. The studies were carried out in patients with newly diagnosed multiple myeloma who were also receiving other treatments. The cancers seen include solid tumours and cancers of the blood and the immune system.

[1] Revlimid is marketed in Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece Ireland, Italy, Luxembourg, Malta, Netherland, Poland, Portugal, Slovenia, Slovakia, Spain, Sweden and United Kingdom.

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Although the studies were carried out in patients for whom Revlimid is not currently approved, the CHMP was concerned that the results could also be relevant for the approved patient population. The review was carried out to evaluate available data on the risk of new cancers with Revlimid in the approved population and to issue an opinion on whether its marketing authorisation should be maintained, varied, suspended or withdrawn across the EU.

Which data has the CHMP reviewed?

The CHMP reviewed all available data on new cancers in the approved population. These included data from studies and post-marketing data. The Committee also reviewed the available data from the three studies in newly diagnosed multiple myeloma.

What are the conclusions of the CHMP?

The CHMP concluded that an increased risk of new cancers, such as skin cancers and some invasive solid tumours, was observed in studies in the approved population. 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).

The CHMP weighed the benefits of Revlimid against the risks in the approved patient population (patients who have already been treated in the past). It concluded that its benefits, such as improved survival, continue to outweigh its risk but recommended that the prescribing information for Revlimid be updated with a warning and advice to doctors on the risk of new cancers. The prescribing information will also be updated with data in newly diagnosed multiple myeloma showing a four-fold increase in the number of new cancers in patients being treated with Revlimid.

The full changes made to the information to doctors and patients are detailed under the 'All documents' tab.

What are the recommendations for patients and prescribers?

- Doctors should take the risk of new cancers into account before starting treatment with Revlimid.
- Doctors should carefully evaluate patients before and during treatment using standard screening for new cancers and initiate treatment as appropriate.
- Doctors are also reminded that the current review concludes that the benefits of Revlimid outweigh its risks in the approved population. The CHMP's conclusion does not cover its use in patients for whom the medicine has not been approved.
- In the event of the occurrence of a new cancer, doctors should report cases promptly according to EU and national requirements.
- Patients who have any questions should speak to their doctor or pharmacist.

A European Commission decision on this opinion will be issued in due course.

The current European public assessment report for Revlimid can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.