EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Celgene Europe Limited withdraws its application for an extension of the indication for Revlimid (lenalidomide)

The European Medicines Agency has been formally notified by Celgene Europe Limited of its decision to withdraw its application for the centrally authorised medicine Revlimid for an extension of the therapeutic indication in patients with newly diagnosed multiple myeloma and for the addition of new pack sizes.

On 24 December 2010, Celgene Europe Limited submitted an application for a variation of the marketing authorisation for Revlimid to extend the indication to maintenance treatment of newly diagnosed multiple myeloma patients who have not progressed following initial treatment with melphalan, prednisone and Revlimid or following autologous stem cell transplantation.

This variation was part of a grouped application that also included applications for two new strengths and a variation to add new pack sizes of 7 capsules for the existing 5 mg, 10 mg, and 15 mg strengths. At the time of the withdrawal, the applications were under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that it decided to withdraw its application for the extension of indication for Revlimid and the addition of new pack sizes because the CHMP considers that additional, more mature data are required for it to reach a clear benefit-risk conclusion. The company retains the application for the two new strengths.

Revlimid was first authorised in the European Union on 14 June 2007 and it is currently indicated in combination with dexamethasone for the treatment of multiple myeloma patients who have received at least one prior therapy.

Revlimid continues to be authorised in the currently approved indication.

More information about Revlimid and the status of the scientific assessment at the time of the withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the Agency's website after the 18-21 June 2012 CHMP meeting.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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