26 July 2018
EMA/CHMP/475938/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lenalidomide Accord

lenalidomide

On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lenalidomide Accord, intended for the treatment of multiple myeloma. The applicant for this medicinal product is Accord Healthcare Limited.

Lenalidomide Accord will be available as capsules (2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg). The active substance of Lenalidomide Accord is lenalidomide, an immunomodulating agent (ATC code: L04AX04) that works in a number of different ways including cytokine modulation, induction of T-cell proliferation, anti-proliferation of multiple myeloma cells and inhibition of angiogenesis.

Lenalidomide Accord is a generic of Revlimid which has been authorised in the EU since 14 June 2007. Studies have demonstrated the satisfactory quality of Lenalidomide Accord and its bioequivalence to the reference product Revlimid. A question and answer document on generic medicines can be found here.

The full indication is:

"Multiple myeloma

Lenalidomide Accord as monotherapy is indicated for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.

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

Lenalidomide Accord in combination with dexamethasone is indicated for the treatment of multiple myeloma in adult patients who have received at least one prior therapy."

It is proposed that Lenalidomide Accord be prescribed by physicians experienced in the treatment of cancer.

Detailed recommendations for the use of this product will be described in the summary of product

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.