10 December 2020
EMA/CHMP/651085/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lenalidomide Krka d.d.

lenalidomide

On 10 December 2020, 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 Krka d.d., intended for the treatment of multiple myeloma, myelodysplastic syndromes, and follicular lymphoma. The applicant for this medicinal product is KRKA, d.d., Novo mesto.

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

Lenalidomide Krka d.d. is a generic of Revlimid, which has been authorised in the EU since 14 June 2007. Studies have demonstrated the satisfactory quality of Lenalidomide Krka d.d., 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 Krka d.d. as monotherapy is indicated for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.

Lenalidomide Krka d.d. as combination therapy with dexamethasone, or bortezomib and dexamethasone, or melphalan and prednisone (see section 4.2) is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.

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

[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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Myelodysplastic syndromes

Lenalidomide Krka d.d. as monotherapy is indicated for the treatment of adult patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.

Follicular lymphoma

Lenalidomide Krka d.d. in combination with rituximab (anti-CD20 antibody) is indicated for the treatment of adult patients with previously treated follicular lymphoma (Grade 1 – 3a).

Lenalidomide Krka d.d. should be prescribed by physicians experienced in the use of cancer therapies.

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