30 May 2024
EMA/CHMP/227643/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pomalidomide Krka

pomalidomide

On 30 May 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Pomalidomide Krka, intended for the treatment of multiple myeloma.

The applicant for this medicinal product is KRKA, d.d., Novo mesto.

Pomalidomide Krka will be available as 1, 2, 3 and 4 mg hard capsules. The active substance of Pomalidomide Krka is pomalidomide, an immunomodulator (ATC code: L04AX06). Pomalidomide works in different ways, including cytokine modulation, induction of T-cell proliferation, inhibition of multiple myeloma cell proliferation and inhibition of angiogenesis.

Pomalidomide Krka is a generic of Imnovid, which has been authorised in the EU since 05 August 2013. Studies have demonstrated the satisfactory quality of Pomalidomide Krka, and its bioequivalence to the reference product Imnovid. A question and answer document on generic medicines can be found here.

The full indication is:

> Pomalidomide Krka in combination with bortezomib and dexamethasone is indicated in the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide.
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> Pomalidomide Krka in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.

Treatment with Pomalidomide Krka should be initiated and supervised by a physician experienced in the treatment of multiple myeloma.

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

[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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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.