14 December 2023
EMA/CHMP/554066/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pomalidomide Viatris

pomalidomide

On 14 December 2023, 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 Viatris, intended for multiple myeloma. The applicant for this medicinal product is Viatris Limited.

Pomalidomide Viatris will be available as 1 mg, 2 mg, 3 mg and 4 mg hard capsules. The active substance of Pomalidomide Viatris is pomalidomide, an immunomodulator (ATC code: L04AX06) 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.

Pomalidomide Viatris is a generic of Imnovid, which has been authorised in the EU since 05 August 2013. Studies have demonstrated the satisfactory quality of Pomalidomide Viatris 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 Viatris 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 Viatris 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 Viatris should be carried out under the supervision of physicians 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 made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[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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