26 June 2023
EMA/294651/2023
EMEA/H/C/005729

Public statement

Lenalidomide Krka d.d. (SRD) (lenalidomide)

Withdrawal of the marketing authorisation in the European Union

On 8 June 2023, the European Commission withdrew the marketing authorisation for Lenalidomide Krka d.d. (lenalidomide) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, KRKA, d.d., Novo mesto, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Lenalidomide Krka d.d. was granted marketing authorisation in the EU on 11 February 2021 for the treatment of multiple myeloma, myelodysplastic syndromes and follicular lymphoma. The marketing authorisation was initially valid for a 5-year period.

Lenalidomide Krka d.d. is a generic medicine of Revlimid. There are other generic medicinal products of Revlimid authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Lenalidomide Krka d.d. will be updated to indicate that the marketing authorisation is no longer valid.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union