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Public statement

Pregabalin Sandoz GmbH (pregabalin)

Withdrawal of the marketing authorisation in the European Union

On 4 October 2023, the European Commission withdrew the marketing authorisation for Pregabalin Sandoz GmbH (pregabalin) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Sandoz GmbH, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Pregabalin Sandoz GmbH was granted marketing authorisation in the EU on 19 June 2015 for the treatment of epilepsy and generalised anxiety disorder (GAD). The marketing authorisation was initially valid for a 5-year period. It was subsequently granted unlimited validity in 2020.

Pregabalin Sandoz GmbH is a generic medicine of Lyrica. There are other generic medicinal products of Lyrica authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Pregabalin Sandoz GmbH will be updated to indicate that the marketing authorisation is no longer valid.

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