28 March 2022
EMA/522684/2021
EMEA/H/C/003962

Public statement

Pregabalin Mylan Pharma

Withdrawal of the marketing authorisation in the European Union

On 3 November 2021 the European Commission withdrew the marketing authorisation for Pregabalin Mylan Pharma (pregabalin) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Mylan S.A.S, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Pregabalin Mylan Pharma was granted marketing authorisation in the EU on 25 June 2015 for the treatment of neuropathic pain, epilepsy and generalised anxiety disorder (GAD). The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2019.

Pregabalin Mylan Pharma 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Assessment Report (EPAR) for Pregabalin Mylan Pharma will be updated to indicate that the marketing authorisation is no longer valid.

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