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Public statement

Esmya (ulipristal acetate)

Withdrawal of the marketing authorisation in the European Union

On 18 July 2024, the European Commission withdrew the marketing authorisation for Esmya (ulipristal acetate) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Gedeon Richter Plc., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Esmya was granted marketing authorisation in the EU on 23 February 2012 for the treatment of uterine fibroids. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2016.

Esmya is an identical product to Ryeqo and Yselty, which are authorised in the EU to treat uterine fibroids.

The European Public Assessment Report (EPAR) for Esmya will be updated to indicate that the marketing authorisation is no longer valid.

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