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Public statement

Repso

Withdrawal of the marketing authorisation in the European Union

On 19 July 2017, the European Commission withdrew the marketing authorisation for Repso (leflunomide) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Teva B.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Repso was granted marketing authorisation in the EU on 14 March 2011 for the treatment of active rheumatoid and active psoriatic arthritis. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2016.

Repso is a generic medicine of Arava. There are other generic medicinal products of Arava authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Repso will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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