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Public statement

Rienso

Withdrawal of the marketing authorisation in the European Union

On 13 April 2015, the European Commission withdrew the marketing authorisation for Rienso (ferumoxytol) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Takeda Ltd, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Rienso was granted marketing authorisation in the EU on 15 June 2012 for the treatment of iron deficiency anaemia in adult patients with chronic kidney disease. The marketing authorisation was initially valid for a 5-year period.

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Assessment Report (EPAR) for Rienso will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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