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Public statement

Raplixa

Cessation of validity of the marketing authorisation in the European Union

On 19 March 2018, the European Commission withdrew the marketing authorisation of Raplixa (human fibrinogen / human thrombin) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Mallinckrodt Pharmaceuticals Ireland Limited, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Raplixa was granted marketing authorisation in the EU on 19 March 2015 as supportive treatment where standard surgical techniques are insufficient for improvement of haemostasis. The marketing authorisation was initially valid for a 5-year period.

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Report (EPAR) for Raplixa will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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