EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Development and Evaluation

Public statement

Refludan (lepirudin)

Withdrawal of the marketing authorisation in the European Union

On 13 March 1997 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Refludan (lepirudin). Refludan was approved for anticoagulation in adult patients with heparin-induced thrombocytopenia (HAT) type II and thromboembolic disease mandating parenteral antithrombotic therapy.

The marketing authorisation holder (MAH) responsible for Refludan was Celgene Europe Ltd.

The European Commission was notified by 3 letters dated 31 March 2012, 2 April 2012 and 30 April 2012 of the MAH's decision to voluntarily withdraw the marketing authorisation for Refludan for commercial reasons.

On 24 April 2012 the European Commission issued a decision to withdraw the marketing authorisation for Refludan. Pursuant to this decision the European Public Assessment Report for Refludan will be updated to reflect the fact that the marketing authorisation is no longer valid.

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