20 February 2012
EMA/128419/2012
Human Medicines Development and Evaluation

Public statement on

Xigris (drotrecogin alfa (activated))

Withdrawal of the marketing authorisation in the European Union

On the 22 August 2002 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Xigris, drotrecogin alfa (activated), which had been approved for the treatment of adult patients with severe sepsis with multiple organ failure when added to best standard care. The use of Xigris should be considered mainly in situations when therapy can be started within 24 hours after the onset of organ failure.

The marketing authorisation holder (MAH) responsible for Xigris was Eli Lilly Nederland B.V. The European Commission was notified by a letter dated 24 October 2011 of the MAH's decision to voluntarily withdraw the marketing authorisation as of the Commission Decision date for Xigris. On 28 November 2011 the European Commission issued a decision withdrawing the marketing authorisation for Xigris.

Pursuant to this decision the European Public Assessment Report for Xigris will be updated to reflect that the marketing authorisation is no longer valid.

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