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Human Medicines Development and Evaluation

Public statement on

Regranex (becaplermin)

Withdrawal of the marketing authorisation in the European Union

On the 29 March 1999 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Regranex (becaplermin), which had been approved, in association with other good wound care measures, to promote granulation and thereby the healing of full-thickness, neuropathic, chronic, diabetic ulcers less than or equal to 5 cm^2.

The marketing authorisation holder (MAH) responsible for Regranex was Janssen-Cilag International NV. The European Commission was notified by a letter dated 20 June 2012 of the MAH's decision to voluntarily withdraw the marketing authorisation as of the Commission Decision date for Regranex for commercial reasons. Regranex was marketed in France, Ireland, Germany, Netherlands, Sweden, Spain and UK.

On 16 July 2012 the European Commission issued a decision to withdraw the marketing authorisation for Regranex.

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the European Public Assessment Report for Regranex will be updated to reflect that the marketing authorisation is no longer valid.

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