European Medicines Agency

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PUBLIC STATEMENT ON

Ultratard
(Insulin human (rDNA))

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 7 October 2002 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Ultratard, insulin human, 40 IU/ml and 100 IU/ml, 10 ml vial, which have been approved for treatment of diabetes mellitus.

The marketing authorisation holder (MAH) responsible for Ultratard is NovoNordisk A/S. The European Commission was notified by the MAH of its decision through the MAH's letter dated 25 September 2006 to voluntarily withdraw the marketing authorisation for Ultratard for commercial reasons.

Therapeutic alternatives are available throughout the European Union.

On 14 November 2006 the European Commission issued a decision to withdraw the marketing authorisation for Ultratard. Pursuant to this decision the European Public Assessment Report for Ultratard will be updated to reflect that the marketing authorisation is no longer valid.

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