European Medicines Agency

London 14 April 2009
EMEA/86738/2009

PUBLIC STATEMENT ON

Velosulin
(Insulin human (rDNA))

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 7 October 2002, the European Commission granted a marketing authorisation valid throughout the European Union for the medicinal product Velosulin (insulin human) 10ml (3.5 mg/ml) for subcutaneous or intravenous use[1], indicated for the treatment of diabetes mellitus.

On 18 December 2008, the marketing authorisation holder (MAH) responsible for Velosulin, Novo Nordisk A/S notified the European Commission of its decision to voluntarily withdraw its marketing authorization for commercial reasons.

On 30 January 2009, the European Commission issued a decision to withdraw the marketing authorisation for Velosulin. Pursuant to this decision the European Public Assessment Report for Velosulin will be updated to reflect that the marketing authorisation is no longer valid.

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[1] Correction was made to the Route of Administration from “intravenous and intramuscular” to “subcutaneous or intravenous”.

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