



European Medicines Agency

London 12 December 2008
EMA/674212/2008

PUBLIC STATEMENT ON

Nespo (darbepoetin alfa)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 8 June 2001 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Nespo, darbepoetin alfa, which had been approved for the treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adults and paediatric patients and treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.

The marketing authorisation holder (MAH) responsible for Nespo was Dompé Biotec S.p.A. The European Commission was notified by letter dated 10 November 2008 of the MAH's decision to voluntarily withdraw the marketing authorisation for Nespo for commercial reasons.

On 5 December 2008 the European Commission issued a decision to withdraw the marketing authorisation for Nespo. Pursuant to this decision the European Public Assessment Report for Nespo will be updated to reflect that the marketing authorisation is no longer valid.

Noël Wathion
Head of Unit for the Post-Authorisation Evaluation
of Medicinal Products for Human use