European Medicines Agency

London, 7 April 2009
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PUBLIC STATEMENT ON

Dynepo
(epoetin delta)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 18 March 2002 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Dynepo (epoetin delta), which had been approved for the treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adult patients.

The marketing authorisation holder (MAH) responsible for Dynepo was Shire Pharmaceutical Contract Limited. The European Commission was notified by letter dated 17 February 2009 of the MAH's decision to voluntarily withdraw the marketing authorisation for Dynepo for commercial reasons.

On 17 March 2009 the European Commission issued a decision to withdraw the marketing authorisation for Dynepo. Pursuant to this decision the European Public Assessment Report for Dynepo will be updated to reflect that the marketing authorisation is no longer valid.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

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.europa.eu http://www.emea.europa.eu