European Medicines Agency

London 16 December 2008
EMEA/680805/2008

PUBLIC STATEMENT ON

Neupopeg
(pegfilgrastim)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 22 August 2002 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Neupopeg, pegfilgrastim, which had been approved for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

The marketing authorisation holder (MAH) responsible for Neupopeg 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 Neupopeg for commercial reasons.

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the European Public Assessment Report for Neupopeg will be updated to reflect that the marketing authorisation is no longer valid.

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