European Medicines Agency

London 23 May 2006
EMEA/184565/2006

PUBLIC STATEMENT ON
DAQUIRAN (pramipexole)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 27 October 1997 the European Commission granted a marketing authorisation for the whole European Union to Dr. Karl Thomae GmbH, for Daquiran (pramipexole), indicated for treatment of the signs and symptoms of advanced idiopathic Parkinson's disease in combination with levodopa, i.e. over the course of the disease, when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or “on off” fluctuations).

Daquiran was not marketed anywhere in the European Union. On 22 December 2005 the Marketing Authorisation Holder notified the European Commission of its decision to voluntarily withdraw the Marketing Authorisation for Daquiran as there were no plans to market this product in the future. It should be noted that there are still two Community Marketing Authorisations valid throughout the European Union for pramipexole i.e. Sifrol and Mirapexin.

On 2 February 2006 the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "Daquiran". Pursuant to this decision the European Public Assessment Report for Daquiran has been removed from the EMEA website.

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.eu.int http://www.emea.eu.int