

London, 29 September 2004 EMEA/88093/04

PUBLIC STATEMENT ON TALUVIAN (Apomorphine Hydrochloride)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 28 May 2001 the European Commission granted a marketing authorisation for the whole European Union to Abott SpA Italy, for Taluvian (apomorphine hydrochloride), indicated for the treatment of erectile dysfunction.

Taluvian has been marketed only in Spain. On 13 May 2004 the Marketing Authorisation Holder notified the European Commission of its decision to voluntarily withdraw the Marketing Authorisation for Taluvian for commercial reasons. There is still one Community Marketing Authorisation valid throughout the European Union for medicinal products containing apomorphine hydrochloride i.e. Uprima.

On 13 July 2004 the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "Taluvian". Pursuant to this decision the European Public Assessment Report for Taluvian has been removed from the EMEA website.

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