European Medicines Agency

London 4 August 2006
EMEA/304680/2006

PUBLIC STATEMENT ON

FORTOVASE
(Saquinavir (free base))

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 20 August 1998 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Fortovase, soft gel capsules, intended for the treatment of HIV-1infected adult patients. Fortovase should only be given in combination with ritonavir and other antiretroviral medicinal products.

On 17 May 2006, the European Commission was notified by Roche Registration Limited of their decision to voluntarily withdraw the marketing authorisation for Fortovase for commercial reasons. Therapeutic alternatives are available throughout the European Union, including Invirase, the 200 mg hard capsule and 500 mg film-coated tablet formulations of saquinavir as a mesylate salt.

On 27 June 2006 the European Commission issued a decision to withdraw the marketing authorisation for Fortovase. Pursuant to this decision the European Public Assessment Report for FORTOVASE has been removed from the EMEA website.

The Marketing Authorisation Holder for Fortovase will continue to be responsible for any remaining product on the market until the expiry date (January 2007) of the latest released batch in the European Union.

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