The European Agency for the Evaluation of Medicinal Products
Post-authorisation Evaluation of Medicines for Human Use

London, 18 May 2004
EMEA/10089/04

PUBLIC STATEMENT ON
ALLEX (Desloratadine)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 15 January 2001 the European Commission granted a marketing authorisation for the whole European Union to SP Europe, for Allex (desloratadine), indicated for the relief of symptoms associated with allergic rhinitis (AR) and with chronic idiopathic urticaria (CIU).

Allex was not marketed anywhere in the European Union. On 2 February 2004 the Marketing Authorisation Holder notified the European Commission of its decision to voluntarily withdraw the Marketing Authorisation for Allex for commercial reasons. There are still three Community Marketing Authorisations valid throughout the European Union for medicinal products containing desloratadine i.e. Aerius, Azomyr and Neoclarityn.

On 10 March 2004 the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "Allex". Pursuant to this decision the European Public Assessment Report for Allex 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