European Medicines Agency

London 27 March 2008
Doc. Ref.: EMEA/136288/2008

PUBLIC STATEMENT ON
BEXTRA
(valdecoxib)

NON-RENEWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 27 March 2003 the European Commission granted a marketing authorisation for the whole European Union to Pharmacia – Pfizer EEIG for Bextra (valdecoxib).

Bextra (valdecoxib) is a non-steroidal anti-inflammatory drug (NSAID) with Cox-2 selectivity.

In the context of the review of Cox-2 inhibitors, the European Commission issued a decision for suspension of the marketing authorisation of Bextra in October 2005 (see http://www.emea.europa.eu/pdfs/human/press/pus/35823405en.pdf). Bextra has not been marketed in Europe since 2005.

The Marketing Authorisation Holder did not apply to renew the marketing authorisation. Consequently, the five-year marketing authorisation for Bextra expired on 27 March 2008.

Noël Wathion
Head of Unit
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.europa.eu http://www.emea.europa.eu