European Medicines Agency
Press office

London, 7 April 2005
Doc. Ref. EMEA/121637/2005

European Medicines Agency statement on the suspension of use of Bextra

Following discussions with the European Medicines Agency, Pfizer has agreed to the suspension of use of **Bextra** (valdecoxib) in Europe as an interim measure pending finalisation of the assessment of COX-2 inhibitors. Pfizer has agreed to similar actions in the United States at the request of the Food and Drug Administration.

The European Medicines Agency has an ongoing safety review of the COX-2 class of medicines. Contraindications and warnings concerning the cardiovascular safety of all COX-2 medicines were introduced in the information for prescribers and patients in February 2005.

The Agency had previously issued a statement on 15 December 2004 concerning safety issues for patients undergoing coronary artery bypass graft (CABG) surgery and serious skin reactions relating to the use of two COX-2 medicines, including Bextra. Contraindications for patients undergoing CABG surgery and additional information and warnings on the occurrence of serious skin reactions were introduced.

Until the completion of the ongoing review, prescribers are advised to monitor carefully patients being treated with Bextra and not to initiate treatment of new patients. Patients receiving Bextra should speak to their physician regarding their current treatment.

The Agency will continue to monitor the safety of the COX-2 class of medicines and review all new data as it becomes available.

A further update will be made after the 18-21 April 2005 CHMP meeting.

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1. The scientific name of Bextra is valdecoxib, which is part of the class of COX-2 selective inhibitors. Bextra is approved in the European Union for the symptomatic relief in the treatment of osteoarthritis or rheumatoid arthritis and for the treatment of primary dysmenorrhoea. Pfizer was granted a marketing authorisation for Bextra in March 2003.
2. The February 2005 EMEA announcement of regulatory action for COX-2 inhibitors is available [here].
3. The December 2004 EMEA statement on serious skin reactions with valdecoxib is available [here].
4. This press release, together with other information about the work of the EMEA, can be found on the EMEA web site at http://www.emea.eu.int

Media enquiries only to:
Martin Harvey
EMEA press officer
Tel. (+44-20) 74 18 84 27, Fax (44-20) 74 18 84 09
E-mail: press@emea.eu.int