Medicines Authority Statement

FOR IMMEDIATE RELEASE
January 27, 2005

RE: Update on the ongoing review of COX-2 inhibitors, by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP)

Following the decision by Merck & Co., to globally withdraw Vioxx ® from the market, the Medicines Authority is actively participating in a holistic class review of COX-2 inhibitors being carried out by the European Medicines Agency's (CHMP) on Celebrex ® (celecoxib), Onsenal ® (celecoxib), Dynastat ® (parecoxib), Bextra ® (valdecoxib), Arcoxia ® (etoricoxib) and Prexige ® (lumiracoxib).

On 18 January 2005, the CHMP held hearings with Pfizer (for celecoxib, parecoxib and valdecoxib), Merck & Co., (for etoricoxib) and Novartis (for lumiracoxib) regarding the assessment being carried out on these medicines. Further to its assessment of data submitted on celecoxib by Pfizer, the Committee requested further clarifications and analyses, in particular of data from the Adenoma Prevention with Celecoxib (APC) and Prevention of Spontaneous Adenoma Polyps (PreSAP) studies. Data on other COX-2 inhibitors (etoricoxib, lumiracoxib, parecoxib and valdecoxib) are currently being assessed also.

The Committee for Medicinal Products for Human Use will continue its discussions on the review at its next meeting on 14-17 February 2005 and should reach a final decision in the next coming months. Following the decision taken by the CHMP on these medicines the Medicines Authority will execute any recommendations made by the CHMP in a harmonised European approach. Further information about the work of the CHMP on the review of COX-2 inhibitors, may be found on the EMEA web site at http://www.emea.eu.int/htms/hotpress/h21227104.htm

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