

# PRESS STATEMENT

**Date:** 10<sup>TH</sup> June 2005  
**Time:** EMBARGO NOT BEFORE 00.01 10<sup>TH</sup> JUNE  
**Subject:** NSAID's



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## NON STERIODAL ANTI INFLAMMATORY DRUGS

Non-steroidal anti-inflammatory drugs (NSAIDs) are important medicines in the treatment of arthritic and other painful conditions. The known side effects are described in product information, including patient information leaflets.

The Medicines and Healthcare products Regulatory Agency (MHRA) continually reviews the safety of all licensed medicines in the UK. The MHRA is aware of new epidemiological study published in this week's British Medical Journal, suggesting an increased risk of myocardial infarction (heart attack) associated with both traditional and selective 'COX-2' inhibitor anti-inflammatory medicines. The Committee on Safety of Medicines (CSM) has recently reviewed the evidence of cardiovascular safety for selective COX-2 inhibitors and issued advice to prescribers, restricting their use in patients with cardiovascular disease. The evidence relating to traditional NSAIDs is less clear.

The MHRA is currently participating in a detailed European-wide review of the cardiovascular safety of traditional (non-selective) NSAIDs. The MHRA will carefully examine the new study, in the context of all other evidence on this issue, and seek advice from CSM. In the meantime, prescribers should note existing CSM advice regarding the use of anti-inflammatory medicines, in particular that the lowest effective dose should be used for the shortest period of time necessary.

Ibuprofen has an excellent safety record which is why it has been made available as an over-the-counter medicine. There are a number of epidemiological studies regarding the cardiovascular safety of ibuprofen. The new study has limitations as identified by the authors and needs to be viewed in the context of a number of other studies which have not shown an increased risk of MI with ibuprofen. The MHRA will review the new study in the context of all other available evidence and will issue advice as appropriate.

**ENDS**

Notes to Editor:

COX-2 selective group of NSAIDs ('coxibs') are relatively new anti-inflammatory medicines which are thought to produce less in the way of gastrointestinal side effects than older 'non-selective' NSAIDs. Currently, marketed selective COX-2 inhibitors include celecoxib (Celebrex), etoricoxib (Arcoxia) and the injectable drug

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parecoxib (Dynastat, which is for short term use in hospitals). Rofecoxib was withdrawn by the Marketing Authorisation (MA) holder in 2004, because of concerns over cardiovascular safety and valdecoxib has recently been withdrawn (April 2005) because of an increased risk of serious skin reaction.