

Notice Information: Human Medicines - Advisory
10 June 2005

Part 1. Product Information

- a) Title: European-wide review of the cardiovascular safety of traditional (non-selective) NSAIDs
- b) Product Name/Type: (non-selective) NSAIDs
- c) Active Substance: (non-selective) NSAIDs

Part 2. Problem/Issue

- a) Problem/Issue:

The Irish Medicines Board is currently participating in a detailed European-wide review of the cardiovascular safety of traditional (non-selective) NSAIDs. The IMB is aware of the 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 IMB will carefully examine the new study, in the context of all other evidence on this issue. The IMB advises healthcare professionals and patients/consumers to note the existing IMB advice regarding use of these medicines, in particular that the lowest effective dose should be used for the shortest period of time necessary. Consumers/patients who have concerns should seek the advice of their general practitioner, but in the meantime should not immediately cease the use of current medication in the absence of medical advice. Non-steroidal anti-inflammatory drugs (NSAIDs) are well known medicines in the treatment of arthritis and other painful conditions and their known side effects are outlined in product information, which includes the patient information leaflets. The IMB states that it has also recently reviewed the evidence of cardiovascular safety for selective COX-2 inhibitors in conjunction with the Regulatory Authorities of the other EU Member States. Currently, these medicines are restricted for use in patients with cardiovascular disease. The evidence relating to traditional NSAIDs is less clear. There are a number of epidemiological studies regarding the cardiovascular safety of ibuprofen. This new study in the British Medical Journal 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 myocardial infarction with ibuprofen. The IMB states that following the pan European review it will take whatever regulatory actions are deemed appropriate in the best interest of public health.

Part 3. Action to be taken

a) Action to be taken:

Consumers/patients who have concerns should seek the advice of their general practitioner, but in the meantime should not immediately cease the use of current medication in the absence of medical advice.

Part 4. Enquiries

a) All enquiries should be made to:

FOR FURTHER INFORMATION: Siobhan Molloy/Avril Collins (01) 676 01 68 or (086) 817 50 66

Part 5. Keywords

a) Keywords:

NSAIDs