

## Notice Information: Human Medicines - Warning 20 December 2004

### Part 1. Product Information

- a) Title: Cardiovascular events (i.e. acute myocardial infarction and stroke) in patients taking Celecoxib
- b) Product Name/Type: Celecoxib
- c) Product Classification: COX-2 (cyclo-oxygenase-2) inhibitors

### Part 2. Problem/Issue

- a) Problem/Issue: The Irish Medicines Board (IMB) has been informed by Pfizer of a clinical study that shows an increased risk of major fatal or non-fatal cardiovascular events (i.e. acute myocardial infarction and stroke) in patients taking celecoxib compared to patients given placebo. Celecoxib is a member of the class of medicines called COX-2 (cyclo-oxygenase-2) inhibitors which are authorised for the treatment of the symptoms of osteoarthritis or rheumatoid arthritis. The study, Adeomona Prevention with Celecoxib trial (ACP) was designed to investigate a new use of celecoxib to prevent colon polyps. However, the study has now been discontinued due to the finding that there is an increased risk of cardiovascular adverse events in patients taking celecoxib compared to those taking placebo. This trial was not conducted in Ireland. A separate trial sponsored by Pfizer (Prevention of Spontaneous Adenoma Polyps (PreSAP) trial), does not appear to confirm this risk. This trial has also now been stopped based on the results of the ACP trial. This trial was conducted in Ireland and the investigators and patients are being informed of the new information. The IMB has requested the results of both studies and, in conjunction with its experts and EU colleagues, will review them as soon as they are available. In parallel, the European Medicines Agency is currently conducting a review of all COX-2 inhibitor medicines, looking at cardiovascular safety.

### Part 3. Action to be taken

a) Action to be taken:

Information to prescribers and patients issued by the EMEA on 22 October 2004 remains valid: Prescribers are advised to follow carefully the latest version of the summary of product characteristics for COX-2 inhibitors, especially regarding the warnings and precautions in patients with a history of cardiovascular disease. Patients should be aware that all COX-2 medicines available in Europe already contain warnings regarding heart problems. If you have any concerns about your treatment you are advised to consult your prescriber.

#### **Part 4. Enquiries**

a) All enquiries should be made to:

FOR INFORMATION: Siobhan Molloy Tel: (01) 676 01 68 or (086) 817 50 66 Weber Shandwick FCC

#### **Part 5. Keywords**

a) Keywords:

Celecoxib COX-2 (cyclo-oxygenase-2) inhibitors