European Medicines Agency
Press office

London, 2 August 2005
Doc. Ref. EMEA/250423/2005

Questions and Answers on non-selective NSAIDs
CHMP review of safety of non-selective NSAIDs

What are the conclusions of the CHMP on cardiovascular safety of non-selective NSAIDs?
Following the assessment of available evidence on thrombotic risk (in particular heart attack and stroke) and pending the ongoing review of other safety issues, the CHMP currently does not recommend any changes to the advice to patients and prescribers.

What are NSAIDs?
NSAIDs are non-steroidal anti-inflammatory drugs. They have been available on the market for many years and are important in the treatment of arthritis and other painful conditions. COX-2 inhibitors are a subset of the class of NSAIDs, which is made up of two types: the older, conventional "non-selective" NSAIDs and the newer "COX-2 inhibitors" which have more recently become available.

How does the COX-2 inhibitors review relate to non-selective NSAIDs?
Concerns were raised regarding an increased risk of cardiovascular events (including heart attacks and strokes) when using COX-2 inhibitors. In November 2004, the EMEA began a Europe-wide review of the COX-2 inhibitors at the request of the European Commission and this was broadened in April 2005 to also include serious skin reactions. The review of COX-2 inhibitors was finalised in June 2005 and the advice published at that time remains valid (see Question and Answer document on the EMEA web site (http://www.emea.eu.int/pdfs/human/press/pr/21074505en.pdf). When the CHMP reviewed the safety data for the COX-2 inhibitors, it compared them to non-selective NSAIDs. This suggested the need to assess the safety of non-selective NSAIDs as well, and the review started in June 2005.

Which non-selective NSAIDs and which data are being looked at through this review?
Diclofenac, Etodolac, Ibuprofen, Indomethacin, Ketoprofen, Meloxicam, Nabumetone, Naproxen and Nimesulide. As part of the review on cardiovascular safety of non-selective NSAIDs, the Committee has looked at available epidemiological and clinical data generated by clinical trials and market surveillance.

What are the next steps/possible regulatory actions?
The Committee is reviewing other already known safety concerns (gastro-intestinal safety and serious skin reactions) with non-selective NSAIDs and expects to conclude during the plenary meeting of 12-15 September 2005. The Committee will then advise if further actions may be necessary and the EMEA will promptly inform the public of the conclusions.

What are the recommendations for patients and prescribers?
- Patients and prescribers should continue to use the products as currently recommended.
- Doctors and patients should closely follow the product information for non-selective NSAIDs (whether they are prescription or over-the-counter products). They should use the lowest effective dose for the shortest possible duration of treatment to control symptoms.
- Doctors should prescribe on the basis of the overall safety profiles of non-selective NSAIDs as set out in product information, and individual risk factors.
- Patients who have concerns or questions should talk to their doctor or pharmacist at a routine appointment.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.eu.int http://www.emea.eu.int