



European Medicines Agency

London, 2 August 2005

EMEA/247323/2005

EMEA PRESS RELEASE

The EMEA Committee on Medicinal Products for Human Use (CHMP) has assessed available data on the cardiovascular safety of non-selective NSAIDs, including clinical trials and epidemiological studies. The review on the safety of non-selective NSAIDs had been initiated following a request from the European Commission in June 2005.

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.

The CHMP wishes at this stage to emphasise the following points:

- Non-selective NSAIDs are widely used effective medicines in the treatment of arthritis and other painful conditions.
- Prescribing should be based on overall safety profiles of non-selective NSAIDs (for instance potential gastro-intestinal concerns) as set out in the product information, and individual risk factors.
- However, all patients should take the lowest effective dose of non-selective NSAIDs for the shortest time necessary to control symptoms.

The CHMP is reviewing available data on gastro-intestinal safety and serious skin reactions for non-selective NSAIDs and expects to be able to communicate its overall viewpoint on the different safety aspects considered in this review in September 2005.

--ENDS--

NOTES:

1. Non-selective NSAIDs included in this review (whether prescription or non-prescription products) are: Diclofenac, Etodolac, Ibuprofen, Indomethacin, Ketoprofen, Meloxicam, Nabumetone, Naproxen and Nimesulide.
2. A previous review had identified an increase in the risk of thrombotic adverse cardiovascular reactions such as heart attack or stroke with selective Cox-2 inhibitors (e.g. celecoxib, etoricoxib, lumiracoxib and parecoxib), which had led to revised prescribing recommendations. The advice adopted in June 2005 for selective Cox-2 inhibitors remains unchanged (see EMEA website for [press release](#)).
3. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at <http://www.emea.eu.int>
4. A Question and Answer document has been published and can be found [here](#).

Media enquiries only please:

Martin Harvey Allchurch

EMEA press officer

Tel. (44-20) 74 18 84 27, E-mail: press@emea.eu.int