



European Medicines Agency
Press office

London, 26 September 2006
Doc. Ref. EMEA/378695/2006

Press release

European Medicines Agency update on review of non-selective NSAIDs

One year on from its October 2005 review, the European Medicines Agency is to look again at the cardiovascular safety of non-selective non-steroidal anti-inflammatory drugs (NSAIDs).

In October 2005 the Agency's scientific committee, the Committee for Medicinal Products for Human Use (CHMP), recommended a number of changes in the way healthcare professionals prescribe non-selective NSAIDs to ensure consistency across the EU. The Committee also undertook to maintain these products under surveillance.

New data and analyses are now available on the cardiovascular safety of non-selective NSAIDs stemming from clinical and epidemiological studies, which signal a potential increased thrombotic risk (such as heart attack or stroke) for some of these NSAIDs especially when used in long-term treatment. The CHMP has now been asked to review the cardiovascular safety of NSAIDs in the context of their overall benefit-risk profile.

The Committee has begun reviewing available safety data from clinical and epidemiological studies. It will give a scientific opinion on the cardiovascular safety of non-selective NSAIDs during its next meeting of 16-19 October 2006, including recommendations on how to address any safety concerns that may be identified.

Since the October 2005 review, three non-selective NSAIDs have been further examined: ketoprofen, ketorolac and piroxicam. While the recommendations are for a more cautious use for all three of these compounds, the Committee was concerned that piroxicam may have a less favourable gastro-intestinal safety profile and higher risk of skin reactions compared to other non-selective NSAIDs. At the request of the European Commission, the Committee has now started a formal review of the overall benefit-risk profile of piroxicam. With respect to ketoprofen and ketorolac, the CHMP has concluded that their benefits continue to outweigh the risks associated with their approved use.

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NOTES:

1. The press release following the October 2005 review of NSAIDs can be found [here](#).
2. A question and answer document on the review of non-selective NSAIDs can be found [\[here\]](#).
3. A question and answer document on ketoprofen, ketorolac and piroxicam, and additional key elements for the use and recommended warnings, can be found [\[here\]](#).
4. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: <http://www.emea.europa.eu>

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