



European Medicines Agency
Press office

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Press release

European Medicines Agency update on non-selective NSAIDs

The Agency's scientific committee, the Committee for Medicinal Products for Human Use (CHMP), concluded, at its meeting of 10-13 October 2005, that, on the basis of the data reviewed, there are no new safety concerns regarding cardiovascular and gastrointestinal safety and serious skin reactions with non-selective NSAIDs (non-steroidal anti-inflammatory drugs). NSAIDs remain important treatments for arthritis and other painful conditions.

The review follows the Agency's findings in June 2005 on safety issues relating to selective NSAIDs (COX-2 inhibitors). The review was carried out at the request of the European Commission to look at non-selective NSAIDs to determine whether there were safety issues that required further action.

The CHMP noted, however, that information for patients and healthcare professionals varies for the different non-selective NSAIDs already approved by the Member States across the European Union. The Committee recommended that the product information be made consistent across the EU to ensure that patients and healthcare providers everywhere in the EU are given the same safety information about these products.

The Committee identified a set of key elements that should be included at national level in the product information for all non-selective NSAIDs relating to cardiovascular and gastrointestinal safety and serious skin reactions. This is not based on new information, but reflects a common position on safety issues which are already well known among doctors and pharmacists in the EU. The recommendations for key elements relate to contraindications, warnings and precautions for use, interactions with other medicines, and undesirable effects (See EMEA website for [key elements](#)).

As for all medicinal products marketed in the European Union, NSAIDs are being continuously monitored and if there are any concerns impacting on the benefit-risk balance, appropriate actions will be taken.

--ENDS--

NOTES:

1. Non-selective NSAIDs included in this review are: diclofenac, etodolac, ibuprofen, indomethacin, ketoprofen, meloxicam, nabumetone, naproxen, nimesulide and piroxicam.
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, 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. The CHMP reviewed available data on cardiovascular and gastrointestinal safety and serious skin reactions for non-selective NSAIDs following a request from the European Commission in June 2005. A statement on the cardiovascular safety of NSAIDs was made in August 2005 and can be found [here](#).
4. A Question and Answer document has been published and can be found [here](#).
5. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: <http://www.emea.eu.int>

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