European Medicines Agency
*Press office*

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# Questions and Answers on the EMEA review of cardiovascular and gastrointestinal safety and serious skin reactions with non-selective NSAIDs

**What is the main conclusion of the EMEA on the safety of non-selective NSAIDs?**
The European Medicines Agency has finalised its review of non-selective NSAIDs and has concluded, on the basis of the data reviewed, that there are no new concerns regarding cardiovascular and gastrointestinal safety and serious skin reactions for this class of medicinal products.

**What recommendations is the CHMP making?**
The CHMP noted 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 key elements of the product information be made consistent across the EU to ensure that patients and healthcare providers everywhere are given the same safety information about these products regarding contraindications, warnings and precautions for use, interactions with other medicines and undesirable effects.
The Committee's recommendations are not based on new information, but reflect a common position on safety aspects of these medicines that are already well known among doctors and pharmacists in the EU.

**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. There are two types of NSAIDs: the older, conventional 'non-selective' NSAIDs, and 'selective' NSAIDs (COX-2 inhibitors), which have become available more recently.

**Why was the review of non-selective NSAIDs carried out?**
Concerns were raised regarding the safety of non-selective NSAIDs following recent investigations into the risk of cardiovascular events (including heart attacks and strokes) and skin reactions with COX-2 inhibitors. 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 website). When the CHMP reviewed the safety data for the COX-2 inhibitors, it compared them to data for non-selective NSAIDs. This suggested that there was also a need to review the safety of non-selective NSAIDs. This review of the cardiovascular, gastrointestinal and skin safety of non-selective NSAIDs started in June 2005 at the request of the European Commission.

**Which non-selective NSAIDs and what data were reviewed?**
The systemic prescription (oral and injectable) formulations of the following non-selective NSAIDs were reviewed: diclofenac, etodolac, ibuprofen, indomethacin, ketoprofen, meloxicam, nabumetone, naproxen, nimesulide and piroxicam. As part of the review of cardiovascular and gastrointestinal safety and serious skin reactions, the Committee looked at a variety of data sources, including epidemiological, clinical-trial and post-marketing-surveillance data.

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**Are there any further steps?**

As for any medicinal product 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.

**What are the general recommendations on NSAIDs for patients and prescribers?**

- Doctors and patients should closely follow the up-to-date 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 on the basis of individual risk factors.
- Patients who have concerns or questions should talk to their doctor or pharmacist at a routine appointment.