European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency review concludes positive benefit-risk balance for non-selective NSAIDs

The European Medicines Agency has concluded that the benefit-risk balance for non-selective non-steroidal anti-inflammatory drugs (NSAIDs) remains favourable. This conclusion was drawn following a review announced in September 2006 of new thrombotic cardiovascular safety data.

The Agency's Committee for Medicinal Products for Human Use (CHMP), based on currently available information, concluded that:

- Non-selective NSAIDs are important treatments for arthritis and other painful conditions.
- It cannot be excluded that non-selective NSAIDs may be associated with a small increase in the absolute risk for thrombotic events, especially when used at high doses for long-term treatment.
- The overall benefit-risk balance for non-selective NSAIDs remains favourable when used in accordance with the product information, namely on the basis of the overall safety profile of the respective non-selective NSAID, and taking into account the patient's individual risk factors (e.g. gastrointestinal, cardiovascular and renal).

These conclusions are without prejudice to the outcome of the ongoing Article 31 referral procedure for piroxicam, in which the benefit-risk balance is currently being assessed.

Non-selective NSAIDs have been closely monitored by the Agency since initial recommendations were made in October 2005. This latest review is based on newly-available data and analyses on cardiovascular safety stemming from clinical and epidemiological studies which signal a potentially increased thrombotic risk (such as heart attack or stroke) for non-selective NSAIDs, especially when used at high doses and in long-term treatment. Previous reviews of the safety of non-selective NSAIDs and COX-2 inhibitors have also been taken into account.

The Committee confirmed its previous advice for doctors and patients to continue to use the lowest effective dose for the shortest possible duration to control symptoms.

As for all medicinal products marketed in the European Union, non-selective NSAIDs are being continuously monitored and appropriate actions will be taken if any concerns arise.

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NOTES:

1. The procedure was initiated in accordance with Article 5(3) of Regulation (EC) No 726/2004. The CHMP opinion for this procedure can be found here.
2. A question and answer document on the review of non-selective NSAIDs can be found here.
3. The press releases following the October 2005 review of non-selective NSAIDs can be found here and from September 2006 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: www.emea.europa.eu

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