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Press Office

Press release

European Medicines Agency starts new review of cardiovascular risks of non-selective NSAIDs

CHMP to update its 2006 opinion in light of more recently published evidence

The European Medicines Agency (EMA) is reviewing the latest available data on the cardiovascular safety of non-selective NSAIDS (non-steroidal anti-inflammatory drugs).

NSAIDS have been the subject of several European reviews in relation to gastrointestinal and cardiovascular safety and the occurrence of serious skin reactions. At the outcome of the last review on the cardiovascular safety of non-selective NSAIDs, in 2006, the Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the overall benefit-risk balance remained positive, but the possibility of a small increased risk of thrombotic events such as heart attacks or stroke with non-selective NSAIDs could not be excluded. This was particularly seen when NSAIDs were used at high doses and for long-term treatment. Further epidemiological studies were needed to obtain additional data on pertinent safety aspects of NSAIDs and therefore the Agency recommended in 2006 that the European Commission fund an independent epidemiological study to further explore the risk of gastrointestinal and cardiovascular toxicity of these medicines.

Since 2006, a number of new studies on the cardiovascular safety of NSAIDs have been published. Recently, results from the independent research project 'Safety Of non-Steroidal anti-inflammatory drugs' (SOS) funded by the European Commission under the 7th framework program to evaluate the safety of NSAIDs, have become available. The CHMP will now review the results of this meta-analysis thoroughly, together with any other available clinical data (including data from clinical trials and epidemiological studies) and post-marketing safety reports on non-selective NSAIDs, to clarify whether there is any need to update the opinion issued in 2006.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The online version of the meta-analysis 'Stroke Risk and Nonsteroidal Anti-inflammatory Drugs. A Systematic Review of Observational Studies' record published before inclusion in an issue of the Pharmacoepidemiology and Drug Safety can be found on the following website: Pharmacoepidemiology and Drug Safety 'early view' : http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1099-1557/earlyview
3. The 'Safety Of non-Steroidal anti-inflammatory drugs' (SOS) project is led by the ERASMUS University in Rotterdam. More information on this project can be found on the following website: http://www.sos-nsaids-project.org/
4. The European review of non-selective NSAIDS is being conducted in the context of a formal review, initiated at the request of the MHRA under Article 5(3) of Regulation (EC) No 726/2004, on 19 October 2011. The review includes nationally authorised medicines such as diclofenac, etodolac, ibuprofen, indomethacin, ketoprofen, meloxicam, nabumetone, naproxen, nimesulide and piroxicam.
5. Non-selective NSAIDS are indicated in the relief of all grades of pain and inflammation in a wide range of conditions, including arthritic conditions (such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and acute gout), acute musculo-skeletal disorders (such as periarthritis (for example frozen shoulder), tendinitis, tenosynovitis and bursitis) and other painful conditions resulting from trauma (including fracture, low back pain, sprains, strains, dislocations, orthopaedic, dental and other minor surgery).
6. The press release on the review of the gastro-intestinal and cardiovascular safety and serious-skin reactions with non-selective NSAIDS dated 17 October 2005 is available on the Agency's website: http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2009/11/WC500014403.pdf
7. The press release on the review of the cardiovascular safety with non-selective NSAIDS dated 24 October 2006 is available on the Agency's website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2009/12/news_detail_000752.jsp&mid=WC0b01ac058004d5c1&jsenabled=true
8. The press release on the review of the cardiovascular safety and serious-skin reactions with selective COX-2 inhibitors date June 2005 is available on the Agency's website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2010/01/news_detail_000969.jsp&mid=WC0b01ac058004d5c1
9. All other opinions and documents adopted by the CHMP at their September 2011 plenary meeting will be published on Friday, 23 October 2011 at 12.00 noon UK time on a dedicated web page.
10. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu