



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Review of diclofenac-containing medicines started

The European Medicines Agency has started a review of diclofenac-containing medicines to assess their cardiovascular safety.

Diclofenac is a widely used non-selective non-steroidal anti-inflammatory drug (NSAID), a type of medicine used to relieve pain and inflammation. A recent review of scientific studies by the Agency's Committee for Medicinal Products for Human Use (CHMP) assessed the latest data on the risk of cardiovascular side effects (such as heart attack or stroke) with non-selective NSAIDs. It concluded that the latest available data provide further evidence on the known risk with these medicines. Overall, the studies consistently indicate a small increase in risk with diclofenac compared with other non-selective NSAIDs, similar to the risks of COX-2 inhibitors (another class of painkillers).

The review will cover diclofenac-containing medicines formulated for systemic use (such as those taken by mouth or injection). The European Medicines Agency will evaluate the impact of the latest information on the benefit-risk balance of diclofenac and consider the need to update the existing treatment advice with regard to cardiovascular risk.

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### More about the medicine

Diclofenac is authorised for the relief of pain and inflammation in a wide range of conditions, including arthritic conditions and acute musculoskeletal disorders. It is currently available in the EU in a number of different formulations. Most formulations are for systemic use (given as treatment throughout the body, such as oral and injectable medicines), which are covered by the current review. Diclofenac-containing medicines have been authorised by national approval procedures in the EU Member States and have been available for many years under a wide range of trade names.

Diclofenac is a non-selective NSAID. Non-selective NSAIDs act by blocking the effects of the two cyclooxygenase (COX) enzymes, known as COX-1 and COX-2, resulting in a reduced production of substances called prostaglandins. In addition to diclofenac, this class of medicines also includes ibuprofen and naproxen. A different class of NSAIDs, called 'selective COX-2 inhibitors' (also known as 'coxibs'), acts by blocking the COX-2 enzyme only. Since some prostaglandins are involved in causing pain and inflammation at sites of injury or damage in the body, a reduced production of prostaglandins reduces pain and inflammation.



### **More about the procedure**

The review of diclofenac has been initiated at the request of the UK medicines agency, under Article 31 of Directive 2001/83/EC.

The review of diclofenac follows a recent CHMP review of studies on the cardiovascular safety of non-selective NSAIDs, under Article 5(3) of Regulation (EC) No 726/2004, which concluded on 18 October 2012. More information on the outcome of this review is available on the European Medicines Agency website<sup>1</sup>.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As diclofenac-containing medicines are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh is a regulatory body that represents national medicines regulatory authorities of the EU Member States.

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<sup>1</sup> See:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2012/10/news\\_detail\\_001637.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/10/news_detail_001637.jsp&mid=WC0b01ac058004d5c1)