



European Medicines Agency  
Press Office

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## **Public statement**

### **European Medicines Agency announces regulatory action on COX-2 inhibitors**

The European Medicines Agency has announced a number of regulatory actions for the COX-2 inhibitor class of medicines following discussions at the 14-17 February 2005 meeting of the Committee for Medicinal Products for Human Use (CHMP).

The CHMP concluded that the available data show an increased risk of cardiovascular adverse events for COX-2 inhibitors as a class. The data also suggest an association between duration and dose of intake and the probability of suffering a cardiovascular event.

The following urgent safety restrictions have been taken for COX-2 inhibitors available in the European Union:

- A contra-indication is introduced for all COX-2 inhibitors in patients with ischaemic heart disease or stroke
- As a further measure, a contra-indication is introduced for etoricoxib in patients with hypertension (high blood pressure) whose blood pressure is not under control
- A warning is introduced for prescribers to exercise caution when prescribing COX-2 inhibitors for patients with risk factors for heart disease, such as hypertension, hyperlipidaemia (high cholesterol levels), diabetes and smoking, as well as for patients with peripheral arterial disease
- Given the association between cardiovascular risk and exposure to COX-2 inhibitors, doctors are advised to use the lowest effective dose for the shortest possible duration of treatment

These are interim measures pending the finalisation of the class review, expected in April 2005.

The Committee also concluded that more research is needed in the field to evaluate the cardiovascular safety of COX-2 inhibitors, and that ongoing cardiovascular trials should continue as planned.

The review of COX-2 inhibitors by the European Medicines Agency began in October 2004 at the request of the European Commission. Hearings were held with the Marketing Authorisation Holders on 18 January and 15 February 2005.

An updated question and answer document on COX-2 inhibitors is available on the EMEA website.

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#### **NOTES:**

1. The EMEA review of the COX-2 inhibitor class of medicines was announced on 22 October 2004 and can be found [\[here\]](#). The EMEA issued further statements on 17 December 2004 [\[here\]](#), 22 December 2004 [\[here\]](#) and 20 January 2004 [\[here\]](#). The updated question and answer document is available [\[here\]](#).
2. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at <http://www.emea.eu.int>

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