



When prescribed in accordance with these additional contraindications and precautions, the Committee concluded that the balance of benefits and risks remains positive for these COX-2 inhibitors used in their target patient populations. In addition to any ongoing studies, the CHMP emphasised the importance for the authorisation holders for COX-2 inhibitors in the EU (Merck Sharp & Dohme, Novartis and Pfizer) to continuously and carefully monitor and assess cardiovascular safety and serious skin reactions.

The Committee assessed safety data for COX-2 inhibitors versus some conventional NSAIDs during the course of the review procedure for the COX-2 inhibitors. On the basis of these data and following a request from the European Commission, the Committee has now decided to look at the safety profile of NSAIDs to determine the need for further steps. This will build on a review already started by the Committee's Pharmacovigilance Working Party on the safety of the most commonly used NSAIDs.

It is unclear if the findings for COX-2 inhibitors are also relevant for conventional NSAIDs. Pending any future recommendations, healthcare professionals and patients should closely follow the product information for conventional NSAIDs (whether prescription or non-prescription products) and COX-2 inhibitors. Patients who have concerns or questions should talk to their doctor or pharmacist.

--ENDS--

#### 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 [\[here\]](#), 20 January 2005 [\[here\]](#), 17 February 2005 [\[here\]](#) and 7 April 2005 [\[here\]](#).
2. An updated question and answer document can be found [\[here\]](#).
3. The revised product information of celecoxib, etoricoxib, lumiracoxib and parecoxib can be found [\[here\]](#).
4. The COX-2 inhibitors that were reviewed are celecoxib, etoricoxib, lumiracoxib, parecoxib and valdecoxib.
5. Lumiracoxib is currently only authorised in the United Kingdom and is not yet being marketed.
6. Valdecoxib was authorised in the European Union as Bextra and Valdyn in March 2003. The marketing authorisation holders are Pfizer and Pharmacia-Pfizer respectively. The recommendation for suspension also applies to Valdyn.
7. The suspension of a marketing authorisation is a temporary measure in response to public health concerns, usually for a renewable period of one year, during which time a marketing authorisation holder may conduct additional studies to provide data and/or analysis in support of the benefits and risks of the product.
8. 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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