



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDIA STATEMENT.

11th August

Medicines Regulator cancels registration of anti inflammatory drug, Lumiracoxib

Australia's medicines Regulator, the Therapeutic Goods Administration (TGA) has cancelled the registration of the osteoarthritis drug, Lumiracoxib because of serious liver side effects associated with the use of the drug.

Lumiracoxib, marketed by Novartis Pharmaceuticals under the brand name of Prexige, is a Cox 2 inhibitor belonging to the group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs).

Lumiracoxib was first approved in Australia in July 2004 but has only recently become widely used since being listed on the Pharmaceutical Benefits Scheme (PBS) in 2006.

According to the TGA's Principal Medical Adviser, Dr Rohan Hammett, as of 10th August 2007 the TGA had received 8 reports of serious liver adverse reactions to the drug, including two deaths and two liver transplants.

"The TGA and its expert advisory committee, the Adverse Drug Reactions Advisory Committee (ADRAC), have urgently investigated these reports. ADRAC has today recommended the cancellation of the registration of Lumiracoxib due to the severity of the reported side effects associated with this drug," Dr Hammett said.

"The TGA has taken this advice to cancel the registration of Lumiracoxib in order to prevent further cases of severe liver damage.

"It seems that the longer people are on the medicine, the greater the chance of liver injury. The TGA is, therefore, advising people to stop taking the Lumiracoxib immediately and to discuss alternative treatments with their doctor," Dr Hammett said.

Approximately 60 000 people take Lumiracoxib in Australia which is typically prescribed for: symptomatic relief in the treatment of osteoarthritis, relief of acute pain, including post-operative pain and pain related to dental procedures and relief of pain due to primary dysmenorrhoea.

Further information can be obtained by contacting the TGA Info Line on 1800 004 599 (8.30 am-8.30 pm seven days a week), or Novartis Pharmaceuticals on 1800 671 203

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