European Medicines Agency

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PRESS RELEASE
European Medicines Agency recommends withdrawal of the marketing authorisations for lumiracoxib-containing medicines

The European Medicines Agency (EMEA) has recommended the withdrawal of the marketing authorisations for all lumiracoxib-containing medicines, because of the risk of serious side effects affecting the liver. Lumiracoxib is a non-steroidal anti-inflammatory drug (NSAID) that belongs to the group 'COX-2 inhibitors'. It is used for symptomatic relief in the treatment of osteoarthritis of the hip and knee.

Finalising a review of available information on the safety of lumiracoxib, which concentrated on worldwide data on liver side effects, the Agency's Committee for Medicinal Products for Human Use (CHMP) concluded at its December 2007 meeting that the risks of lumiracoxib-containing medicines are greater than their benefits. The CHMP therefore recommended that the marketing authorisation for these medicines should be withdrawn in all European Union (EU) Member States where they are approved.

The Europe-wide review was started on 15 November 2007 following assessment of reports of serious liver injury by the United Kingdom. The CHMP was asked to give a scientific opinion on whether the marketing authorisations for lumiracoxib should be revoked (withdrawn), suspended or changed across the EU. On 19 November 2007 the United Kingdom suspended the marketing authorisation of this medicine. Similar regulatory action was taken in Germany, Cyprus and Belgium.

The liver safety of lumiracoxib has been monitored continuously since its launch in 2005. In August 2007, the product information was updated with contraindications for patients with potential liver problems and advice to doctors that they should frequently monitor patients treated with lumiracoxib for liver reactions. More spontaneous reports of serious liver problems have been received since then, which have increased the concerns regarding hepatic safety for lumiracoxib. In addition, the CHMP considered that the proposed measures to reduce the risk for liver reactions can not assure adequate patient safety, and are not considered realistic given the approved clinical indication.

Consequently, the CHMP is now recommending the withdrawal of the marketing authorisations.

Patients taking lumiracoxib-containing medicines should contact their doctor as they may need to change to other medicines if there is a need for treatment.

The CHMP's opinion will now be forwarded to the European Commission for the adoption of a decision.

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Notes:

1. More information about the review is available in a separate question-and-answer document.
2. Lumiracoxib is authorised in the European Union in Austria, Belgium, Czech Republic, Cyprus, Denmark, Estonia, Finland, Germany, Greece, Hungary, Iceland, Latvia, Lithuania, Luxembourg, Malta, Nederland, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the United Kingdom (UK) under the trade names Prexige, Stellige, Hirzia and Frexocel.
3. The review of lumiracoxib was conducted under Article 107 of the Community code relating to medicinal products for human use (Directive 2001/83/EC). This type of procedure is initiated in cases where a Member State intends to withdraw, suspend or change the marketing

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authorisation of a nationally authorised medicine as a result of the evaluation of new safety data. It provides for a harmonised European approach because the CHMP is asked to prepare an opinion on whether or not regulatory action should be implemented throughout the European Union.

4. The EMEA reviewed the safety of the class of COX-2 inhibitors in 2004 and 2005. The outcome of this review can be found here.
5. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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