European Medicines Agency
Press office

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PRESS RELEASE
EMEA recommends strengthening warnings and contraindications for etoricoxib-containing medicines used in the treatment of rheumatoid arthritis and ankylosing spondylitis

Finalising a review of the benefits and risks of etoricoxib-containing medicines, the European Medicines Agency (EMEA) has concluded that these medicines can be used to treat rheumatoid arthritis and ankylosing spondylitis, but recommended that their product information should be updated concerning the risk of cardiovascular side effects.

Etoricoxib is a non-steroidal anti-inflammatory drug (NSAID). It is currently indicated to relieve the symptoms of osteoarthritis, rheumatoid arthritis and pain and signs of inflammation associated with acute gouty arthritis. In addition, an application is currently under evaluation to extend the indication of the etoricoxib-containing medicine Arcoxia to treat ankylosing spondylitis.

In the context of the evaluation of the application for extension of indication, concerns were raised over the cardiovascular safety of etoricoxib-containing medicines when used to treat ankylosing spondylitis at a dose of 90 mg once a day. These concerns also extended to the treatment of rheumatoid arthritis which is used at the same dose.

The EMEA's Committee for Medicinal Products for Human Use (CHMP) was asked by France to look at the benefits and risks of etoricoxib for the long-term treatment of rheumatoid arthritis and ankylosing spondylitis to determine whether the marketing authorisations for these medicines should be maintained, varied, suspended or withdrawn across the European Union. The review did not concern osteoarthritis and acute gouty arthritis.

Following review of all available data, the CHMP concluded that the benefits of etoricoxib-containing medicines outweigh their risks for the treatment of rheumatoid arthritis and ankylosing spondylitis when used at a dose of 90 mg once a day and therefore recommended that the extension of indication for Arcoxia to include ankylosing spondylitis be granted and that the indication in rheumatoid arthritis could be maintained. However, the Committee recommended updating the existing contraindication in patients with hypertension that is not adequately controlled to state that patients whose blood pressure is persistently above 140/90 mmHg and has not been adequately controlled should not take the medicine. In addition, the CHMP concluded that warnings should be added to the product information for etoricoxib-containing medicines, stating that high blood pressure should be controlled before treatment is begun and should be monitored for two weeks after the start of treatment and regularly thereafter.

Doctors should prescribe etoricoxib-containing medicines according to the updated product information. Doctors and patients are advised to monitor closely any signs or symptoms of cardiovascular side effects.

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Notes:
1. More information is available in a question-and-answer document.
2. Etoricoxib-containing medicines are approved at the level of the Member States.

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3. The review of etoricoxib-containing medicines was initiated under Article 31 of the Community code relating to medicinal products for human use (Directive 2001/83/EC). An article 31 referral may be initiated in specific cases where the interest of the Community is involved. The expression 'Community interest' has a broad meaning but it refers particularly to the interests of the public health in the Community, for example following concerns related to the quality, efficacy and/or safety of a medicinal product or new pharmacovigilance information.
4. A review was initiated, under Article 6(12) of Commission Regulation EC No 1084/2003, for Arcoxia because of disagreement between Member States on the safety during the assessment of the extension of indication to ankylosing spondylitis in the context of the mutual recognition procedure.
5. Etoricoxib was included in previous referrals on the safety of COX-2 selective inhibitors. This led to updates in the product information to include class warnings on the risk of cardiovascular thrombotic, gastrointestinal and severe skin reactions with COX-2 selective inhibitors. A contraindication in patients with hypertension whose blood pressure is not adequately controlled was included in product information specifically for etoricoxib because of evidence of higher rates of cardiorenal events than other COX-2 inhibitors.
6. 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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