European Medicines Agency
Press office

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Press release

EMEA statement following withdrawal of Vioxx (rofecoxib)

EU regulators met with the marketing authorisation holder of Vioxx (rofecoxib), Merck Sharp & Dohme, on 4-5 October 2004 at the informal meeting of the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) held in Scheveningen, The Netherlands. Merck Sharp & Dohme updated the EU regulators on the data leading to the worldwide withdrawal of this medicinal product on Thursday 30 September 2004. This withdrawal was based on the results of the clinical trial, 'APPROVe', in patients with intestinal polyps, which had shown an increased risk of confirmed serious thrombotic events (including myocardial infarction and stroke) compared to placebo, following long- term use (over 18 months).

The EU regulators agreed during the informal CHMP meeting to review available long-term data on cardiovascular safety for all licensed COX-2 inhibitors (celecoxib, etoricoxib, parecoxib, rofecoxib and valdecoxib) in the next two weeks. Based on this review the Pharmacovigilance Working Party and the CHMP will discuss during their October meetings whether further actions are needed.

The European Medicines Agency has previously reviewed the class of COX-2 inhibitors in a formal procedure (a referral under Article 31 of the Community Code on human medicines) that was concluded in November 2003. This review included safety aspects relating to the stomach, intestine and cardiovascular system (heart and blood vessels) and the skin.

Based on data available at the time, the scientific committee of the EMEA considered that the overall benefits of COX-2 inhibitors outweighed the risk of side effects for the target patient population. There were 3 areas, however that needed to be brought to the attention of prescribers and patients. These related to possible side effects affecting the stomach and intestine, heart and skin. Particular caution was advised for patients who had a known medical history of gastrointestinal or heart problems and if they were taking aspirin at the same time. Such patients should be closely followed by the prescribers and treatment adjusted if necessary. The recommendations applied to all substances included in the referral procedure, whether authorised in Europe through the centralised procedure (celecoxib, parecoxib and valdecoxib) or through the mutual recognition procedure (celecoxib, etoricoxib and rofecoxib). The product information of these products has been revised accordingly in order to add or strengthen warnings.

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Information for prescribers

When prescribing Vioxx:

This product has been withdrawn due to serious thrombotic events. Patients on Vioxx should be reviewed and alternative treatment considered.

When considering switching patients to other COX-2 inhibitors, prescribers are advised to carefully follow the revised summary of product characteristics (SPC), especially regarding the warnings and precautions in patients with a history of cardiovascular disease.

When prescribing other COX-2 inhibitors:

Prescribers are advised to carefully follow the revised summary of product characteristics, especially regarding the warnings and precautions in patients with a history of cardiovascular disease.

Information for patients

Patients currently taking Vioxx:

Please be aware that Merck Sharp & Dohme has withdrawn this medicine due to serious cardiovascular events. You are advised to consult your doctor at the next available opportunity to discuss your treatment.

Patients currently taking other COX-2 inhibitors:

The new data relate to Vioxx. It is unclear if these new data are also relevant for other COX-2 inhibitors. These medicines already contain warnings regarding heart problems. If you have any concerns about your treatment you are advised to consult your prescriber.

--ENDS--

NOTES FOR EDITORS

1. Vioxx contains rofecoxib, a cyclo-oxygenase-2 (COX-2 inhibitor) non-steroidal anti-inflammatory medicine (NSAID) first authorised in the UK in 1999, and thereafter also in EU Member States through the mutual recognition procedure. It is used as a treatment for osteoarthritis, rheumatoid arthritis (Vioxx) and higher dose-strengths are indicated for short-term relief of acute pain (Vioxx Acute).
2. Information on the outcome of the EMEA review of nationally approved COX-2 medicinal products (containing celecoxib, etoricoxib and rofecoxib) was published in June 2004 and can be found here.
3. More information on centrally authorised COX-2 inhibitors can be found in the European public assessment reports here for Bextra/Valdyn (valdecoxib), here for Dynastat/Rayzon (parecoxib) and here for Onsenal (celecoxib).
4. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at the following location: http://www.emea.eu.int

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