European Medicines Agency

28 November 2005
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP) OPINION FOLLOWING AN ARTICLE 31 REFERRAL

FOR ALL MEDICINAL PRODUCTS CONTAINING CELECOXIB, ETORICOXIB, LUMIRACOXIB, PARECOXIB, AND VALDECOXIB

International Non-Proprietary Name (INN): LUMIRACOXIB

BACKGROUND INFORMATION

The COX-2 inhibitors celecoxib, etoricoxib, lumiracoxib, parecoxib, rofecoxib and valdecoxib comprise a relatively new group of substances whose common pharmacological action is the selective inhibition of cyclooxygenase-2. COX-2 inhibitors have been introduced in medical practice for treatment of patients with chronic inflammatory degenerative diseases such as rheumatoid arthritis and osteoarthritis.

In September 2004, the Marketing Authorisation Holder of rofecoxib informed the EMEA that new clinical trial (APPROVe) data for rofecoxib have revealed a risk of thrombotic cardiovascular events. These data resulted in the worldwide withdrawal of rofecoxib (Vioxx) from the market on 30 September 2004 by the Marketing Authorisation Holder and raised questions regarding the cardiovascular safety of other Cox-2 inhibitors.

Further to discussions at the CHMP October 2004 plenary meeting, the European Commission recommended that this public health issue on all aspects of cardiovascular safety including thrombotic events and cardio-renal events should be the subject of Community referrals under Article 31 of Directive 2001/83/EC, as amended regarding decentrally authorised products containing celecoxib, etoricoxib and lumiracoxib and subject to a review procedure under Article 18 of Council Regulation (EEC) No 2309/93, as amended regarding the centrally authorised products containing celecoxib (Onsenal), parecoxib (Dynastat/Rayzon) and valdecoxib (Bextra/Valdyn). These review procedures were started in November 2004.

On 18 November 2004, the CHMP requested comprehensive cardiovascular safety information for these products.

On 7 April 2005, the FDA (Food and Drug Administration) and the EMEA requested Pfizer to voluntarily withdraw Bextra (valdecoxib) from the market. Pfizer agreed to suspend sale and marketing of Bextra worldwide pending further discussions on the unfavorable risk versus benefit due to data on serious skin reactions.

On 20 April 2005, Pfizer presented data on serious skin reactions for valdecoxib during a hearing.

Therefore, on 20 April 2005 further to a request from the EC, the CHMP broadened the scope of the procedure under Article 31 of Directive 2001/83/EC, as amended and the review procedure under Article 18 of Council Regulation (EEC) No 2309/93, to include the assessment of serious skin reactions in the ongoing class review in addition to the cardiovascular safety aspects.

The Marketing Authorisation Holder of lumiracoxib provided written explanations by 10 January and 10 May 2005. Oral explanation was given by the Marketing Authorisation Holder on 18 January 2005.

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Upon consideration of all available data, the CHMP adopted an opinion for lumiracoxib on 23 June 2005 recommending the maintenance of the Marketing Authorisations for lumiracoxib containing medicinal products in the indications stated in the Summary of Product Characteristics as set out in Annex III.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the amended Summary of Product Characteristics in Annex III.

On the basis of the CHMP Opinion, the European Commission issued a Decision on 28 November 2005.

* **Notes:** The information given in this document and Annexes reflect only the CHMP Opinion dated 23 June 2005. The competent authorities of the Member States will continue to keep the product under regular review.