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**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP) OPINION
FOLLOWING AN ARTICLE 31(2) REFERRAL**

PIROXICAM CONTAINING MEDICINAL PRODUCTS

International Non-Proprietary Name (INN): piroxicam

BACKGROUND INFORMATION *

Piroxicam is a non-steroidal anti-inflammatory drug (NSAID) with anti-inflammatory, analgesic and antipyretic properties. Piroxicam is authorised in the European Union following national marketing procedures.

Further to a request from the European Commission the CHMP reviewed safety data on non-selective NSAIDs. This review, which concluded in October 2005, did not reveal any new safety concerns for the class of NSAIDs as a whole. However a need to further evaluate the benefit/risk balance of some non-selective NSAIDs including piroxicam was identified. This review was finalised in June 2006. The review found that limited epidemiological data and spontaneous adverse drug reaction data provided a signal of increased risk of gastrointestinal and skin reactions (including life-threatening bullous reactions) for piroxicam relative to other non-selective NSAIDs.

The CHMP considered that the assessment raised concerns on the benefit/risk balance of piroxicam and informed the European Commission accordingly.

On 2 August 2006, the European Commission referred the matter to the EMEA under Article 31 of Directive 2001/83/EC, as amended, for piroxicam containing medicinal products. The reasons for referral concerned the risk of gastrointestinal and skin reactions.

The referral procedure started on the 21 September 2006.

The Rapporteur and Co-Rapporteur appointed were Dr Rossi and Dr Calvo-Rojas respectively.

Written explanations were provided by the Marketing Authorisation Holders (MAH) on 18 December 2006 and 13 April 2007. The MAHs presented oral explanations to the CHMP on 22 and 23 May 2007.

Based on the available data the CHMP considered that the benefit/risk balance for systemic formulations of piroxicam is positive in the treatment of symptomatic relief of osteoarthritis, rheumatoid arthritis or ankylosing spondylitis; however the CHMP considered that the benefit/risk balance of piroxicam in the treatment of acute conditions is negative and that these indications should be revoked. A number of restrictions on use, contraindications and strengthened warnings have been added to the Summary Product Characteristics and Package Leaflet in relation to gastrointestinal and skin safety.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the amended product information in Annex III and the conditions of the Marketing Authorisation in Annex IV.

The final opinion was converted into a Decision by the European Commission on 7 September 2007.

*** Notes:** the information given in this document and annexes reflects only the CHMP Opinion dated 21 June 2007. The Member states competent Authorities will continue to keep the product under regular review.