European Medicines Agency
Evaluation of Medicines for Human Use

London, 29 May 2007
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 30 REFERRAL FOR

Xefo and associated names

International Non-Proprietary Name (INN): lornoxicam

BACKGROUND INFORMATION

Xefo and associated names, 4mg and 8mg film-coated tablets, 8mg rapid film coated tablet, and 8mg powder and solvent for solution for injection, is a non-steroidal anti-inflammatory drug (NSAID), used for short-term relief of acute mild to moderate pain, symptomatic relief of pain and inflammation in osteoarthritis and symptomatic relief of pain and inflammation in rheumatoid arthritis.

On 16 May 2006 Nycomed Denmark Aps presented to the EMEA a referral under Article 30 of Directive 2001/83/EC, in order to harmonise the nationally authorised Summaries of Product Characteristics (SPC), Package Leaflets and Labelling of the medicinal product Xefo and associated names.

The basis for referral was that there were divergences in the Summaries of Product Characteristics of Xefo and associated names approved across EU Member States, with respect to the short-term relief of acute mild to moderate pain, symptomatic relief of pain and inflammation in osteoarthritis and symptomatic relief of pain and inflammation in rheumatoid arthritis.

The procedure started on 2 June 2006. The Marketing Authorisation Holder provided supplementary information on 21 September 2006 and 12 January 2007.

During its February 2007 meeting, the CHMP, in the light of the overall submitted data and the scientific discussion within the Committee, was of the opinion that the proposal for the harmonisation of the SPC, Labelling and Package leaflet was acceptable and that they should be amended.

The CHMP gave a positive opinion on 22 February 2007 recommending the harmonisation of the SPC, labelling and package leaflet for Xefo and associated names.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amended SPC, labelling and package leaflet in Annex III.

A Decision was issued by the European Commission on 29 May 2007.

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