The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

3 August 1998
CPMP/1500/98-EN

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)

OPINION FOLLOWING AN ARTICLE 10 REFERRAL

MIZOLLEN

International Non-Proprietary Name (INN): Mizalostine

BACKGROUND INFORMATION

In January 1996 Lorex Synthelabo UK, submitted applications for Mutual Recognition of the Marketing Authorisation granted by the UK Competent Authorities for Mizollen, modified release tablets 10 mg. The Mutual Recognition procedure started on 13 February 1996. The Reference Member State was the UK and the Concerned Member States were Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain and Sweden. The Concerned Member State, Sweden not being able to agree with the Mutual Recognition of the Marketing Authorisation granted by the Reference Member State referred the reasons for disagreement to the EMEA on 13 May 1996.

The reasons concerned the potential for mizolastine to prolong the QT interval and the potential implications for the benefit risk profile and for the SPC for the medicinal product.

The Reference Member State sent its report to the EMEA on 15 May 1996.The matter was referred to the CPMP on 22 May 1996. Written and an oral explanations were provided by the Marketing Authorisation Holder on 15 October and 17 December 1996, respectively.

The CPMP adopted a positive opinion on 18 December 1996 recommending the granting of the Marketing Authorisation for Mizollen with amendments to the SPC of the Reference Member State.

A copy of the final opinion for Mizollen is provided on the Internet, together with Annex I and Annex II, which contains the amended SPC. Annex III provides an overall summary of the CPMP scientific evaluation

The final Opinion was converted into a Decision by the European Commission on 1 April 1997

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