



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

London, 22 September, 1997
CPMP/375/97

**COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS
OPINION FOLLOWING AN ARTICLE 12 REFERRAL**

CHLORMEZANONE

International Non-Proprietary Name (INN): **Chlormezanone**

BACKGROUND INFORMATION

On 25 September 1996, Germany presented a referral for chlormezanone under Article 12 of Council Directive 75/319/EEC as amended. Germany requested the CPMP “to give an opinion on whether there is an unfavourable benefit/risk relation for chlormezanone in the indication where it is most widely used in the EU, that is lower back pain with muscle contracture”.

According to the CPMP opinion given on 22 January 1997, the risk/benefit balance of chlormezanone-containing compounds was considered to be unfavourable, and the Committee recommended the withdrawal of the marketing authorisations of all chlormezanone-containing medicinal products.

Some of the Marketing Authorisation Holders of chlormezanone appealed against the opinion and grounds for appeal were submitted on 21 March 1997.

On 14 May 1997, the CPMP having considered the grounds for appeal adopted a final opinion maintaining the conclusions of the opinion dated 22 January 1997.

A copy of the final opinion for chlormezanone is provided on the Internet, together with Annex C which provides the scientific conclusions. Translations of the opinion and Annex C, are also provided on the Internet in French, German, and Spanish.

The final opinion was converted into a Decision by the European Commission on 27 August 1997.