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

London, 3 April, 1997
CPMP/931/95 and CPMP/835/95

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS
OPINIONS FOLLOWING AN ARTICLE 12 REFERRAL

ZAGAM 100MG and 200MG TABLETS

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

BACKGROUND INFORMATION

On 6 June 1995, Denmark requested the CPMP, under Article 12 of Council Directive 75/319/EEC, to provide an Opinion "on the risks and benefit of the fluoroquinolone containing product ZAGAM" following a Rapid Alert from France dated 31 May 1995 which informed Member States of 643 case reports over 7 months, of which 80% concerned phototoxicty.

CPMP Opinions were adopted on 19 December 1995, recommending:

- withdrawal of the Marketing Authorisation for the 100mg strength
- variation of the Marketing Authorisation for the 200mg strength
  - changes to parts of the SPC (SPC provided in Annex 1 of the Opinion)
    - therapeutic indications
    - posology and method of administration
    - contra-indications
    - special warnings and precautions for use
    - interaction with other medicinal products and other forms of interaction
    - undesirable effects
    - pharmacodynamic properties
  - specific obligations for the MAHs as to provide the Committee with
    - the findings of studies investigating photomutagenicity and photocarcinogenicity by the end of 1996
    - six monthly updates on efficacy and safety for at least two years from the date of the Opinion

A copy of the final Opinions for ZAGAM are provided on the Internet, together with Annexes. Translations of the Opinions and their Annexes, are also provided on the Internet in French, German, and Spanish.

The final Opinions for ZAGAM 200mg and ZAGAM 100mg were converted into Decisions by the European Commission on 6 May 1996 and 13 June 1996 respectively.

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