CPMP/931/95

**FINAL OPINION OF THE COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS IN ACCORDANCE WITH ARTICLE 12 OF DIRECTIVE 75/319/EEC AS AMENDED**

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| Name of product: | ZAGAM |
| International non-proprietary name (INN): | Sparfloxacin |
| Strength: | 100 mg |
| Pharmaceutical form: | White film coated tablets |
| Route of administration: | Oral administration |

Basis for Opinion

On June 6, 1995 Denmark presented a referral under Article 12 of Council Directive 75/319/EEC as amended, and asked the CPMP to formulate an opinion on risks and benefits of ZAGAM 100 mg (Sparfloxacin) tablets. The ground for referral was a Rapid Alert sent to all Member States, dated May 31, 1995 from France informing of 643 case reports over a period of 7 months, 80% of which concern UV exposure-related toxicity (letter from Denmark appended).

The initial time frame agreed on June 6, 1995 by the CPMP was 90 days, extended to an extra period of 90 days on September 12, 1995.

A consolidated list of questions was sent to the Marketing Authorisation Holders on July 18, 1995. Written explanation was provided by the Marketing Authorisation Holders on August 21, 1995. On request of the Marketing Authorisation Holders, oral explanation was provided on September 21, 1995 and November 17, 1995.

Opinion

The Committee, having considered the matter on *December 19, 1995* is of the opinion that the marketing authorisations for ZAGAM 100 mg (Sparfloxacin) should be withdrawn.

The scientific conclusions presented by the European Agency for the Evaluation of Medicinal Products following the opinion of the Committee for Proprietary Medicinal Products formulated under Article 12 of Council Directive 75/319/EEC are attached as an Annex.

The present opinion is forwarded to the Commission, to Member States and to the marketing authorisation holders together with a report describing the assessment of the medicinal product and stating the reasons for its conclusions together with its annexes and appendices .

London, *19 December 1995*

Prof. J M Alexandre
Chairman, on behalf of the CPMP

**ANNEX**

**Scientific conclusions presented by the European Agency for the Evaluation of Medicinal Products following an opinion of the Committee for Proprietary Medicinal Products**

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**formulated under Article 12 of Council Directive[1] 75/319/EEC of 20 May 1975**

The Committee considered the referral made under Article 12 of Council Directive 75/319/EEC for ZAGAM 100 mg (Sparfloxacin).

The Committee agreed on very restricted indications for Sparfloxacin following an evaluation of the risks and benefits of the product. The selected dosage regimen for the approved indication is 400 mg as a single dose on the first day and 200mg/day in a single daily dose thereafter. The duration of maintenance therapy is 10 days on an average to a maximum of 14 days. This regimen can be administered with 2 tablets of 200 mg on the first day and 1 tablet of 200 mg for the following days.

The Committee considered the risk/benefit balance of the 100 mg strength. It concluded that it should not be maintained on the market because the 100 mg strength does not correspond to the approved indication. This strength was developed for some indications (acute non-gonnococcal urethritis in men for example) which were not approved. In addition, the presence on the market of the 100 mg strength would increase the risk of non-compliance to the recommended posology for the agreed therapeutic indication of Sparfloxacin.

The 100 mg strength is not useful for the treatment of patients with severe renal failure for which dose spacing is recommended. The dosage schedule for severe renal impaired patients does not necessitate the lower strength of Sparfloxacin.

Given the proposed posology and agreed indication for Sparfloxacin, it was considered that the 100 mg strength has an unfavourable risk/benefit ratio.

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[1] OJ No L 147 of 09.06.1975 p 13 as last amended by Council Directive 93/39/EEC of 14.06.93; OJ No L 214 of 24.08.1993 p 22