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

London, 22 October, 1998
EMEA/34168/98
CPMP/1000-1001/97 and CPMP/255-257/98

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)
OPINIONS FOLLOWING AN ARTICLE 12 REFERRAL

Terfenadine

International Nonproprietary Name (INN): Terfenadine

BACKGROUND INFORMATION

Article 12 of Council Directive 75/319/EEC as amended was invoked for reasons of community interest by France on 10 February 1997, requesting that the CPMP "give an opinion on whether there is an unfavourable benefit/risk ratio for terfenadine in relation to its arrhythmogenic potential and to its serious cardiac adverse effects. The opinion should take into account the global safety profile of terfenadine in comparison with existing alternative non sedative anti-histaminic drugs available for the same indications in the European Union."

On 19 November 1997, the CPMP adopted five Opinions recommending that:

- the Marketing Authorisations for all terfenadine 120 mg tablet and all terfenadine-pseudoephedrine tablet formulations should be withdrawn (CPMP/1000-1/97),
- the Marketing Authorisations for all terfenadine 30 mg tablet, 60 mg tablet and 6 mg/ml oral suspension formulations should be varied and the Summary of Product Characteristics (SPC) amended.

One Marketing Authorisation Holder for terfenadine 60 mg tablet formulation appealed against the Opinion. The appeal related to the wording of the section 4.5 ("Interaction with other medicinal products and other forms of interaction") of the amended SPC.

On 25 February 1998, the CPMP, having considered the grounds for appeal submitted on 21 January 1998, adopted three final Opinions (CPMP/255-7/98) for terfenadine 30 mg tablet, 60 mg tablet and 6 mg/ml oral suspension formulations revising the SPC annexed to its Opinions dated 19 November 1997.

Copies of the final Opinions for all formulations of terfenadine containing medicinal products are available on the Internet together with the scientific conclusions and grounds for restriction in Annex B and the amended SPC for terfenadine 30 mg tablet, 60 mg tablet and 6 mg/ml oral suspension formulations in Annex I. Translations of such Opinions are available on the Internet in French, German and Spanish.

On the basis of the final Opinions the European Commission adopted Decisions on 22 September 1998 which were addressed to the concerned Member States for compliance within 30 days.

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