



29 January 2004
CPMP/6236/04

**COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)
SUMMARY INFORMATION ON A REFERRAL OPINION FOLLOWING AN
ARBITRATION PURSUANT TO ARTICLE 29 OF DIRECTIVE 2001/83/EC, FOR
FLUCONAZOL TIEFENBACHER 50 MG, 100 MG, 150 MG, 200 MG CAPSULES, HARD**

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

BACKGROUND INFORMATION

Fluconazole is a triazole antifungal agent used against a variety of fungal infections. Fluconazole acts by inhibition of the formation of ergosterol, an important component of the fungal cell membrane.

A marketing authorisation for Fluconazol Tiefenbacher was granted in Sweden to Alfred E. Tiefenbacher GmbH & Co Germany, on 4 October 2002. An application for mutual recognition of Fluconazol Tiefenbacher was submitted to Germany and the Mutual Recognition Procedure started on 24.10.2002.

On 23 January 2003 Germany presented to the EMEA a referral under Article 29 of Council Directive 2001/83/EC, as amended. The referral by Germany related to the teratogenic and QT-prolongation potential of the active ingredient, the triazole antifungal fluconazole addressed in sections 4.3 and 4.6 of the SPC.

The referral procedure started 23 January 2003.

During its July 2003 meeting, the CPMP, in the light of the overall submitted data and the scientific discussion within the Committee, was of the opinion that a marketing authorisation should be granted provided amendment to the summary of product characteristics. A positive opinion was therefore adopted on 24 July 2003.

The scientific conclusions and the grounds for the amendment of the Summary of Product Characteristics are set out in Annex II, together with the amended Summary of Product Characteristics in the Annex III.

The final opinion was converted into a Decision by the European Commission on 1 December 2003.