WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

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PHA Information Exchange Service

ALERT

WITHDRAWAL OF TRIAZOLAM

United Kingdom, Germany, Finland

United Kingdom. The Committee on Safety of Medicines has alerted health professionals that all products containing the benzodiazepine, triazolam (Halcion®: Upjohn and generic preparations), have been withdrawn as from 2 October 1991 because of concerns relating to safety.

Information recently made available to the UK Licensing Authority from controlled clinical trials, indicates that, compared with other benzodiazepines, treatment with triazolam is associated with a much higher frequency of serious, though reversible, psychiatric adverse effects, particularly loss of memory and depression. These reactions have been reported previously with high dose formulations of triazolam (1 mg or more) and initially there was little evidence to suggest that such problems occur at the doses used in the UK (0.125 - 0.25 mg).

The newly available information in addition to reports of similar adverse reactions at doses of 0.125 - 0.25 mg received through the UK adverse reaction reporting ("yellow card") scheme, has led the Committee to advise that, on the information presently available, the margin of safety for triazolam in relation to dose is unacceptable, and that the risks of treatment outweigh the benefits.

Practitioners will be aware that all benzodiazepines are associated with dependence and that their duration of use should not exceed 28 days. Nevertheless, the Committee recognizes that withdrawal of triazolam will cause difficulties for some patients and advises that such patients be re-assessed and, if hypnotic treatment needs to be continued, an alternative benzodiazepine should be prescribed.[1]

Germany. The Federal Health Office has suspended the marketing authorization of pharmaceutical products containing triazolam (Halcion®: Upjohn) until 29 February 1992 in order to reconsider the safety/efficacy ratio of these products.[2]

Finland. The National Agency for Welfare and Health has decided to suspend the registration of pharmaceutical products containing triazolam (Halcion®: Upjohn) for an undetermined period of time, in order to reassess the risk/benefit ratio.[3]

References:

1) Fax to WHO from the Committee on Safety of Medicines, 2 October 1991.
2) Fax to WHO from the Federal Health Office, 2 October 1991.
3) Fax to WHO from the National Agency for Welfare & Health, 4 October 1991.

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